

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/10/2020
----	--------------	----------------------------------------------------------

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12051077]
2.	Birth Date:	(b) (6) 1979
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/10/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Nov/10/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Subject had a lump on the neck]
	Start Date:	Jul/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Subject had a shortness of breath complaints]
	Start Date:	Jul/UNK/2020
	Ongoing:	YES

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** HIV STATUS

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/10/2020
2.	Weight:	[107.0]
3.	Unit:	kg
4.	Height:	[185.0]
5.	Unit:	cm
6.	Body Mass Index:	[31.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Nov/10/2020
2.	Randomization Number:	[116063]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
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	[BRDH56]
5.b	Sample ID	[BRDH57]
5.c	Sample ID	[BSHR31]
5.d	Sample ID	[BSHR32]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
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	[BRDH50]
-----	-----------	----------

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/10/2020 15:20
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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**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
----	---------------------------------------------------------------------	------------------------------------------------------------

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/2/2020
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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/2/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BR5PLR]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/2/2020 11:18
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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

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

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

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

(b) (4)

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1205**Site Name:** (1205) Hacettepe University Medical Faculty**Subject No:** 12051077**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8X97]
5.b	Sample ID	[BN8X98]
5.c	Sample ID	[BNM4VM]
5.d	Sample ID	[BNM4VN]

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** V5\_MONTH12\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V6\_MONTH24\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1205**Site Name:** (1205) Hacettepe University Medical Faculty**Subject No:** 12051077**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1205**Subject No:** 12051077**Generated By:**

(b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Status:** Not Started**Site Name:** (1205) Hacettepe University Medical Faculty**Subject Initials:** ---**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 Version:** 22-Apr-2020 21:03

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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?	
----	----------------------------------------------------------------------	--

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Illness Details**

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** 1205**Site Name:** (1205) Hacettepe University Medical Faculty**Subject No:** 12051077**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Nasal Septum Deviation	Jan/19/2021 UNK:UNK	NO End Date Time:  Jan/20/2021 UNK: UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Encapsulated Lipoma	Jan/19/2021 UNK:UNK	NO End Date Time:  Jan/20/2021 UNK: UNK	<a href="#">Repeating Pages</a>

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nasal Septum Deviation]
4.	Start Date Time:	Jan/19/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p>NO</p>
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Deviated Septum Operation was performed on 19Jan21 due to Nasal Septum Deviation]</p>

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021168918]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Encapsulated Lipoma]
4.	Start Date Time:	Jan/19/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/20/2021 UNK:UNK
6.	Toxicity Grade:	2

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p>NO</p>
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Encapsulated lipoma excising operation was performed on 19Jan21.]</p>

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021139636]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**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	[ ]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**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?	

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Dec/4/2020  Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[ ]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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?	

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** C4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1205**Site Name:** (1205) Hacettepe University Medical Faculty**Subject No:** 12051077**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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:** 1205**Site Name:** (1205) Hacettepe University Medical Faculty**Subject No:** 12051077**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Jan/6/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1205      **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077      **Subject Initials:** ---

**Generated By:**      **Generated Time (GMT):** 29-Mar-2021 13:11  
(b) (4)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3  Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	-----------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Disposition - Follow-Up**

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

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---------------------------------------------	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/6/2021

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[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, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 17:05:06 (UTC+03:00) Istanbul	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-04-2021 13:54:09 (UTC+03:00) Istanbul		Edit - All signatures invalidated

**Affidavit:**

N/A

Serhat Unal	Approved	Feb-22-2021 13:43:11 (UTC+03:00) Istanbul	BOOK	Signed
-------------	----------	----------------------------------------------	------	--------

**Affidavit:**

By my dated signature below, I, SerhatUnal, 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.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Nov-10-2020 17:01:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 17:01:43 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Nov-10-2020 17:02:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Nov/10/2020	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:01:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12051077	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Nov-10-2020 17:01:26 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1979	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Nov-10-2020 17:02:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Nov-10-2020 17:02:30	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00) Istanbul		(b) (4), (b) (6)	LATINO(A) OR OF S PANISH ORIGIN
-------------------------	--	------------------	------------------------------------

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

Date	Location	User	Value	Reason
Nov-10-2020 17:02:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-10-2020 17:04:52 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020	Initial Entry



**Header Text:** C4591001

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-10-2020 17:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-10-2020 17:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-10-2020 17:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Nov-10-2020 17:13:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH N 1 umber: Medical His hyperten tory Term: sion Start Date: UNK/U NK/201 6 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Nov-10-2020 17:13:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 17:13:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**1.a Start Date:**

Date	Location	User	Value	Reason
Nov-10-2020 17:13:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Nov-10-2020 17:13:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Feb-19-2021 13:39:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH 2</b> <b>Number:</b> <b>Medical History</b> Subject had a lump on t <b>Term:</b> he neck <b>Start Date:</b> Jul/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Feb-19-2021 13:39:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 13:39:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Subject had a lump on the neck	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Feb-19-2021 13:39:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Jul/UNK/2020	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Feb-19-2021 13:39:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

*I.c*

Date	Location	User	Value	Reason
Feb-19-2021 13:40:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 3 <b>H Num</b> <b>ber:</b> <b>Medica</b> Subject had a <b>l Histor</b> shortness of <b>y Term:</b> breath compl aaints <b>Start D</b> Jul/UNK/202 <b>ate:</b> 0 <b>Ongoin</b> YES <b>g:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Feb-19-2021 13:40:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 13:40:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Subject had a shortness of breath complaints	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Feb-19-2021 13:40:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Jul/UNK/2020	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Feb-19-2021 13:40:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-10-2020 17:07:29 (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:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 107.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Nov-10-2020	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

17:09:47 (UTC+03:00) Istanbul		(b) (4), (b) (6)	185.0	
-------------------------------------	--	------------------	-------	--

**5. Unit:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 31.3	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 36.2 <b>Temperature Unit:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

			<b>Temperatur Fore e Location:: HEAD</b>	
--	--	--	----------------------------------------------	--

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Nov-10-2020 17:09:47 (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
------	----------	------	-------	--------

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Nov-10-2020 17:09:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry
----------------------------------------------------	-----------------	------------------------	--------------------------------	---------------

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Nov-10-2020 17:13:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Nov-10-2020 17:13:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 116063	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 17:15:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-10-2020 17:15:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 17:15:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				Please review and correct as appropriate.
Nov-10-2020 17:15:13 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRDH5 : 6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDH56	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:16 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRDH5	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Istanbul			:	7	
----------	--	--	---	---	--

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:16 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDH57	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSHR3 : 1	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:17:47 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHR31	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-10-2020	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

17:18:01 (UTC+03:00) Istanbul		(b) (4), (b) (6)	<b>Sample ID</b> BSHR3 : 2	
-------------------------------------	--	------------------	----------------------------------	--

**5.d Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:18:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHR32	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 17:14:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-10-2020 17:14:20 (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-10-2020 17:14:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 17:14:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				Please review and correct as appropriate.
Nov-10-2020 17:14:20 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 17:14:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BRDH5 : 0	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 17:14:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDH50	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020 15:20	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
-------------------------	--	------------------	--	--

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00) Istanbul			CIFIED OBSERVATIO N PERIOD	
-------------------------	--	--	-------------------------------	--

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

Date	Location	User	Value	Reason
Nov-10-2020 17:10:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Nov-10-2020 17:12:04 (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:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-02-2020 10:53:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or sy N stemic symptom O s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F A T I G U E  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

2.b Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

2.c Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**2.d Symptom:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
: NO

2.e Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

Istanbul			RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	N O
----------	--	--	-------------------------------------------------------------------------------------------------------	--------

2.f Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+03:00) Istanbul		(b) (4), (b) (6)	OR WORSE NEW MUSCLE PAIN	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
-------------------------	--	------------------	-----------------------------------	-------------------------------------------------------------------------------------------------------

2.g Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE ED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**2.h**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO</p>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

2.h Symptom:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

Istanbul				
----------	--	--	--	--

5.a

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00) Istanbul		(b) (4), (b) (6)	
-------------------------	--	------------------	--

**5.b**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT I NJE CTI ON S ITE	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
--	--	--	-----------------------------------------------------------------------------------------	----

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:08 (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
Dec-02-2020 10:54:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 36.2 <b>Temperature Unit:</b> <b>Temperature Location:</b> HEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**2.a Temperature:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-02-2020 10:54:37 (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
Dec-02-2020 10:54:37 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-02-2020 10:57:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-02-2020 10:57:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-02-2020 10:58:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 10:57:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				Please review and correct as appropriate.
Dec-02-2020 10:57:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-02-2020 10:58:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BR5PL : R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-02-2020 10:58:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5PLR	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

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

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020 11:18	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

(UTC+03:00) Istanbul		(b) (4), (b) (6)		
-------------------------	--	------------------	--	--

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00) Istanbul			CIFIED OBSERVATIO N PERIOD	
-------------------------	--	--	-------------------------------	--

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

Date	Location	User	Value	Reason
Dec-02-2020 11:31:50 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-06-2021 11:20:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the l</b> <b>ast day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry
----------------------------------------------------	-----------------	---------------------	-----------------------------	---------------

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> F A T I G U E  <b>Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

2.b Symptom:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

2.c Symptom:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI L LS <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

2.d Symptom:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (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
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (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
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

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

(b) (4)

Istanbul			RH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	N O
----------	--	--	-------------------------------------------------------------------------------------------------------	--------

**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

**2.h**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED J OINT PAIN  <b>Were fever o</b> NO <b>r systemic sy</b> <b>mptoms pres</b> <b>ent on the las</b> <b>t day the Sub</b> <b>ject Diary w</b> <b>as completed</b> <b>?:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

2.h Symptom:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (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
Jan-06-2021 11:21:46 (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
Jan-06-2021 11:21:46 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1205 Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077 Subject Initials: ---

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

(b) (4)

Istanbul				
----------	--	--	--	--

5.a

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

(UTC+03:00)  
Istanbul

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

**5.b**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW EL LI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT I NJE CTI ON S ITE	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
--	--	--	------------------------------------------------------------------------------------------------	--

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 11:21:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 11:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

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

(b) (4)

				Please review and correct as appropriate.
Jan-06-2021 11:22:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/6/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BN8X9 : 7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:24 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8X97	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:40 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BN8X9	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

Istanbul			:	8	
----------	--	--	---	---	--

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 11:22:40 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8X98	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-06-2021 11:23:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNM4V <b>D:</b> M	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 11:23:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNM4VM	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jan-06-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (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:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

11:23:34 (UTC+03:00) Istanbul		(b) (4), (b) (6)	<b>Sample I</b> BNM4V <b>D:</b> N	
-------------------------------------	--	------------------	--------------------------------------	--

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 11:23:34 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNM4VN	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (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
Feb-19-2021 23:42:30 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-19-2021 13:42:33 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Both symptoms were added on MHx page of Inform as

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				separately.
Feb-16-2021 22:47:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Per SAE report, "the subject had a lump on the neck and shortness of breath complaints for 6-7 months". Please add those 2 symptoms into MHx module.
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nasal Septum Deviation	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO End Date Time:  Jan/20/2021 UN K:UNK	Initial Entry
----------------------------------------------------	-----------------	--------------------------------	---------------------------------------------------------------------------	---------------

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-05-2021 17:54:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Mar-05-2021 16:54:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-05-2021 16:54:00 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 2	New Information
Feb-28-2021 21:30:54 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As this AE led to surgery and hospitalization, please re-consider if the AE grade was 2.

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 1	Initial Entry
----------------------------------------------------	-----------------	--------------------------------	-------------------------	---------------

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-16-2021 22:54:11 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Closed	Updated in SDB
Feb-16-2021 14:13:39 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Answered	Nasal Septum Deviation and Encapsulated Lipoma serious adverse events were sent to the safety report on 09.Feb.2021.
Feb-11-2021 11:55:56 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Opened	SAE RECON:Nasal Septum Deviation(Onset

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				date:19Jan2021) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Feb-11-2021 11:55:04 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Nasal Septum Deviation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 14:48:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00)  
Istanbul

Is this serious event associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

YES

Did this serious event result in persistent or significant disability/incapacity?

NO

Is this serious event life threatening?

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify</i> :  Deviated Sept	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			um Operation was performed on 19Jan21 due to Nasal Septum Deviation	
--	--	--	---------------------------------------------------------------------	--

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-26-2021 01:00:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-22-2021 13:54:10	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	An elective procedure was

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

(UTC+03:00) Istanbul				performed for this volunteer as scheduling of the procedure.
Feb-19-2021 19:59:08 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Sorry, not clear. Was this an elective procedure?
Feb-19-2021 13:01:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-19-2021 13:01:01 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Feb-16-2021 18:45:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ Per report, the subject underwent surgery. Pls clarify if this was an elective procedure. Thanks
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 14:48:48 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Mar-08-2021 11:39:10 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021168918	AER updated
Mar-04-2021 13:54:09 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021139636	updated to matched SDB
Feb-19-2021 10:06:36 (UTC+03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021168918	new AER for the event

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Istanbul				
Feb-15-2021 10:34:27 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021139636	Initial Entry

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 01:52:49 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	ok.
Mar-05-2021 17:07:45 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Any timing details have not been stated in

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

				report.
Mar-05-2021 01:13:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ Pls advise if at any given time the subject had a biopsy. Thanks
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Encapsulated Lipo ma	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/20/2021 UN K:UNK	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-05-2021 17:54:53 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Mar-05-2021 16:54:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-05-2021 16:54:42 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	New Information
Feb-28-2021 21:31:38 (UTC+03:00) Istanbul	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: As this AE led to surgery and hospitalization, please re-consider if the AE grade was 2.
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

Date	Location	User	Value	Reason
Feb-11-2021 04:15:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Encapsulated Lipoma : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1205

Site Name: (1205) Hacettepe University Medical Faculty

Subject No: 12051077

Subject Initials: ---

Generated By:

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

(b) (4)

			NO	
--	--	--	----	--

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

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

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify</i> :  Encapsulated lipoma excising operation was performed on 19Jan21.	Initial Entry

**10. Latest Action Taken with Study Treatment:**

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

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

Date	Location	User	Value	Reason
Feb-09-2021 14:54:35 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-11-2021 04:15:19 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021139636	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Dec/04/2020

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

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-04-2020 10:25:22 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Dec/4/2020	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Dec/04/2020

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Assessments*

Date	Location	User	Value	Reason
Dec-04-2020 10:26:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 10:25:31 (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.
Dec-04-2020 10:25:31 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Dec/04/2020

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF  
Audit Trail History

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

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Dec-04-2020 10:26:05 (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
Dec-04-2020 10:26:05 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Dec/4/2020  Contact Outcome:  VISIT NOT AR RANGED, REA CTION NO LON GER PRESENT	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 13:52:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-06-2021 13:52:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-06-2021 13:52:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)



**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1205      **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-19-2021 14:07:46 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Jan/19/2021	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-20-2021 11:29:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-20-2021 06:16:57 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-19-2021 14:32:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1205 **Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077 **Subject Initials:** ---

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

(b) (4)

				complete this date.
Jan-19-2021 14:32:06 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:03 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ASSESS ELIGIBIL ITY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Jan-06-2021 13:52:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-10-2020 17:13:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Nov-10-2020 17:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jan-06-2021 13:52:29 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/6/2021	Initial Entry
Nov-10-2020 17:13:55 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/10/2020	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1205

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject No:** 12051077

**Subject Initials:** ---

**Generated By:**

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

(b) (4)

Nov-10-2020 17:07:14 (UTC+03:00) Istanbul	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/10/2020	Initial Entry
----------------------------------------------------	-----------------	-------------------------	-----------------------------------	---------------

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1205

**Subject No:** 12051077

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1205) Hacettepe University Medical Faculty

**Subject Initials:** ---

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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Dec-02-2020 14:55:32 (UTC+03:00) Istanbul	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3f31\Final\Final On: 01-Apr-2021 05:11 (GMT)