

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/15/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11951003]
2.	Birth Date:	UNK/UNK/1967
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/15/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Autoimmune thyroiditis]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** HIV STATUS

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**HIV Status**

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

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/15/2020
2.	Weight:	[76.6]
3.	Unit:	kg
4.	Height:	[159.0]
5.	Unit:	cm
6.	Body Mass Index:	[30.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** RANDOMIZATION

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/15/2020
2.	Randomization Number:	[107833]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BNMDDS]
5.b	Sample ID	[BNMDDT]
5.c	Sample ID	[BN8WTH]
5.d	Sample ID	[BN8WTJ]

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**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BN8WTK]
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/15/2020 11:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/5/2020
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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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
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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/5/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN86F7]
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**eCRF Audit Trail History**

**Vaccination**

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/7/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
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	[BN8KMY]
5.b	Sample ID	[BN8KMZ]
5.c	Sample ID	[BNLWRP]
5.d	Sample ID	[BNLWRR]

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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?	
----	--	--

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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:** 1195      **Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Spondylolisthesis L4/5	Feb/5/2021 UNK: UNK	NO End Date Time: Mar/9/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Headache	Mar/10/2021 13:30	YES	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Nausea	Mar/11/2021 11:00	YES	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Vertigo	Mar/11/2021 11:00	YES	<a href="#">Repeating Pages</a>

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Spondylolisthesis L4/5]
4.	Start Date Time:	Feb/5/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/9/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [due to Lumal spine syndrome]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
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	[2021153480]

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Mar/10/2021 13:30
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nausea]
4.	Start Date Time:	Mar/11/2021 11:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Vertigo]
4.	Start Date Time:	Mar/11/2021 11:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

#	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:** 1195

**Subject No:** 11951003

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Medication Error**

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

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**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

#	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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**Radiation Treatment**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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?	

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**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:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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



**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/26/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Withdrawal Of Consent**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Death Details**

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

**Cause of Death**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/11/2021
----	--------------	--



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Feb/11/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BN8L2B]
5.b	Sample ID	[BN8L2C]
5.c	Sample ID	[BNLWBV]
5.d	Sample ID	[BNLWBW]

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BN8L29]
-----	-----------	----------

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/11/2021 12:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001**Visit:** V102\_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1195**Subject No:** 11951003**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Verified**Site Name:** (1195) Medizentrum Essen Borbeck**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Electronic Sample Tracking**

1.	Data Origin	SITE	<a href="#">Comments</a>
2.	Sample Type	NASAL_SWAB	<a href="#">Comments</a>
3.	Sample Collected?	YES Date of Collection: Mar/10/2021	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8L7R]
-----	-----------	----------

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO	<a href="#">Comments</a>
2.	Treatment Name	[BNT162b2]	<a href="#">Comments</a>
3.	Formulation:	INJECTION	<a href="#">Comments</a>
4.	Dose Date Time:	Mar/10/2021 10:02	<a href="#">Comments</a>
5.	Anatomical Location:	DELTOID MUSCLE	<a href="#">Comments</a>
6.	Body Side:	LEFT	<a href="#">Comments</a>
7.	Route:	INTRAMUSCULAR	<a href="#">Comments</a>
8.	Actual Dose:	[30.0]	<a href="#">Comments</a>
9.	Unit:	ug	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	30 MINUTES	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES	<a href="#">Comments</a>

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

**Contact Outcome**

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



**Header Text:** C4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Disposition - Treatment**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/7/2020

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Axel Schaefer	Approved	Mar-12-2021 20:40:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-16-2020 13:24:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
1	Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
2	Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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VACCINATION - Comments

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

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Item	Date	User	Comment
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Form	Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable



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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** C4591001

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Item	Date	User	Comment
Form	Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
2	Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) (b) (4)	Not Applicable

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Item	Date	User	Comment
3	Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6) (b) (4)	Not Applicable

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Item	Date	User	Comment
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
Comments

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

**Form Status:** Data Complete, Verified

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**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

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

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Item	Date	User	Comment
Form	Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
Form	Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Comments

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Item	Date	User	Comment
1	Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
1	Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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3	Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable
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4	Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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

**Site No:** 1195

**Subject No:** 11951003

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**Form:** VACCINATION - Comments

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Item	Date	User	Comment
Form	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
Form	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

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1	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable



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Item	Date	User	Comment
4	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
4	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
5	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
5	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
6	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
6	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
7	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
7	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
8	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
8	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
9	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
9	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

Item	Date	User	Comment
10	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
10	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Item	Date	User	Comment
11	Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	
11	Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(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, Signed, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Axel Schaefer	Approved	Mar-12-2021 20:40:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-11-2021 14:39:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Mar-11-2021 13:47:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Axel Schaefer	Approved	Feb-22-2021 21:16:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 16:00:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Feb-17-2021 19:24:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-17-2021 12:56:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Feb-16-2021 13:59:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Feb-11-2021 21:03:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-11-2021 14:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Jan-31-2021 19:59:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-29-2021 16:28:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Jan-27-2021 08:01:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-26-2021 18:05:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Dec-09-2020 19:05:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-07-2020 11:55:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Nov-08-2020 14:01:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-05-2020 13:09:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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**Affidavit:**

N/A

Axel Schaefer	Approved	Nov-03-2020 19:34:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**Affidavit:**

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

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

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



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-15-2020 14:43:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Oct-15-2020 14:43:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Consent Was:*

Date	Location	User	Value	Reason
Oct-15-2020 14:44:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Oct/15/2020	Initial Entry

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-15-2020 14:43:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11951003	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-15-2020 14:43:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/1967	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-15-2020 14:44:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-15-2020 14:44:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 14:44:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-15-2020 14:53:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-15-2020 14:55:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-15-2020 14:55:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-15-2020 14:55:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Oct-15-2020 15:20:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Hysterectomy <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date: UNK/UNK/2001	Transcription Error
Oct-15-2020 15:19:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Hysterectomy <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-15-2020 15:19:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Oct-15-2020 15:19:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hysterectomy	Initial Entry

*1.a Start Date:*

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Oct-15-2020 15:19:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Oct-15-2020 15:20:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2001	Transcription Error
Oct-15-2020 15:19:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Oct-15-2020 15:22:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>ber:</b> <b>Medical Histor</b> Autoimmune th <b>y Term:</b> yroiditis <b>Start Date:</b> UNK/UNK/201 7 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-15-2020 15:22:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Oct-19-2020 16:38:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 22:36:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no treatment with ummunosopressive drugs
Oct-15-2020 18:10:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	is the patient under systemic treatment with immunosopressive drugs?
Oct-15-2020 15:22:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Autoimmune thyroiditis	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Oct-15-2020 15:22:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Oct-15-2020 15:22:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-15-2020 15:27:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Date:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 76.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 159.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.3	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb			
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7.a

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: Temperature: 37.3 Temperature Unit: Temperature Location: Cavity	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX 113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-15-2020 15:26:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-15-2020 21:00:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 107833	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 19:21:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 19:21:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 19:21:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 19:21:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 19:21:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 19:21:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNMDDS	Initial Entry

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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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 19:21:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNMDDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 19:22:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNMDDT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 19:22:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNMDDT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 19:22:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8WTH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 19:22:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8WTH	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-15-2020 19:22:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8WTJ	Initial Entry

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**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, Locked, Frozen, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-15-2020 19:22:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8WTJ	Initial Entry

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 15:12:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 15:12:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 19:25:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 15:12:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 15:12:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 19:25:05	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
 Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1195 **Site Name:** (1195) Medizentrum Essen Borbeck  
**Subject No:** 11951003 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 12:55

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	<b>Sample ID:</b> BN8WTK
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 19:25:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8WTK	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-16-2020 04:04:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_EC001_2_02
Oct-15-2020 22:23:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW4988801;A dosing date is provided on a Treatment eCRF, but the patient does not have a Randomization number recorded. Please review and

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

				update as appropriate.
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020 11:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Oct-15-2020 15:30:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-15-2020 15:12:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-05-2020 13:09:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry



**Header Text:** C4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 16:03**Site No:** 1195**Subject No:** 11951003**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1195) Medizentrum Essen Borbeck**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.c Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.d Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.e Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.f Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sys temic symptoms present on the las t day the Subject Diary was comple ted?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.g Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.h Symptom:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction:	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Date:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: Temperature: 37.0 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

6.a

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Nov-05-2020 13:10:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**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, Locked, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-05-2020 13:10:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-05-2020 15:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 13:10:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 13:10:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-05-2020 15:20:09	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

**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, Locked, Frozen, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC+01:00) Sarajevo,  
Skopje, Warsaw, Zagreb

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

**Sample ID:** BN86F7

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-05-2020 15:20:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN86F7	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020 10:55	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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, Locked, Frozen, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 13:11:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-07-2020 13:33:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020	Initial Entry

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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

2.b Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.c Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.f Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or syst</b> NO <b>emic symptoms pr</b> <b>esent on the last d</b> <b>ay the Subject Dia</b> <b>ry was completed</b> <b>?:</b>	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

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2.g Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUS CLE 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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syst</b> NO <b>emic symptoms pr</b> <b>esent on the last d</b> <b>ay the Subject Dia</b> <b>ry was completed?</b> :	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

2.h Symptom:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOIN T 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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> RE :: DN ES S <b>Were injection site rea</b> NO <b>ctions present on the la</b> <b>st day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction: SWELLING  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-07-2020 13:33:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-07-2020 11:55:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-07-2020 11:55:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-07-2020 11:55:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 11:55:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 11:55:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-07-2020 11:55:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN8KMY	Initial Entry

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Site No: 1195

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Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

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5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 11:55:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8KMY	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 11:56:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8KMZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 11:56:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8KMZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 11:56:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLWRP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 11:56:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNLWRP	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-07-2020 11:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLWRR	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

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**5.d Sample ID**

Date	Location	User	Value	Reason
Dec-07-2020 11:56:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNLWRR	Initial Entry

**Header Text:** C4591001

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

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

**Site No:** 1195

**Subject No:** 11951003

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

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Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

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**Site Name:** (1195) Medizentrum Essen Borbeck

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Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

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**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

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Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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 18:13:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 12:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	patient is going on 02Mar 2021 into the hospital. As soon as we get more information I update this form.
Feb-17-2021 12:35:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical monitor_ pls provide further information on how diagnosis was made and treatment during hospital stay in a FU form. Thanks
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Spondylolisthesis L4/5	Initial Entry

**4. Start Date Time:**

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 11:58:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Mar/9/2021 UNK:UNK	New Information
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	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-15-2021 09:30:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Spondylolisthesis L4/5: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse

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Generated By: (b) (4)

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				Event Number" is blank.
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NO</p>	Initial Entry

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**Header Text:** C4591001

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**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-08-2021 16:37:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 18:29:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Reissued: Candidate	Confirm that additional details have been collected week of 3/5/2021
Feb-15-2021 10:57:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	more information at this time point not available. Patient will be hospitalized on 02 Mar 2021.
Feb-15-2021 07:18:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Lumal spine syndrome]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and

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Generated By: (b) (4)

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Form Status: Data Complete, Queries

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Subject Initials: ---

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				update as necessary. (b) (4)
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  due to LUMINALS pinesyndrome	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Feb-23-2021 17:45:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 12:51:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the appointment was only to discuss when the patient can be hospitalized. NO more information available.
Feb-17-2021 12:36:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor_ Per report "the subject had an appointment... for pain therapy", would you pls provide further details from this appointment in a FU form. Thanks.
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Mar-12-2021 15:04:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021153480 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please

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Generated By: (b) (4)

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Form Status: Data Complete, Queries

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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				confirm correct outcome. If safety update is required, please submit a ffup form
Mar-11-2021 12:00:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 12:00:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Mar-11-2021 11:58:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Spondylolisthesis L4/5: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 13:05:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-15-2021 09:30:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021153480	Initial Entry

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Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headache	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-11-2021 12:01:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021 13:30	New Information
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021 10:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	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
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:01:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nausea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021 11:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:02:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vertigo	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021 11:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	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
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 12:03:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Dec-07-2020 13:33:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-07-2020 13:33:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 18:05:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Jan-29-2021 16:28:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible per other protocol al lowance(s) and confirmed to have received only placebo at Vaccination 1/2	New Information
Jan-26-2021 18:15:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 18:14:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-26-2021 18:14:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible per local/national re commendations and confirm ed to have received only pla cebo at Vaccination 1/2	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-26-2021 18:15:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-26-2021 18:15:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1195

**Subject No:** 11951003

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

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

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

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-11-2021 14:39:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Consent Was:*

Date	Location	User	Value	Reason
Feb-11-2021 14:48:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/11/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION  
- eCRF Audit Trail History

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Feb-11-2021 14:49:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-11-2021 14:49:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-11-2021 14:49:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> <b>Result::</b> <b>Not Done::</b>	Initial Entry  Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-11-2021 14:50:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-11-2021 14:50:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-11-2021 14:50:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-11-2021 14:51:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 14:50:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:50:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-11-2021 14:51:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN8L2B	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:51:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8L2B	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 14:51:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8L2C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:51:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8L2C	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-11-2021 14:52:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLWBV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:52:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNLWBV	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-11-2021 14:52:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLWBV	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**5.d Sample ID**

Date	Location	User	Value	Reason
Feb-11-2021 14:52:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNLWBW	Initial Entry

**Header Text:** C4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-11-2021 14:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-11-2021 14:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 14:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BN8L29	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8L29	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021 12:42	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 14:53:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-12-2021 08:12:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	As per site confirmation - updated PD tracker
Mar-11-2021 14:13:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An swere d	Date is correct. Patient was hospitalized until 09 Mar 2021.
Mar-11-2021 09:32:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 3: Op ened	PDQ: Date of visit V102_VAX4 is out of window for 4 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Mar-10-2021 10:40:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Mar/1 0/202 1	New Information
Feb-19-2021 15:06:10 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb				
Feb-19-2021 12:22:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swere d	Changed data per query
Feb-18-2021 20:11:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Opene d	DM: Thank you for your response. The date may remain. Please mark all forms for this is visit as "Not Applicable" as a form level comment until data is available for entry.
Feb-18-2021 16:01:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: An swere d	its not possible to delete the date!!
Feb-17-2021 17:46:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-17-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query	Response satisfies

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

15:16:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6)	1: Closed	query
Feb-17-2021 12:56:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-17-2021 12:56:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-15-2021 22:56:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: As the visit was erroneous, please enter ERRONEOUS for the visit. Additionally, all pages where data was entered should have a form level comment of "Not Applicable."
Feb-15-2021 11:38:00 (UTC+01:00) Sarajevo, Skopje, Warsaw,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this visit was entered by mistake. Patient had V101

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

Zagreb				
Feb-12-2021 08:31:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7235787;The Date of Visit at Visit V102_VAX4 is the same as the other Date of Visit at Visit V101_VAX3. Please review for duplication and update as appropriate.
Feb-11-2021 14:56:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Feb/1 1/202 1	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-10-2021 10:40:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-17-2021 12:56:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applic <b>entifier:</b> able <b>Test::</b> Not Applic able <b>Result::</b> Not Applic able <b>Not Done::</b> Not Applic able	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-11-2021 14:57:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 10:38:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry
Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:37:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-10-2021 10:38:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry
Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:37:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:25	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

(UTC+01:00) Sarajevo,  
Skopje, Warsaw, Zagreb

(autocalc)

NASAL\_SWAB

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 10:39:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Mar-10-2021 10:38:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 10:38:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/10/2021	Initial Entry
Mar-10-2021 10:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-18-2021 20:11:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-18-2021 16:01:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-18-2021 16:00:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-17-2021 17:03:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thanks for clarifying. Please enter a form level comment of "Not Applicable" while V102 is pending. Form can be

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951003**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

				updated when data is available.
Feb-17-2021 12:57:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	it was entered by mistake. If the patient is coming back for V102 I update this form
Feb-16-2021 09:52:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Please complete details on this form. Thank you.
Feb-15-2021 11:37:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 11:37:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-12-2021 11:36:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/11/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 10:35:05	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6)		
Feb-19-2021 12:21:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN8L7R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:00 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN8L7R	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-17-2021 15:24:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 12:58:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	when the patient is coming back for V102 I update this form
Feb-16-2021 09:52:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete details on this form. Thank you.
Feb-15-2021 11:38:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-10-2021 10:40:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Header Text: C4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 11/Feb/2021 of the corresponding Visit. Please review and update as appropriate.
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021 10:02	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/11/2021 12:42	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951003

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:55

Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**8. Actual Dose:**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry
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Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951003

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:55

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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-15-2021 11:38:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 10:39:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
Mar-10-2021 10:39:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-19-2021 12:22:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-19-2021 12:22:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:57:46 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1195

**Subject No:** 11951003

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

Skopje, Warsaw, Zagreb				
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090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1195

**Subject No:** 11951003

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 12:55

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***1. Subject Status***

Date	Location	User	Value	Reason
Dec-07-2020 13:33:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-15-2020 15:26:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-15-2020 14:55:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

***2. Subject Status Date***

Date	Location	User	Value	Reason
Dec-07-2020 13:33:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/7/2020	Initial Entry
Oct-15-2020 15:26:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/15/2020	Initial Entry
Oct-15-2020 14:55:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

090177e196ae2f9c\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1195

**Site Name:** (1195) Medizentrum Essen Borbeck

**Subject No:** 11951003

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 12:55

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-03-2020 18:57:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry