

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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: 11951131

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

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

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/19/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11951131]
2.	Birth Date:	UNK/UNK/1953
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: 11951131

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	Oct/19/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, 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: 11951131

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

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

1.	Date of Completion/Discontinuation/Death	Oct/19/2020
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: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

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](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	Apr/1/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pollinosis]
	Start Date:	Oct/1/1999
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Psoriasis vulgaris]
	Start Date:	Oct/1/1999
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes mellitus type 2]
	Start Date:	Oct/24/2019
	Ongoing:	YES

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[scoliosis]
	Start Date:	Aug/30/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[retropatellar arthrosis]
	Start Date:	Dec/11/2017
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[reflux esophagitis]
	Start Date:	Oct/12/2015
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Postmenopausal]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[umbilical hernia]
	Start Date:	Apr/30/2020
	Ongoing:	NO End Date: May/11/2020

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Header Text: C4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1195) Medizentrum Essen Borbeck
Site No: 1195	Subject Initials: ---
Subject No: 11951131	Generated Time (GMT): 29-Mar-2021 12:55
Generated By: (b) (4)	

[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: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

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](#)

Vital Signs

1.	Date:	Oct/19/2020
2.	Weight:	[88.4]
3.	Unit:	kg
4.	Height:	[159.0]
5.	Unit:	cm
6.	Body Mass Index:	[35.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Oct-2020 15:58**Site No:** 1195**Subject No:** 11951131**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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: RANDOMIZATION

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

1.	Randomization Date :	Oct/19/2020
2.	Randomization Number:	[270712]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNMDPS]
5.b	Sample ID	[BNMDPT]
5.c	Sample ID	[BN868V]
5.d	Sample ID	[BN868W]

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8693]
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/19/2020 13:26
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: 11951131

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

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](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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	Nov/7/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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](#)

Vital Signs

1.	Date:	Nov/7/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	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: 11951131

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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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: Nov/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	[BN86GS]
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/7/2020 11:43
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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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/5/2020
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: 11951131

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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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/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	[BN8KLY]
5.b	Sample ID	[BN8KLZ]
5.c	Sample ID	[BNLWPP]
5.d	Sample ID	[BNLWPR]

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

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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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: 11951131

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:	[]
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951131

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: 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: 11951131

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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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951131

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?	
----	--	--

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: 11951131

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:	

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951131

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: 11951131

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_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: 11951131

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:	
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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: 11951131

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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. DELETED	ADVERSE EVENT	1	umbilical hernia	Dec/2/2020 UNK:UNK	NO End Date Time: Dec/4/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	umbilical hernia	Nov/24/2020 UNK:UNK	NO End Date Time: Dec/3/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Pain injection side	Jan/26/2021 14:30	NO End Date Time: Jan/27/2021 15:00	Repeating Pages
4.	ADVERSE EVENT	4	Headache	Jan/26/2021 18:00	NO End Date Time: Jan/28/2021 12:00	Repeating Pages
5.	ADVERSE EVENT	5	Chills	Feb/16/2021 22:00	NO End Date Time: Feb/17/2021 17:00	Repeating Pages
6.	ADVERSE EVENT	6	Headache	Feb/17/2021 08:00	NO End Date Time: Feb/17/2021 18:00	Repeating Pages

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[umbilical hernia]
4.	Start Date Time:	Dec/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/4/2020 UNK:UNK
6.	Toxicity Grade:	+
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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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: [umbilical hernia recurrence]
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	[2020483017]

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[umbilical hernia]
4.	Start Date Time:	Nov/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/3/2020 UNK:UNK
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).	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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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: [unknown]
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	[2020483017]

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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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)	[Pain injection side]
4.	Start Date Time:	Jan/26/2021 14:30
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/27/2021 15:00
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: 11951131
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen
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?:	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	[]

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[Headache]	
4.	Start Date Time:	Jan/26/2021 18:00	
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/28/2021 12:00	
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?	YES	Comments

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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?:	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	[]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Feb/16/2021 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 17:00
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: 11951131
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen
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?:	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	[]

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Feb/17/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/17/2021 18:00
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?	YES

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Header Text: C4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1195
Subject No: 11951131
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Frozen
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?:	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	[]

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: 11951131

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.						Repeating Pages

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1195

Subject No: 11951131

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	[]

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951131

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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:	//

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: 11951131

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.						Repeating Pages

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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?	

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951131

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.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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

[Back to Form](#)

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: 11951131

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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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: 11951131

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:	

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: 11951131

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:	

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

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?	

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: 11951131

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: 11951131

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: 11951131

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/5/2020
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: 11951131

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/25/2021
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: 11951131

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
----	---	--

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1195

Subject No: 11951131

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: 11951131

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/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: C4591001	Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1195) Medizentrum Essen Borbeck
Site No: 1195	Subject Initials: ---
Subject No: 11951131	Generated Time (GMT): 29-Mar-2021 12:55
Generated By: (b) (4)	

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: 11951131

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: 11951131

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	Jan/26/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1195

Subject No: 11951131

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 Jan/26/2021
----	--------------	--

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: 11951131

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: 11951131

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 :	Jan/26/2021
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:** 11951131**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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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: Jan/26/2021
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	[BN8KYD]
5.b	Sample ID	[BN8KYF]
5.c	Sample ID	[BNLW8H]
5.d	Sample ID	[BNLW8J]

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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: Jan/26/2021
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	[BN8KY2]
-----	-----------	----------

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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:	Jan/26/2021 10:18
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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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/16/2021
2.	Erroneous Visit	

Header Text: C4591001**Visit:** V102_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1195**Subject No:** 11951131**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 _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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/16/2021
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	[BN8L3T]
-----	-----------	----------

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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/16/2021 09:56
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

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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: 11951131

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: 11951131

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: 11951131

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: 11951131

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: 11951131

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: 11951131

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/5/2020

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: 11951131

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: 11951131

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	Feb-22-2021 21:35:53 (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.

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, 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-19-2020 13:31:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, 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-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
3	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001
Visit: V1_DAY1_VAX1_L
Form Version: 10-Oct-2020 15:58
Site No: 1195
Subject No: 11951131
Generated By: (b) (4)
Form: LAB URINALYSIS - PREGNANCY TEST - Comments
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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Item	Date	User	Comment
4	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
5	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Item	Date	User	Comment
6.a	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
6.a	Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Nov-07-2020 14:38:52 (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: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Nov-07-2020 14:16:56 (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: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
1	Nov-07-2020 14:16:56 (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: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
2	Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

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Site No: 1195

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
3	Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
4	Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

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Site No: 1195

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
5	Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

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Site No: 1195

Subject No: 11951131

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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Item	Date	User	Comment
6.a	Nov-07-2020 14:16:56 (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: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Nov-07-2020 14:16:56 (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: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Deleted, Frozen

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	Jan-28-2021 19:58:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Patient took 1 paracetamol 500mg on 27 Jan 2021

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-26-2021 18:01:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
2	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
4	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

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Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
5	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

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Site No: 1195

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Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
6.a	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V101_VAX3

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Site No: 1195

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
6.a	Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
Form	Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
1	Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
2	Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V102_VAX4

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Site No: 1195

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Item	Date	User	Comment
3	Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1195) Medizentrum Essen Borbeck

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Item	Date	User	Comment
4	Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V102_VAX4

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Item	Date	User	Comment
5	Feb-16-2021 11:27:38 (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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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Item	Date	User	Comment
6.a	Feb-16-2021 11:27:38 (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: 11951131

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	Feb-22-2021 21:35:53 (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	Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Feb-16-2021 14:47:26 (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	Feb-16-2021 11:25:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Axel Schaefer	Approved	Jan-31-2021 20:24:23 (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-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Jan-27-2021 08:23:16 (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 18:00:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Jan-25-2021 21:06:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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:** 11951131**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-25-2021 13:47:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Jan-21-2021 14:02:27 (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-21-2021 10:44:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit

N/A

Axel Schaefer	Approved	Jan-19-2021 16:44:32 (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.

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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Jan-19-2021 15:34:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Dec-23-2020 21:02:56 (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	Dec-22-2020 12:54:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Dec-09-2020 19:41:49 (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	Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Axel Schaefer	Approved	Dec-06-2020 13:10:25 (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	Dec-05-2020 12:46:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Axel Schaefer	Approved	Dec-05-2020 12:33:48 (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	Dec-05-2020 12:31:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
Affidavit: N/A				
Axel Schaefer	Approved	Nov-10-2020 09:18:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	BOOK	Signed

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

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	Nov-07-2020 14:16:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		Edit - All signatures invalidated
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Affidavit:

N/A

Axel Schaefer	Approved	Nov-04-2020 17:50:58 (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.

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: COHORT_SELECTION - 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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-19-2020 13:30:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 13:30:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - 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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-19-2020 13:30:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: DEMOGRAPHY - 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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-19-2020 13:29:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11951131	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-19-2020 13:30:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1953	Transcription Error
Oct-19-2020 13:29:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: UNK/UNK/1968	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-19-2020 13:30:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-19-2020 13:30:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 13:30:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 13:31:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - 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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-19-2020 13:31:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 13:31:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 13:31:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1195**Subject No:** 11951131**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Jan-21-2021 10:44:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: Apr/1/2000 Ongoing: YES	Transcription Error
Oct-19-2020 18:50:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: Oct/1/2000 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:50:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:50:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 10:44:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/1/2000	Transcription Error

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Oct-19-2020 18:50:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2000	Initial Entry
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1.a Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:50:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-19-2020 18:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term pollinosis : Start Date: Oct/1/199 9 Ongoing: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pollinosis	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/1999	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:52:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History Term: Psoriasis vulgaris Start Date: Oct/1/1999 Ongoing: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:36:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 19:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no systemic treatment with steroids or immunosuppressive drugs for the ongoing psoriasis
Oct-20-2020 18:26:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	is the patient under systemic treatment with steroids or immunosuppressive drugs for the ongoing psoriasis?
Oct-19-2020 18:53:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Psoriasis vulgaris	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/1999	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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)

1.d

Date	Location	User	Value	Reason
Oct-19-2020 18:54:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbr: 4 er: Medical History: diabetes mellitus Term: type 2 Start Date: Oct/24/2019 Ongoing: YES	Initial Entry

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetes mellitus type 2	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/24/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Oct-19-2020 18:54:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: scoliosis Start Date: Aug/30/2018 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: scoliosis	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/30/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:54:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-19-2020 18:55:55 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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			r: Medical History Term: retropatellar art hrosis Start Date: Dec/11/2017 Ongoing: YES
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1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:55:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-19-2020 18:55:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: retropatellar arthrosis	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:55:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2017	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:55:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Oct-19-2020 18:57:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History Term: reflux esophagitis	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

			Start Date:	Oct/12/2015
			Ongoing:	YES

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:57:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-19-2020 18:57:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: reflux esophagitis	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 18:57:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2015	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 18:57:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-28-2020 18:12:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Postmenopausal Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-28-2020 18:12:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-28-2020 18:12:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Postmenopausal	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-28-2020 18:12:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Oct-28-2020 18:12:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Dec-08-2020 15:56:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: umbilical hernia Start Date: Apr/30/2020 Ongoing: NO End Date: May/11/2020	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

1.i Line/MH Number:

Date	Location	User	Value	Reason
Dec-08-2020 15:56:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Dec-08-2020 15:56:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: umbilical hernia	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Dec-08-2020 15:56:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/30/2020	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Dec-08-2020 15:56:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/11/2020	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-19-2020 13:33:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-21-2021 10:45:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88.4	Transcription Error
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 159.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

Jan-21-2021 10:45:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.0	Transcription Error
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 37.2 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

Oct-19-2020 13:32:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Skopje, Warsaw, Zagreb		(b) (4), (b) (6)		
Nov-07-2020 14:38:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review and update as appropriate.
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55

Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Applicable Not Done:: Not Applicable	Initial Entry
Nov-07-2020 14:38:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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)	Choriogonadotropin Beta_PX1 13
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6.a Result:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-07-2020 14:38:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-19-2020 18:49:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-07-2020 14:38:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: RANDOMIZATION - 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. Randomization Date :

Date	Location	User	Value	Reason
Oct-19-2020 18:49:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 270712	Initial Entry

Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**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-19-2020 16:40:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 16:40:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 16:40:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 16:40:09 (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-19-2020 16:40:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 16:40:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMDPS	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:40:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMDPS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 16:40:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNMDPT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:40:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNMDPT	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 16:41:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN868V	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:41:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN868V	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-19-2020 16:41:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN868W	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:41:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN868W	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, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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-19-2020 16:41:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 16:41:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 16:41:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 16:41:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8693	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 16:41:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8693	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020 13:26	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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

7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 18:49:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - 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 - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-19-2020 13:33:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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
Nov-07-2020 14:16:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	Initial Entry

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**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-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

			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
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED M USCLE PAIN Were fever or syst emic symptoms pr esent on the last d ay the Subject Dia ry was completed? : NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**2.g Symptom:**

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD 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
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT P AIN Were fever or syst emic symptoms pr esent on the last da y the Subject Diar y was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE : DN ES S Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction SW :: ELL ING Were injection site rea ctions present on the la st day the Subject Diar y was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti PAIN on:: AT INJ ECTIO N SIT E Were injection site r NO eactions present on t he last day the Subj ect Diary was compl eted?:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 14:16:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 16:01**Site No:** 1195**Subject No:** 11951131**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - 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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.6 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Applicable
		Test::	Not Applicable
		Result::	Not Applicable
		Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-07-2020 14:16:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
Nov-07-2020 14:17:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-07-2020 14:17:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-07-2020 14:47:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-07-2020 14:17:10 (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-07-2020 14:17:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-07-2020 14:47:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN86GS	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-07-2020 14:47:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN86GS	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020 11:43	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951131

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

7. Route:

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-07-2020 14:17:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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-05-2020 12:31:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020	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:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**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
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

			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-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED M USCLE PAIN Were fever or syst emic symptoms pr esent on the last d ay the Subject Dia ry was completed? : NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**2.g Symptom:**

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD 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-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT P AIN Were fever or syst emic symptoms pr esent on the last da y the Subject Diar y was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE : DN ES S Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction SW :: ELL ING Were injection site rea ctions present on the la st day the Subject Diar y was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reacti PAIN on:: AT INJ ECTIO N SIT E Were injection site r NO eactions present on t he last day the Subj ect Diary was compl eted?:	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 12:31:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
Dec-05-2020 12:31:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-05-2020 12:31:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-05-2020 12:46:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-05-2020 12:31:53 (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-05-2020 12:31:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-05-2020 12:46:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8KLY	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:46:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8KLY	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-05-2020 12:46:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8KLZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:46:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8KLZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-05-2020 12:47:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLWPP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:47:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLWPP	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-05-2020 12:47:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNLWPR	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-05-2020 12:47:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLWPR	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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
Jan-19-2021 15:34:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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
Dec-07-2020 16:30:49 (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: 11951131

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
Jan-28-2021 19:56:34 (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: 11951131

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
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1195

Subject No: 11951131

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
Feb-18-2021 14:09:26 (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: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-22-2020 15:27:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you for your response. FU has been noted. Thank you.
Dec-21-2020 08:02:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-18-2020 19:05:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for confirming, would you kindly send a FU report with this information so this is added to safety. Please include further information on clinical presentation if available. Thank you.
Dec-14-2020 18:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	yes I confirm

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Header Text: C4591001

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Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec-14-2020 02:48:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Would you kindly confirm if the subject had an elective surgery for the umbilical hernia? Thank you.
Dec-10-2020 18:27:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	it was only a hernia no complication
Dec-09-2020 23:38:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per SAE report AER# 2020483017, the event required surgery. Please clarify the complication associated to the hernia that prompted intervention (hernia obstruction/ strangulation...). Kindly provide details in a FU report. Thank you.
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: umbilical hernia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-31-2020 09:49:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-22-2020 15:20:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-22-2020 15:20:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020 UNK:UNK	Transcription Error
Dec-22-2020 12:58:06	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	SAE RECON:

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb		(b) (4), (b) (6)		AER#2020483017 ,onset date was recorded as 02Dec2020 in Safety database however, recorded as 03Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/4/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec-22-2020 12:54:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Answer Auto Query
Dec-15-2020 12:32:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Wait till SAE# is entered.
Dec-07-2020 17:26:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this number is coming from Pfizer.
Dec-07-2020 13:51:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For AE umbilical hernia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE umbilical hernia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect? NO Did this serious event result in death? NO Did this serious event require o r prolong hospitalization? YES Did this serious event result in	Initial Entry

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Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-09-2020 20:18:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 15:56:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-07-2020 15:08:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY-the AE of "umbilical hernia" is reported to be a recurrence of a same prior event. Please review and update as appropriate source data and the medical history page (this page will be unfrozen) thank you

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: umbilical hernia recurrence	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec-05-2020 13:24:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-22-2020 12:54:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020483017	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-19-2021 15:35:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: umbilical hernia	New Information
Dec-29-2020 08:29:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-28-2020 11:02:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	no it's not a worsening it was a new umbilical hernia
Dec-23-2020 12:15:23	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 3: Op	The AE suspicion of umbilical hernia was

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(UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb			ened	reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Dec-22-2020 12:55:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	AE#1 updated
Dec-17-2020 11:08:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON 1: The term in Safety database was reported as 'umbilical hernia recurrence' while 'suspicion of umbilical hernia' in AE CRF. Please confirm correct term and update accordingly.
Dec-14-2020 18:37:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	but it was recovered in May. So its a new hernia not a worsening
Dec-11-2020 16:24:40 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Sarajevo, Skopje, Warsaw, Zagreb				
Dec-11-2020 13:36:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	SAE RECON: AER#2020483017Per CRF completion requirements V10 section 8.50.2.3. If the event of umbilical hernia is an intermittent AE (as reported on Med Hx)the new episodes should be recorded as "worsening of". Please update
Dec-10-2020 18:35:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	yes but if you look at the dates you see that it was before the SAE.
Dec-10-2020 18:24:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Op ened	actually this AE occurred earlier with respect to AE 1 and should be reported as the first one.
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : suspicion of umbili cal he rnia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/24/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:38:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/3/2020 UNK:UNK	Transcription Error
Dec-07-2020 17:25:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/2/2020 UNK:UNK	Transcription Error
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-25-2021 16:29:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-25-2021 15:16:58 (UTC+01:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Sarajevo, Skopje, Warsaw, Zagreb				
Jan-25-2021 13:47:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE umbilical hernia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-25-2021 13:47:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-25-2021 13:47:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associ- ated with congenital anom- aly or birth defect? NO Did this serious event resu- lt in death? NO Did this serious event requ- ire or prolong hospitalizati- on? YES Did this serious event resu- lt in persistent or significa- nt disability/incapacity? NO Is this serious event life th- reatening? NO Other medically important serious event NO	Transcription Error

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1195**Subject No:** 11951131**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1195) Medizentrum Essen Borbeck**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

Jan-25-2021 04:32:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON:Event still recorded as SERIOUS in Safety database while NON SERIOUS in AE CRF. If event is confirmed not serious, please submit a follow up AEM form to clarify and downgrade event in Safety database
Jan-21-2021 20:06:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I updated the onset date in a SAE Follow up. Onset date was 24NOV2020 thats the reason for the deletion
Jan-21-2021 09:06:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020483017 umbilical hernia(onset date:02Dec2020)was reported as serious in Safety database but nonserious in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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			OTHER	
			<i>If Other, specify:</i>	
			unknown	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 17:26:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-07-2020 17:26:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Dec-07-2020 17:25:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE suspicion of umbilical hernia: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving'

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				but AE End Date/Time is present.
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 16:30:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-25-2021 16:29:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020483017	Initial Entry

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Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pain injection side	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 14:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/27/2021 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Skopje, Warsaw, Zagreb

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 19:56:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-01-2021 17:20:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 17:45:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no covid illness visit performed. Headache is a side effect. No potential covid illness.
Jan-29-2021 16:44:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	was a COVID illness visit envisaged due to the onset of headache?
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 18:00	Initial Entry

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Subject No: 11951131

Generated By: (b) (4)

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Subject Initials: ---

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Skopje, Warsaw, Zagreb

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

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/28/2021 12:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	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
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:08:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

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
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/17/2021 18:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	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
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 14:09:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1195

Subject No: 11951131

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - 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 of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-05-2020 13:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-05-2020 13:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-05-2020 13:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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: 11951131

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-25-2021 16:00:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1195

Subject No: 11951131

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 17:16:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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	Transcription Error
Jan-25-2021 16:01:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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-25-2021 16:00:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 16:00:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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
Jan-26-2021 18:00:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/26/2021	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: 11951131

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
Jan-26-2021 18:01:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Sponsor-Defined Identifier:	Not Applicable
		Test::	Not Applicable
		Result::	Not Applicable
		Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 18:01:50 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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:** 11951131**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
Jan-26-2021 18:02:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 18:02:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 18:02:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 18:02:12 (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.
Jan-26-2021 18:02:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 18:02:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8KYD	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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 18:02:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8KYD	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-26-2021 18:02:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN8KYF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 18:02:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN8KYF	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-26-2021 18:03:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLW8H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 18:03:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNLW8H	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-26-2021 18:03:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNLW8J	Initial Entry

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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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 18:03:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNLW8J	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:** 11951131**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
Jan-26-2021 18:03:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 18:03:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 18:03:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 18:03:45 (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.
Jan-26-2021 18:03:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 18:03:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8KY2	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: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 18:03:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8KY2	Initial Entry

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-29-2021 16:14:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 19:54:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	patient had side effects after study vaccination. Its reported in AE section
Jan-28-2021 16:40:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	the patient reported a COVID symptom in the illness diary on Jan 28th: is an in person COVID illness visit or telehealth visit going to be

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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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

				performed?
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 10:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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

Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry
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II. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-26-2021 18:04:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951131

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-16-2021 11:25:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

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, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

Skopje, Warsaw, Zagreb	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (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, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951131**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-16-2021 11:28:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 11:28:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 11:28:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 11:28:19 (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-16-2021 11:28:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 11:28:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN8L3T	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, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 11:28:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN8L3T	Initial Entry

Header Text: C4591001

Visit: V102_VAX4

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Site No: 1195

Subject No: 11951131

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-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 09:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

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Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951131

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

7. Route:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 11:29:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951131

Subject Initials: ---

Generated By: (b) (4)

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

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I. Subject Status

Date	Location	User	Value	Reason
Dec-05-2020 13:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-19-2020 18:49:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-19-2020 13:31:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-02-2021 19:06:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021 16:01:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient had Side effect after Study vaccination. No Covid Illness and no Covid Illness Visit done.
Jan-29-2021 17:28:40 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	the patient reported a COVID symptom in the illness diary on Jan 28th:is an in person COVID illness visit or telehealth visit going to be performed?
Dec-05-2020 13:22:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/5/2020	Initial Entry
Oct-19-2020 18:49:19 (UTC+01:00) Sarajevo,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry

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Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951131

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

Skopje, Warsaw, Zagreb				
Oct-19-2020 13:31:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae2f99\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

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Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1195

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Subject No: 11951131

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-03-2020 19:36:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry