

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: 11951008

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: 11951008

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/15/2020 |
|----|--------------|--|

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11951008] |
| 2. | Birth Date: | UNK/UNK/1970 |
| 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: 11951008

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/15/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1195

Subject No: 11951008

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 _____ |
|----|---|-------------------------|

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1195

Subject No: 11951008

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/15/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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: | [hypercholesterolemia] |
| | Start Date: | Apr/15/2010 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [struma diffusa] |
| | Start Date: | Apr/24/2012 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [depression (controlled)] |
| | Start Date: | Feb/UNK/2020 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Tubal ligation sterilisation] |
| | Start Date: | UNK/UNK/2005 |
| | Ongoing: | NO End Date: UNK/UNK/2005 |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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: | [Haemorrhoids] |
| | Start Date: | UNK/UNK/1999 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Diabetes mellitus II (stable and controlled)] |
| | Start Date: | Jan/3/2020 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [arteriosclerotic Plaque] |
| | Start Date: | Apr/28/2010 |
| | Ongoing: | YES |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: HIV STATUS

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](#)

HIV Status

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1195

Subject No: 11951008

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/15/2020 |
| 2. | Weight: | [70.2] |
| 3. | Unit: | kg |
| 4. | Height: | [158.0] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [28.1] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.9] |
| | 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:** 11951008**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 Done _____ | Comments |
| 2. | Lab Sub-Panel: | Not Done _____ | Comments |
| 3. | Collection Date: | Not Done _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Done _____ [] | Comments |
| 5. | Specimen Type: | Not Done _____ | Comments |

Lab Result

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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/15/2020 |
| 2. | Randomization Number: | [107852] |
| 3. | Randomization Group: | [] |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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/15/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BNMDF3] |
| 5.b | Sample ID | [BNMDF4] |
| 5.c | Sample ID | [BN8WV2] |
| 5.d | Sample ID | [BN8WV3] |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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/15/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN8WTT] |
|-----|-----------|----------|

090177e196ae2f96\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: 11951008

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/15/2020 13:18 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1195

Subject No: 11951008

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 |
|----|---|---|

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

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/3/2020 |
| 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: 11951008

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 |

090177e196ae2f96\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: 11951008

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 |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

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/3/2020 |
|----|-------|------------|

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: 11951008

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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/3/2020 |
| 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 | [BN86D0] |
|-----|-----------|----------|

090177e196ae2f96\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: 11951008

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/3/2020 08:43 |
| 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 |

090177e196ae2f96\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: 11951008

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/2/2020 |
| 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: 11951008

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 |

090177e196ae2f96\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: 11951008

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 |

090177e196ae2f96\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: 11951008

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/2/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN8KG5] |
| 5.b | Sample ID | [BN8KG6] |
| 5.c | Sample ID | [BNLWJZ] |
| 5.d | Sample ID | [BNLWK0] |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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 | Nov/23/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|-------------|
| 1. | Date of Assessment: | Nov/23/2020 |
| 2. | Date of First Symptom Started: | Nov/23/2020 |
| 3. | Symptoms Ongoing? | NO |
| | Date of Last Symptom Resolved: | Nov/26/2020 |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | NO |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | NO |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | NO |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | YES |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | YES |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | NO |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | NO |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|-----|----------------------|----------|
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

Symptoms - Other

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|---------------|------------------------------|----------------------------|-------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Microbiology Specimen

| | | | |
|----|-------------------------------|----------------------------|--------------------------|
| 1. | Actual Date of Collection: | Not Done _____ // | Comments |
| 2. | Specimen Type: | Not Done _____ | Comments |
| 3. | Specimen Collection Location: | Not Done _____ _____ | Comments |
| 4. | Assay Code and Description: | Not Done _____ _____ | Comments |
| 5. | Device Type: | Not Done _____ | Comments |
| 6. | Trade Name: | Not Done _____ | Comments |
| 7. | Test Result: | Not Done _____ | Comments |
| 8. | Comments/Findings/Details: | Not Done _____ [] | Comments |
| 9. | Trade Name Other, Specify: | Not Done _____ [] | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [patient came into the office for a swab test. No self swab necessary.] |

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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/23/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN8KDS] |
|-----|-----------|----------|

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

| | | |
|-----|---------------------------------------|---|
| 1.a | Physician or Healthcare Professional: | SPECIALIST |
| | Occurrence of Visits or Contacts: | NO |
| 1.b | Physician or Healthcare Professional: | EMERGENCY ROOM |
| | Occurrence of Visits or Contacts: | NO |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
| | Occurrence of Visits or Contacts: | YES Number of Visits or Contacts: [1] |
| 1.d | Physician or Healthcare Professional: | URGENT CARE |
| | Occurrence of Visits or Contacts: | NO |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
| | Occurrence of Visits or Contacts: | NO |
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

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? | NO |
|----|--|----|

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance |
|----|----------------------|---------------------------------------|-----------|-----------|------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

| | | | |
|----|---|--------------------------|--------------------------|
| 1. | What is the treatment Identifier? | Not Done _____ [] | Comments |
| 2. | Concomitant Non-drug Treatment Pre-specified: | Not Done _____ | Comments |
| 3. | Treatment: | Not Done _____ | Comments |
| 4. | Treatment: | Not Done _____ [] | Comments |
| 5. | Start Date: | Not Done _____ // | Comments |
| 6. | Ongoing? | Not Done _____ | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

| | | |
|----|--|---|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES Respiratory Illness Diagnosis: [Common cold] Date of Diagnosis: Nov/23/2020 |
| 3. | Toxicity Grade: | 1 |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Category of Clinical Event | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/23/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

| | | | |
|----|--------------------------------|-------------------|--------------------------|
| 1. | Category of Clinical Event: | Not Done _____ | Comments |
| 2. | Subcategory of Clinical Event: | Not Done _____ | Comments |
| 3. | Was a diagnosis obtained? | Not Done _____ | Comments |
| 4. | Toxicity Grade: | Not Done _____ | Comments |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-------------|------------------|---------------|-----------------------------------|--------------|----------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/23/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

| | | | |
|----|-----------------------------|--------------------------|--------------------------|
| 1. | Lab Panel: | Not Done _____ | Comments |
| 2. | Laboratory Name and Address | Not Done _____ [] | Comments |
| 3. | Collection Date: | Not Done _____ // | Comments |
| 4. | Specimen Type: | Not Done _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | C Reactive Protein_PX329 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/23/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Alanine Aminotransferase_PX30 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.c | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Aspartate Aminotransferase_PX28 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/23/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Alkaline Phosphatase_PX35 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.e | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Bilirubin_PX21 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/23/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Blood Urea Nitrogen_PX47 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.g | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Creatinine_PX48 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-----------------------|------------------|---------------|-----------------------------------|--------------|-----------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Sponsor-Defined Identifier | Test: | Result : | Repeating Pages |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |
| | | | | | Not Done | Not Done | Not Done | |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

| | | | |
|----|-----------------------------|--------------------------|--------------------------|
| 1. | Lab Panel: | Not Done _____ | Comments |
| 2. | Laboratory Name and Address | Not Done _____ [] | Comments |
| 3. | Collection Date: | Not Done _____ // | Comments |
| 4. | Specimen Type: | Not Done _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Hemoglobin_PX1 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Hematocrit_PX2 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.c | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Erythrocytes_PX3 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Platelets_PX5 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.e | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Leukocytes_PX7 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Neutrophils_PX608 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.g | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Eosinophils_PX609 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.h | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Monocytes_PX612 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ [] | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.i | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Basophils_PX610 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ [] | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/23/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|-------------|--|--------------------------|
| 5.j | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Lymphocytes_PX611 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ [] | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Date: | Vital Signs Details | | | Form Instance |
|----|----------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Not Done | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | Not Done | Not Done | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

| | | | |
|----|-------|-------------------------|--------------------------|
| 1. | Date: | Not Done _____ // | Comments |
|----|-------|-------------------------|--------------------------|

Vital Signs Details

| | | | |
|-----|--|--------------------------|--------------------------|
| 2.a | Record Identifier: | Not Done _____ 1 | |
| | Systolic: | Not Done _____ [] | Comments |
| | Diastolic: | Not Done _____ [] | Comments |
| | Respiratory Rate in respirations/minute: | Not Done _____ [] | Comments |
| | Heart Rate in beats/minute: | Not Done _____ [] | Comments |

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Date: | Vital Signs Details | | Form Instance |
|----|----------|---------------------------|--------------------------|---------------------------------|
| 1. | Not Done | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | Not Done | Not Done | |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Nov/23/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

| | | | |
|----|-------|-------------------------|--------------------------|
| 1. | Date: | Not Done _____ // | Comments |
|----|-------|-------------------------|--------------------------|

Vital Signs Details

| | | | |
|-----|-----------------------|--------------------------|--------------------------|
| 2.a | Record Identifier: | Not Done _____ 1 | |
| | SPO2 Pulse Oximetry % | Not Done _____ [] | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Repeating Pages |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

| | | | |
|----|------------------------------------|--------------------------|--------------------------|
| 1. | Date Time of Assessment: | Not Done _____ // | Comments |
| 2. | Arterial Blood Gases PaO2 (mmHg): | Not Done _____ [] | Comments |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | Not Done _____ [] | Comments |

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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. | Not Done | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Nov/23/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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? | Not Done _____ [] | Comments |
| 2. | Category: | Not Done _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Done _____ | Comments |
| 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). | Not Done _____ [] | Comments |
| 5. | Start Date: | Not Done _____ // | Comments |
| 6. | Ongoing? | Not Done _____ | Comments |

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

| | | | |
|----|-------------------------|----------------------------|--------------------------|
| 1. | Date of Assessment: | Not Done _____ // | Comments |
| 2. | Location of Assessment: | Not Done _____ | Comments |
| 3. | Type of Imaging Exam: | Not Done _____ _____ | Comments |
| 4. | Assessment: | Not Done _____ | Comments |

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Dec/22/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

| | | |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_A1 |
|----|-------------------------|----------|

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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/22/2020 |
| 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 | [BN8KTV] |
| 5.b | Sample ID | [BN8KTW] |
| 5.c | Sample ID | [BNLW60] |
| 5.d | Sample ID | [BNLW61] |

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

COVID-19 Repeat Swab

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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 | hemorrhoids | Nov/1/2020 UNK:UNK | YES | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | limb pain | Feb/10/2021 01:00 | NO End Date Time: Feb/11/2021 08:00 | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | Chills | Feb/10/2021 01:00 | NO End Date Time: Feb/11/2021 08:00 | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | anal prolapse | Feb/18/2021 UNK:UNK | NO End Date Time: Feb/27/2021 UNK:UNK | Repeating Pages |
| 5. | ADVERSE EVENT | 5 | anal fistula | Feb/25/2021 UNK:UNK | NO End Date Time: Feb/25/2021 UNK:UNK | Repeating Pages |
| 6. | ADVERSE EVENT | 6 | Abscess | Feb/27/2021 UNK:UNK | NO End Date Time: Feb/27/2021 UNK:UNK | Repeating Pages |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

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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Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [+] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [hemorrhoids] |
| 4. | Start Date Time: | Nov/1/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 1 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | 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 |

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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

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

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [limb pain] |
| 4. | Start Date Time: | Feb/10/2021 01:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/11/2021 08:00 |
| 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 |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | |
|-----|--|--------------------|
| 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 | [] |

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Chills] |
| 4. | Start Date Time: | Feb/10/2021 01:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/11/2021 08:00 |
| 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 |

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | |
|-----|--|--------------------|
| 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 | [] |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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Adverse Event Report

| | | |
|----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [4] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [anal prolapse] |
| 4. | Start Date Time: | Feb/18/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/27/2021 UNK:UNK |
| 6. | Toxicity Grade: | 3 |
| 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 |

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Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | |
|-----|--|--|
| 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: [Hemorrhoids] |
| 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 | [2021205401] |

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Header Text: C4591001

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Site No: 1195

Subject No: 11951008

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: | [5] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [anal fistula] |
| 4. | Start Date Time: | Feb/25/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/25/2021 UNK:UNK |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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 |

090177e196ae2f96\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: 11951008

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

| | | |
|-----|--|--------------------|
| 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 | [] |

090177e196ae2f96\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: 11951008

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) | [Abscess] |
| 4. | Start Date Time: | Feb/27/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/27/2021 UNK:UNK |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [due to haemorrhoids] |

090177e196ae2f96\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: 11951008

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

| | | |
|-----|--|--------------------|
| 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 | [] |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951008

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 |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1195

Subject No: 11951008

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 | [] |

090177e196ae2f96\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: 11951008

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: 11951008

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: | // |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951008

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 |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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? | |

090177e196ae2f96\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: 11951008

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: 11951008

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: 11951008

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: 11951008

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

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: 11951008

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 | Oct/29/2020 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Oct/29/2020 Contact Outcome: VISIT ARRANGED |
| 3. | Comments: | [unplanned visit was done due to missing pregnancy test by mistake at Visit 1.urinary pregnancy test on 29/Oct/2020, result: negativ.] |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Oct/29/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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

Vital Signs

| | | | |
|----|-------|-------------------------------|--------------------------|
| 1. | Date: | Not Applicable _____ // | Comments |
|----|-------|-------------------------------|--------------------------|

Vital Signs Details

| | | | |
|-----|-----------------------|----------------------------------|--------------------------|
| 2.a | Record Identifier: | Not Applicable _____ 1 | |
| | Temperature: | Not Applicable _____ [] | Comments |
| | Unit: | Not Applicable _____ _____ | Comments |
| | Temperature Location: | Not Applicable _____ _____ | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Oct/29/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Form Comments](#)[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

| | | | |
|----|---------------------------|-------------------------|--------------------------|
| 1. | Date of Assessment: | Not Done _____ // | Comments |
| 2. | Injection Site Location | Not Done _____ | Comments |
| 3. | Injection Site Body Side: | Not Done _____ | Comments |

Reaction

| | | | |
|-----|-------------------|-------------------|--------------------------|
| 4.a | Reaction: | REDNESS | |
| | Reaction Present: | Not Done _____ | Comments |
| 4.b | Reaction: | SWELLING | |
| | Reaction Present: | Not Done _____ | Comments |

Symptom

| | | | |
|-----|------------------|------------------------|--------------------------|
| 5.a | Symptom: | PAIN AT INJECTION SITE | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.b | Symptom: | FATIGUE/TIREDNESS | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.c | Symptom: | HEADACHE | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.d | Symptom: | VOMITING | |
| | Symptom Present: | Not Done _____ | Comments |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|-----|------------------|-------------------------------|--------------------------|
| 5.e | Symptom: | DIARRHEA | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.f | Symptom: | NEW OR WORSENERED MUSCLE PAIN | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.g | Symptom: | NEW OR WORSENERED JOINT PAIN | |
| | Symptom Present: | Not Done _____ | Comments |
| 5.h | Symptom: | CHILLS | |
| | Symptom Present: | Not Done _____ | Comments |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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: 11951008

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: | |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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: | |

090177e196ae2f96\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: 11951008

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? | |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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: 11951008

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: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Dec/2/2020 |
| 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: 11951008

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/18/2021 |
| 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1195

Subject No: 11951008

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: 11951008

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/18/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Withdrawal Of Consent

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

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: 11951008

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: 11951008

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/18/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1195

Subject No: 11951008

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/18/2021 |
|----|--------------|--|

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: 11951008

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: 11951008

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/18/2021 |
| 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: 11951008

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

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Jan/18/2021 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae2f96\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: 11951008

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/18/2021 |
| 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 | [BN8KVS] |
| 5.b | Sample ID | [BN8KVR] |
| 5.c | Sample ID | [BNLW74] |
| 5.d | Sample ID | [BNLW75] |

090177e196ae2f96\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: 11951008

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/18/2021 |
| 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 | [BN8KVP] |
|-----|-----------|----------|

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

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/18/2021 11:29 |
| 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 |

090177e196ae2f96\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: 11951008

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/9/2021 |
| 2. | Erroneous Visit | |

Header Text: C4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1195

Subject No: 11951008

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

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Feb/9/2021 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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/9/2021 |
| 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 | [BN8L1D] |
|-----|-----------|----------|

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

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/9/2021 09:25 |
| 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 |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Mar/10/2021 |
| 3. | Comments: | [] |

Header Text: C4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

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: 11951008

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: 11951008

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: 11951008

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: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|----------------------|
| 1. | Date of Completion/Discontinuation/Death : | Mar/10/2021 |
| 2. | Phase of Disposition: | OPEN LABEL TREATMENT |
| 3. | Status: | COMPLETED |
| 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: 11951008

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/2/2020 |

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: 11951008

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Axel Schaefer | Approved | Mar-11-2021 13:49:14 (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.

090177e196ae2f96\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: 11951008

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-16-2020 13:29:01 (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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| Form | Nov-06-2020 13:06:26 (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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 1 | Nov-06-2020 13:06:26 (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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 2 | Nov-06-2020 13:06:26 (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: 11951008

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 |
|------|---|------------------|---------------------------------|
| 3 | Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 3 | Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| 3 | Nov-05-2020 10:36:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | not done by mistake Not Done |
| 3 | Nov-05-2020 10:35:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f96\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: 11951008

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 |
|------|---|------------------|----------------|
| 4 | Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 4 | Nov-06-2020 13:06:26 (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: 11951008

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 |
|------|---|------------------|----------------|
| 5 | Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 5 | Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |

090177e196ae2f96\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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 6.a | Nov-06-2020 13:06:26 (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: 11951008

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 |
|------|---|------------------|----------------|
| 6.a | Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 6.a | Nov-06-2020 13:06:26 (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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 6.a | Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| Item | Date | User | Comment |
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| 2 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 3 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

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| Item | Date | User | Comment |
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| 4 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 5 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 6 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 7 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| 8 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| 9 | Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| Item | Date | User | Comment |
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| Form | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| Item | Date | User | Comment |
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| 1 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| 2 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 3 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 4 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen, Verified

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| Item | Date | User | Comment |
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| 5 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen, Verified

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| Item | Date | User | Comment |
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| 6 | Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/23/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/23/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 1 | Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Status: Data Complete, Frozen, Verified

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| Item | Date | User | Comment |
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| 2 | Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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| Item | Date | User | Comment |
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| 3 | Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 4 | Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 1 | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
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| 2 | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| 3 | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| 4 | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| Item | Date | User | Comment |
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| 5.a | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| 5.a | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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| 5.a | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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| Item | Date | User | Comment |
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| 5.a | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| Item | Date | User | Comment |
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| 5.b | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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| 5.b | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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Site No: 1195

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| 5.b | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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| 5.b | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| 5.c | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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Site No: 1195

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| 5.c | Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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Site No: 1195

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Subject No: 11951008

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| 5.d | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

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| 5.d | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5.d | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5.e | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5 h | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5.i | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5.i | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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| 5.j | Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2.a | Nov-23-2020 10:39:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 3 | Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 3 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 4 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 5 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
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| 6 | Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 3 | Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 4 | Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: VITAL SIGNS - TEMP - Comments

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| Form | Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| 1 | Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |
| 1 | Nov-03-2020 15:20:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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.a | Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| 2.a | Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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.a | Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| 2.a | Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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.a | Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |
| 2.a | Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form Version: 10-Oct-2020 15:57

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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 |
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| Form | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
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| 1 | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
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Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
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Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 3 | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
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Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 4.a | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

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| Item | Date | User | Comment |
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| 4.b | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5.a | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5.b | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
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Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5.c | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5.d | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

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| Item | Date | User | Comment |
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| 5.e | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 5 f | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5.g | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 5 h | Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Done |

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Jan-18-2021 14:47:33 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Not Applicable |

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Axel Schaefer | Approved | Mar-11-2021 13:49:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-10-2021 08:20:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Mar-06-2021 16:24:51 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-04-2021 12:49:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Mar-01-2021 19:21:07 (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-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Feb-16-2021 14:02:31 (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-12-2021 10:19:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Feb-11-2021 21:04:59 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-09-2021 10:57:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Jan-31-2021 20:00:03 (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 | Jan-29-2021 16:31:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Jan-18-2021 22:19:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

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-18-2021 08:51:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Dec-23-2020 20:59:54 (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-22-2020 15:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Dec-09-2020 19:10:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-07-2020 12:45:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Dec-02-2020 16:54:56 (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-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Dec-02-2020 10:56:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-02-2020 09:28:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-26-2020 08:46:37 (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 | Nov-24-2020 17:25:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-23-2020 17:37:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

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-23-2020 10:25:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-20-2020 15:15:49 (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 | Nov-18-2020 12:59:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-10-2020 09:03:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

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-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-08-2020 14:07:11 (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 | Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Axel Schaefer | Approved | Nov-03-2020 19:38:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 19:31:07 (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-15-2020 19:31:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

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-15-2020 19:31:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Oct/15/2020 | Initial Entry |

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1195

Subject No: 11951008

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-15-2020 18:59:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 11951008 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Oct-15-2020 18:59:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> UNK/UNK/1970 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 19:32:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-15-2020 19:32:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-15-2020 19:32:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> WHITE | Initial Entry |

090177e196ae2f96\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: 11951008

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](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 19:31:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1195

Subject No: 11951008

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-15-2020 19:34:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-15-2020 19:34:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-15-2020 19:34:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Oct-15-2020 21:04:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: hypercholesterolemia Start Date: Apr/15/2010 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 21:04:42 (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-15-2020 21:04:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: hypercholesterolemia | Initial Entry |

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 21:04:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Apr/15/2010 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 21:04:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2f96\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: 11951008

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: ---

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I.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Oct-15-2020 21:05:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 2 Medical History Term: struma diffusa Start Date: Apr/24/2012 Ongoing: YES | Initial Entry |

I.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 21:05:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-15-2020 21:05:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: struma diffusa | Initial Entry |

I.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 21:05:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Apr/24/2012 | Initial Entry |

I.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 21:05:55 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.c

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

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Header Text: C4591001

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Subject No: 11951008

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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| | | | | |
|---|-----------------|-------------------------|--|---------------------|
| Oct-16-2020 18:22:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 3 Medical History Term: depression (controlled) Start Date: Feb/UNK/2020 Ongoing: YES | Changed Information |
| Oct-15-2020 21:06:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 3 Medical History Term: depression Start Date: Feb/UNK/2020 Ongoing: YES | Initial Entry |

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-15-2020 21:06:27 (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-19-2020 16:42:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-16-2020 18:22:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Oct-16-2020 18:22:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: depression (controlled) | Changed Information |
| Oct-16-2020 17:12:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | please confirm that ongoing depression is controlled and that exclusion criterion 1 is not met |
| Oct-15-2020 21:06:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: depression | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-15-2020 21:06:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/UNK/2020 | Initial Entry |

I.c Ongoing:

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Header Text: C4591001

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Site No: 1195

Subject No: 11951008

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-15-2020 21:06:27 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------------|
| Oct-30-2020 07:14:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Nu 4 mber: Medical Hist Tubal ligation st ory Term: erisation Start Date: UNK/UNK/200 5 Ongoing: NO End Date: UNK/UNK/2 005 | Transcription Error |
| Oct-29-2020 08:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Num 4 ber: Medical Histor Tubal sterilisa y Term: tion Start Date: UNK/UNK/20 05 Ongoing: NO End Date: UNK/UNK /2005 | Initial Entry |

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Header Text: C4591001

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Subject No: 11951008

Generated By: (b) (4)

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Subject Initials: ---

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

I.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020 08:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|---|-----------------------------|--|--|
| Oct-30-2020 11:04:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Cl osed | Discrepancy has been closed. |
| Oct-30-2020 07:14:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: An swered | Transcription Error |
| Oct-30-2020 07:14:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry</u> : Tubal ligati on sterilisati on | Transcription Error |
| Oct-29-2020 09:49:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Op ened | Clarify the term TUBAL STERILISATION as follows. The term appears incomplete. Are you reporting TUBAL LIGATION -STERILISATION ? Or Other? if so then edit as such. Otherwise please clarify the term further. Thank you. |

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Subject No: 11951008

Generated By: (b) (4)

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Subject Initials: ---

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| | | | | |
|--|-----------------|------------------|---|---------------|
| Oct-29-2020 08:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Tubal sterili sation | Initial Entry |
|--|-----------------|------------------|---|---------------|

1.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|--|
| Nov-02-2020 12:17:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 17:57:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | the term is correct |
| Oct-30-2020 16:27:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | no term coding reported for this condition |
| Oct-29-2020 08:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2005 | Initial Entry |

1.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-29-2020 08:52:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2005 | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------------|
| Nov-18-2020 12:59:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 5 Medical History Term: Haemorrhoids Start Date: UNK/UNK/1999 | Transcription Error |

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Header Text: C4591001

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Subject No: 11951008

Generated By: (b) (4)

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| | | | | |
|---|-----------------|-------------------------|---|---------------------|
| | | | Ongoing: YES | |
| Nov-05-2020 18:43:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number 5 : Medical History T Haemorrhoids Start Date: Sep/9/2009 Ongoing: YES | Transcription Error |
| Nov-05-2020 13:47:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 5 : Medical History T Haemorrhoids Start Date: Sep/9/2009 Ongoing: YES | Initial Entry |

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Subject No: 11951008

Generated By: (b) (4)

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Subject Initials: ---

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I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-05-2020 13:47:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|---|-----------------------------|------------------------------------|--|
| Nov-05-2020 23:09:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Nov-05-2020 18:43:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-05-2020 18:43:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Haemorrhoids | Transcription Error |
| Nov-05-2020 14:43:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Spacing: Verbatim Term contains leading, trailing or more than one consecutive space. |
| Nov-05-2020 13:47:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Haemorrhoids | Initial Entry |

I.e Start Date:

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

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Generated By: (b) (4)

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| | | | | |
|---|-----------------|---------------------|------------------------------------|---------------------|
| Nov-18-2020 12:59:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1999 | Transcription Error |
| Nov-05-2020 13:47:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2009 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-05-2020 13:47:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------------|
| Nov-06-2020 19:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH 6 Number: Medical H Diabetes mellitus I istory Ter I (stable and contr m: olled) Start Date Jan/3/2020 : Ongoing: YES | Transcription Error |
| Nov-05-2020 14:25:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Numb 6 er: Medical Histor Diabetes mell y Term: itus II Start Date: Jan/3/2020 Ongoing: YES | Initial Entry |

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1.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-05-2020 14:25:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 6 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|-----------------------------|
| Nov-07-2020 18:23:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-06-2020 19:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---|
| Nov-06-2020 19:57:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Diabetes mellitus II (stable and controlled) | Transcription Error |
| Nov-06-2020 15:17:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | please confirm that ongoing diabetes is stable and controlled and that inclusion criterion 3 is fulfilled |
| Nov-05-2020 14:25:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Diabetes mellitus II | Initial Entry |

1.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-05-2020 14:25:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/3/2020 | Initial Entry |

1.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-05-2020 14:25:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Nov-18-2020 13:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 Medical History Term: arteriosclerotic Plaque Start Date: Apr/28/2010 Ongoing: YES | Initial Entry |

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Header Text: C4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

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I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 13:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Nov-18-2020 13:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> arteriosclerotic Plaque | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-----------------------------------|---------------|
| Nov-18-2020 13:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Apr/28/2010 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---------------------------|---------------|
| Nov-18-2020 13:28:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2f96\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: 11951008

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-15-2020 21:06:37 (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: 11951008

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-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 70.2 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-15-2020 21:07:12 (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-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 158.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-15-2020 21:07:12 (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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 21:07:12 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 28.1 | Initial Entry |

090177e196ae2f96\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: 11951008

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

Skopje, Warsaw, Zagreb

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: Temperature: 36.9 Temperature Unit: Temperature Location: | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-15-2020 21:07:12 (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-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.9 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-15-2020 21:07:12 (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 |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 21:07:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae2f96\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: 11951008

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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|--------------------------|
| Feb-15-2021 15:42:24 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae2f96\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: 11951008 | | Subject Initials: --- | | |
| Generated By: (b) (4) | | Generated Time (GMT): 29-Mar-2021 12:55 | | |
| Skopje, Warsaw, Zagreb | | | | |
| Feb-15-2021 10:38:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | it was not done by mistake. the Pregnancy test was done in an UNS Visit. |
| Feb-15-2021 10:34:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY - Pregnancy test was reported as NOT DONE. However, subject is <60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. If reason exists that test was not necessary, please update MH. |
| Feb-12-2021 21:51:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Candidate | CLINQUERY - Pregnancy test was reported as NOT DONE. However, subject is <60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. If reason exists that test was not necessary, please update MH. |
| Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|------------------|--------------------------------------|---------------------|
| Nov-05-2020 10:36:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-05-2020 10:35:01 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------------|
| Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--------------------------------------|---------------------|
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Nov-05-2020 10:34:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------------|
| Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defi Not Done ned Identifie r: Test:: Choriogonadotr opin Beta_PX1 13 Result:: Not Done Not Done:: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defi Not Applicable ned Identifie r: Test:: Choriogonadotr opin Beta_PX1 13 Result:: Not Applicable Not Done:: Not Applicable | Initial Entry |
| Nov-06-2020 13:06:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defi ned Identifie r: Test:: Choriogonadotr opin Beta_PX1 13 Result:: | Transcription Error |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | Not Done:: | |
|---|-----------------|-------------------------|---|---------------------|
| Nov-03-2020 15:19:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX1 13 Result:: Not Done:: NOT DONE | Transcription Error |
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX1 13 Result:: NEGATIVE Not Done:: | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------------|
| Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Nov-06-2020 13:06:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

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

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Oct-15-2020 21:07:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX1 13 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------------|
| Nov-07-2020 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-03-2020 15:19:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Oct-15-2020 21:07:38 (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 13:52:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-06-2020 13:06:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-06-2020 13:06:10 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|-----------------|------------------|--------------------------------|---------------------|
| Nov-03-2020 15:19:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Transcription Error |
|--|-----------------|------------------|--------------------------------|---------------------|

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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-15-2020 21:10:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Oct-15-2020 21:10:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 107852 | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 19:34:56 (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-15-2020 19:34:56 (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-15-2020 19:35:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-15-2020 19:34:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-15-2020 19:34:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/15/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Oct-15-2020 19:35:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNMDF3 | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 19:35:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNMDF3 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 19:35:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Sample ID:</u> BNMDF4 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 19:35:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNMDF4 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 19:35:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Sample ID:</u> BN8WV2 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 19:35:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8WV2 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 19:36:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Sample ID:</u> BN8WV3 | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Oct-15-2020 19:36:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8WV3 | 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:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 19:36:41 (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-15-2020 19:36:41 (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-15-2020 19:36:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-15-2020 19:36:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-15-2020 19:36:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/15/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Oct-15-2020 19:36:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8WTT | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Oct-15-2020 19:36:57 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8WTT | Initial Entry |

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951008

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-15-2020 22:58:29 (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 |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-15-2020 22:58:29 (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-15-2020 22:58:29 (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 |
|---|-----------------|---------------------|---|---------------|
| Oct-15-2020 22:58:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/15/2020 13:18 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-15-2020 22:58:29 (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 |
|---|-----------------|------------------|----------------------------|---------------|
| Oct-15-2020 22:58:29 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-15-2020 22:58:29 (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-15-2020 22:58:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-15-2020 22:58:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2f96\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: 11951008

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-15-2020 21:08:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

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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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|----------------------------------|---|
| Nov-06-2020 16:38:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | entered in error |
| Nov-06-2020 16:06:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | According to (b) (6) Visit took place on 05.11.2020. Please check and correct. |
| Nov-03-2020 09:53:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 | Initial Entry |

090177e196ae2f96\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: 11951008

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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: FE VE R N O Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: FA TI | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Nov-03-2020 09:53:52 (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-03-2020 09:53:52 (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-03-2020 09:53:52 (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?: | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO | Initial Entry |

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> DIARRHEA | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR WORSE NED MUSC LE 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSE ENED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSE ENED JOINT PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-03-2020 09:53:52 (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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-03-2020 09:53:52 (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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-03-2020 09:53:52 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

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-03-2020 09:54:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 09:54:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier 1 : Temperature: 36.6 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-03-2020 09:54:21 (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-03-2020 09:54:21 (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-03-2020 09:54:21 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1195

Subject No: 11951008

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-03-2020 09:54:21 (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: 11951008

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-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|----------------------------------|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Nov/3/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

6.a

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

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Nov-03-2020 09:54:30 (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-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 09:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2f96\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:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-03-2020 09:54:47 (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-03-2020 09:54:47 (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-03-2020 09:55:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-03-2020 09:54:47 (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-03-2020 09:54:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/3/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-03-2020 09:55:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN86D0 | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Nov-03-2020 09:55:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN86D0 | Initial Entry |

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951008

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-03-2020 10:13:42 (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-03-2020 10:13:42 (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-03-2020 10:13:42 (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-03-2020 10:14:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 08:43 | Transcription Error |
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/3/2020 10:13 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

090177e196ae2f96\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: 11951008

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

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-03-2020 10:13:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2f96\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: 11951008

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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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------------|----------------------------------|---|
| Jan-12-2021 13:13:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Closed | wrong site. |
| Jan-12-2021 11:19:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Opened | Please verify visit date. Source states 4/Dec/2020. |
| Dec-02-2020 09:28:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Dec/2/2020 | Initial Entry |

090177e196ae2f96\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:** 11951008**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-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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: 11951008

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-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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 |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> HEADACHE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> CHILLS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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 NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed? : | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENER 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-02-2020 09:29:05 (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-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW O R WOR SENER JOINT P AIN Were fever or syste NO mic symptoms pre sent on the last day the Subject Diary was completed?: | Initial Entry |

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENER 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-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> REDNESS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

5.b

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-02-2020 09:29:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction SW :: ELL ING Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?: | Initial Entry |

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-02-2020 09:29:05 (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-02-2020 09:29:05 (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-02-2020 09:29:05 (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 |

090177e196ae2f96\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: 11951008

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-02-2020 09:29:05 (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-02-2020 09:29:05 (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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-02-2020 09:29:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-02-2020 09:29:16 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|--|
| Jan-12-2021 13:13:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | wrong site. |
| Jan-12-2021 11:19:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Please verify visit date. Source states 4/Dec/2020. |
| Dec-02-2020 09:29:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-02-2020 09:29:16 (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-02-2020 09:29:16 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | |
|------------------------|------------------|-----------------------------------|
| Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | Date of Collection: Dec/2/2020 |
|------------------------|------------------|-----------------------------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Dec-02-2020 09:29:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KG5 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Dec-02-2020 09:29:26 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN8KG5 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Dec-02-2020 09:29:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KG6 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Dec-02-2020 09:29:38 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN8KG6 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Dec-02-2020 09:29:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNLWJZ | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-02-2020 09:29:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLWJZ | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-02-2020 09:29:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BNLWK0 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-02-2020 09:29:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLWK0 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date of Visit**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|--|
| Nov-23-2020 10:29:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Nov-23-2020 10:25:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Nov-23-2020 10:25:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Nov-23-2020 10:25:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/23/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Nov-23-2020 10:25:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/23/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/23/2020 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|-----------------|
| Dec-07-2020 12:45:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Nov/26/2020 | New Information |
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-23-2020 10:27:07 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**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) | FEVER | |
|--|--|---------------------|-------|--|

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom NO Present: | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUG H | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sympto NEW OR INCREASE ms: D SHORTNESS OF B REATH | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|------------------|----|
| | | | Symptom Present: | NO |
|--|--|--|------------------|----|

4.c Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: YES | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.e

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present: | Initial Entry |

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present: | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom NEW OR INCREASED SORE THROAT Symptom NO Present: | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-23-2020 10:27:07 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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) | Symptoms: DIARRHE A Symptom Present NO : | |
|--|--|---------------------|---|--|

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITIN G Symptom Present NO : | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------|---------------|
| Nov-23-2020 10:27:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

6. Trade Name:

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

7. Test Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:27:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 11951008

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-23-2020 10:29:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---------------------------------------|---------------|
| Nov-23-2020 10:29:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|--|
| Nov-25-2020 12:29:34 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 17:25:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Nov-24-2020 12:09:48 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Please enter reason, as to why sample was not collected, at field 4 of this CRF, named 'If no sample was collected or sample was not collected according to protocol, please provide reason'. Please update. |
| Nov-23-2020 10:32:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | not necessary patient came into the office for swab test. |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------------|--------------------------|--|
| Nov-23-2020 10:29:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | 'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate. |
| Nov-23-2020 10:29:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 17:25:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: patient came into the office for a swab test. No self swab necessar y. | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1195**Subject No:** 11951008**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-23-2020 10:29:32 (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-23-2020 10:29:32 (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-23-2020 10:29:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-23-2020 10:29:32 (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-23-2020 10:29:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/23/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:29:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KDS | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Nov-23-2020 10:29:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KDS | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

1.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

1.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/23/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55***I.c Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

I.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-----------------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

I.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.e

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |
|---|-----------------|---------------------|--|---------------|

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 10:30:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

6. Ongoing?

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:32:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
|---|-----------------|------------------------|--------------------------------|---------------|

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 10:33:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNES S | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:33:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Common cold Date of Diagnosis: Nov/23/2020 | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-23-2020 10:33:08 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/23/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Subcategory of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Was a diagnosis obtained?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:33:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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:** 11951008**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 |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|-------------------|----------|
| | | | Not Done:: | Not Done |
| | | | Lab Normal Range: | Not Done |

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | Initial Entry |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**5.b Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**5.c Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**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 |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|--|--|--|-------------------|----------|
| | | | Not Done:: | Not Done |
| | | | Lab Normal Range: | Not Done |

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**5.c Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55**5.e Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | | ne | |
| | | | Result:: | Not Done | |
| | | | | ne | |
| | | | Not Done:: | Not Done | |
| | | | | ne | |
| | | | Lab Normal Range: | Not Done | |
| | | | | ne | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Iden Not Do | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | |
|------------------------|------------------|--------------------------|----------|
| Skopje, Warsaw, Zagreb | (b) (4), (b) (6) | tifier: | ne |
| | | Test:: | Not Done |
| | | | ne |
| | | Result:: | Not Done |
| | | | ne |
| | | Not Done:: | Not Done |
| | | | ne |
| | | Lab Normal Range: | Not Done |
| | | | ne |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:38:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Nov/23/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Date:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in res Not Done pirations/minute: one Heart Rate in beats/mi Not Done nute: one | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a Diastolic:

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/23/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Nov-23-2020 10:39:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Nov-23-2020 10:39:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/23/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:32 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/23/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. What is the medication identifier?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Medication:

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Nov-23-2020 10:46:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History
on Nov/23/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-23-2020 10:47:11 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Dec-22-2020 15:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/22/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Dec-22-2020 15:25:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/22/2020**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:** 11951008**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:55[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-22-2020 15:25:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-22-2020 15:25:45 (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-22-2020 15:25:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-22-2020 15:25:45 (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. |
| Dec-22-2020 15:25:45 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Dec/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Dec-22-2020 15:25:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KTV | Initial Entry |

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/22/2020

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-22-2020 15:25:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KTV | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-22-2020 15:26:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN8KTV | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-22-2020 15:26:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KTV | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-22-2020 15:26:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BNLW60 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-22-2020 15:26:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLW60 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Dec-22-2020 15:26:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BNLW61 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/22/2020

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Dec-22-2020 15:26:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLW61 | Initial Entry |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

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 |
|---|-----------------|---------------------|--------------|------------------------|
| Nov-05-2020 13:48:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACVOPFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Transcription Error |
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACVOPFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-10-2021 12:07:35 (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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-10-2021 12:08:07 (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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-24-2021 09:28:49 (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: 11951008

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 |
|---|-----------------|---------------------|--------------|--------|
| Mar-04-2021 12:54:30 (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: 11951008

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 |
|---|-----------------|---------------------|--------------|--------|
| Mar-05-2021 09:06:49 (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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

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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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> hemorrhoids | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Nov/1/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

6. Toxicity Grade:

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

090177e196ae2f96\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, Deleted, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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

| | | | | |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 12:22:20 (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: unknown | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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

| | | | | |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 12:22:20 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-03-2020 12:22:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2f96\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, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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-10-2021 12:07:35 (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-10-2021 12:07:35 (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 |
|---|-----------------|---------------------|---------------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: limb pain | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/10/2021 01:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|-----------------|
| Feb-12-2021 10:19:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Feb/11/2021 08:00 | New Information |
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-10-2021 12:07:35 (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 |
|---|-----------------|---------------------|-------------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-10-2021 12:08:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e196ae2f96\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, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Feb-15-2021 11:36:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-15-2021 11:36:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERED/RESOLVED | New Information |
| Feb-12-2021 10:19:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE limb pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:07:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\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, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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-10-2021 12:08:07 (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-10-2021 12:08:07 (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 |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-10-2021 12:08:07 (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-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/10/2021 01:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|-----------------|
| Feb-12-2021 10:19:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Feb/11/2021 08:00 | New Information |
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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-10-2021 12:08:07 (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 |
|---|-----------------|---------------------|-------------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Feb-15-2021 11:36:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-15-2021 11:36:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERED/RESOLVED | New Information |
| Feb-12-2021 10:19:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Chills: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERING/RESOLVING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-10-2021 12:08:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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-24-2021 09:28:49 (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 |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-24-2021 09:28:49 (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 |
|---|-----------------|---------------------|------------------------------------|---|
| Mar-12-2021 06:30:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued: Candidate | Pending SDB update |
| Mar-11-2021 14:12:54 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | the latest Follow up is from 09 Mar 2021 with updated diagnosis |
| Mar-10-2021 12:18:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued: Opened | SAE RECON: Per latest SAE listing last follow up date is 05Mar2021 and term still reported as anal prolapsed by circular hemorrhoids. Please confirm if follow up SAE form updating the term to just ANAL PROLAPSE. |

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | | | |
|---|---|--------------------------------|--|--|
| Mar-08-2021 23:41:31 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 2: Clo sed | Response satisfies query |
| Mar-08-2021 17:24:03 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Rei ssued: Candi date | Pending SDB update |
| Mar-08-2021 12:27:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: An swere d | yes I confirm |
| Mar-08-2021 07:38:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Op ened | SAE RECON:AER#2021205401, term was updated to anal prolapse in Inform but was retained as 'anal prolapsed by circular hemorrhoids' in Safety database. Please confirm if follow up SAE form was submitted to clarify and update event term |
| Mar-05-2021 11:11:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Clo sed | Discrepancy has been closed. |
| Mar-05-2021 09:15:21 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : anal p | Transcription Error |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

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Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | | | |
|---|---|--------------------------------|--|--|
| Skopje, Warsaw, Zagreb | | | rolaps e | |
| Mar-05-2021 09:13:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : anal p rolaps | Transcription Error |
| Mar-05-2021 09:05:35 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: An swere d | Changed data per query |
| Mar-05-2021 08:52:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swere d | the cause of the anal prolaps are the haemorrhoids. So I change the term to anal prolaps. |
| Mar-05-2021 01:35:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 2: Op ened | Medical Monitor_ Per report, an additional event of " abscess" was reported. If information is accurate, pls revise and update AE log for an additional separate AE. Thanks. |
| Mar-04-2021 20:55:39 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Op ened | Multiple concepts in the term ANAL PROLAPS BY CIRCULAR HEAEMORRHOIDS. Split the term into ANAL PROLAPSE and CIRCULAR HEMORRHOIDS and report separately. Thank you. |
| Mar-04-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data | New Information |

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Subject No: 11951008

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

| | | | | |
|---|-----------------|------------------|---|---------------|
| 12:49:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | (b) (4), (b) (6) | Entry : anal p rolaps by cir cular heaem orrhoi ds | |
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : worse ning o f hem orrhoi ds | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/18/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Mar-05-2021 09:56:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-04-2021 12:51:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Mar-04-2021 12:51:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Feb/27/2021 UNK:UNK | New Information |
| Mar-03-2021 14:36:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY- Please confirm if the event "worsening of |

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Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|---------------------------|---|
| | | | | hemorrhoids" remains ongoing (start date Feb 18, 2021). Else, review if update can be applied to end date and outcome status. Thank you |
| Feb-24-2021 09:28:49 (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 |
|---|-----------------|------------------|-------------------------|---------------|
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|--|
| Feb-26-2021 06:46:46 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE worsening of hemorrhoids: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or bir | Initial Entry |

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Generated By: (b) (4)

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Form Status: Data Complete

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Subject Initials: ---

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| | | | | |
|--|--|--|---|--|
| | | | th 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.

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-24-2021 09:28:49 (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 |
|--|-----------------|------------------|--|---------------|
| Feb-24-2021 09:28:49 (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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Header Text: C4591001

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Subject No: 11951008

Generated By: (b) (4)

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Form Status: Data Complete

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Subject Initials: ---

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| | | | | |
|--|--|--|--|--|
| | | | OTHER If Other, specify: Hemorrhoids | |
|--|--|--|--|--|

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-24-2021 09:28:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|--------------------------|
| Mar-04-2021 19:57:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-04-2021 12:57:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Mar-04-2021 | ACV0PFEINFP6000 | auto query | Query 1: Answered | New Information |

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1195**Subject No:** 11951008**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1195) Medizentrum Essen Borbeck**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:55

| | | | | |
|---|-----------------|---------------------------|--|---|
| 12:57:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | | (autoquery) | | |
| Mar-04-2021 12:57:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Mar-04-2021 12:51:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | For AE anal prolaps by circular haemorrhoids: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Mar-03-2021 11:15:05 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2021205401,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form. |
| Feb-24-2021 12:19:06 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-24-2021 09:28:49 (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 |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-26-2021 06:46:46 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2021205401 | Initial Entry |

Header Text: C4591001

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Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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Skopje, Warsaw, Zagreb

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

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Header Text: C4591001

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-04-2021 12:54:30 (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 |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-04-2021 12:54:30 (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 |
|---|-----------------|---------------------|------------------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: anal fistula | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/25/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Feb/25/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

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

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Header Text: C4591001

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Form Status: Data Complete, Frozen

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2 | Initial Entry |
|---|-----------------|---------------------|-------------------------|---------------|

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-04-2021 12:54:30 (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 |
|---|-----------------|---------------------|-------------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Mar-04-2021 12:54:30 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f96\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: 11951008

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) | NO | |
|---|--|---------------------|----|--|

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-04-2021 12:54:30 (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 |
|---|-----------------|---------------------|--|---------------|
| Mar-04-2021 12:54:30 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-04-2021 12:54:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-05-2021 09:06:49 (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 |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-05-2021 09:06:49 (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 |
|---|-----------------|---------------------|-------------------------------|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Abscess | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/27/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Feb/27/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

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

090177e196ae2f96\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: 11951008

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

| | | | | |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-05-2021 09:06:49 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-05-2021 09:06:49 (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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-05-2021 09:06:49 (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 |
|---|-----------------|---------------------|--|---------------|
| Mar-05-2021 09:06:49 (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: OTHER If Other, specify: due to haemorrhoids | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

Skopje, Warsaw, Zagreb

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

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-05-2021 09:06:49 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|--|
| Nov-03-2020 15:19:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-03-2020 15:19:29 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/29/2020 | Transcription Error |
| Nov-03-2020 15:19:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Date of Visit, 29/Nov/2020 is a future date relative to when it was entered on 03/Nov /2020. Please correct. |
| Nov-03-2020 15:19:17 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/29/2020 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------------------|---|
| Nov-03-2020 15:20:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-03-2020 15:19:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Nov-03-2020 15:19:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-03-2020 15:20:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|--|
| Nov-06-2020 06:48:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | As per site confirmation - updated PD tracker |
| Nov-05-2020 19:10:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | the unplanned visit was done only for the pregnancy test |
| Nov-04-2020 11:41:09 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | PDQ : Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate. |
| Nov-03-2020 15:20:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|------------------|--|--|
| | | | | form(s) is/are entered. Please review and update as appropriate. |
| Nov-03-2020 15:20:14 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Oct/29/2020 Contact Outcome: VISIT ARRANGED | Initial Entry |

3. Comments:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------------|
| Nov-03-2020 16:24:36 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: unplanned visit was done due to missing pregnancy test by mistake at Visit 1.urinary pregnancy test on 29/Oct/2020, result: negative. | Transcription Error |
| Nov-03-2020 15:24:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: unplanned visit was done for an urinary pregnancy test on 29/Oct/2020, result: negative | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-03-2020 15:20:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 : Temperature: Not Applicable Temperature Unit: Not Applicable : Temperature Location: Not Applicable | Initial Entry |
| Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 Temperature: Not Done Temperature Unit: Not Done Temperature Location: Not Done | Initial Entry |
| Nov-03-2020 15:20:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 Temperature: Temperature Unit: Temperature Location: | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-03-2020 15:20:30 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-09-2020 09:22:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |
| Nov-03-2020 15:20:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Oct/29/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1195**Subject No:** 11951008**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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 Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Injection Site Location

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: Not Done Reaction Present:: Not Done | Initial Entry |

4.a Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4.a Reaction Present:

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

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: Not Done Reaction Present:: Not Done | Initial Entry |

4.b Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4.b Reaction Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Done Symptom Present:: Not Done | Initial Entry |

5.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Symptom Present:

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> Not Done <u>Symptom Present::</u> Not Done | Initial Entry |

5.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> Not Done <u>Symptom Present::</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Oct/29/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1195**Subject No:** 11951008**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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**5.c Symptom:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Done Symptom Present:: Not Done | Initial Entry |

5.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Done Symptom Present:: Not Done | Initial Entry |

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form Version: 10-Oct-2020 15:57

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

5.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.e Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> Not Done <u>Symptom Present::</u> Not Done | Initial Entry |

5.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> Not Done <u>Symptom Present::</u> Not Done | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/29/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> Not Done <u>Symptom Present::</u> Not Done | Initial Entry |

5.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-03-2020 15:21:02 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae2f96\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: 11951008

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Dec-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/2/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Dec-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-18-2021 08:51:24 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Jan/18/2021 | Initial Entry |

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Jan-29-2021 16:31:44 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per other protocol all owance(s) and confirmed to have received only placebo a t Vaccination 1/2 | New Information |
| Jan-18-2021 14:46:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-18-2021 12:50:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-18-2021 08:51:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-18-2021 08:51:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national rec | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1195

Subject No: 11951008

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

| | | | | |
|--|--|--|---|--|
| | | | ommendations and confirme d to have received only place bo at Vaccination 1/2 | |
|--|--|--|---|--|

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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-18-2021 14:46:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/18/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 14:46:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION | Initial Entry |

090177e196ae2f96\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: 11951008

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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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-18-2021 14:47:12 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/18/2021 | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-18-2021 14:47:23 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Jan/18/2021 | 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: 11951008

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-18-2021 14:52:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/18/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-18-2021 14:52:13 (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-18-2021 14:52:13 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2f96\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: 11951008

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 |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-----------------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Jan/18/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

6.a

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

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Jan-18-2021 14:52:22 (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 |
|---|-----------------|-------------------------|---------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-18-2021 14:52:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2f96\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:** 11951008**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-18-2021 14:53:07 (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-18-2021 14:53:07 (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-18-2021 14:53:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-18-2021 14:53:07 (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-18-2021 14:53:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/18/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Jan-18-2021 14:53:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KVS | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-18-2021 14:53:20 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KVS | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 14:53:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN8KVR | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-18-2021 14:53:28 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KVR | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 14:53:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BNLW74 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-18-2021 14:53:41 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLW74 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 14:53:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BNLW75 | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Jan-18-2021 14:53:47 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BNLW75 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1195**Site Name:** (1195) Medizentrum Essen Borbeck**Subject No:** 11951008**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-18-2021 14:52:43 (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-18-2021 14:52:43 (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-18-2021 14:52:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-18-2021 14:52:43 (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-18-2021 14:52:43 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/18/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Jan-18-2021 14:52:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8KVP | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Jan-18-2021 14:52:53 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8KVP | Initial Entry |

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

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-18-2021 14:54:18 (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-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-18-2021 14:54:18 (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-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/18/2021 11:29 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-18-2021 14:54:18 (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-18-2021 14:54:18 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-18-2021 14:54:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2f96\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: 11951008

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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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|----------------------------------|---------------|
| Feb-09-2021 10:57:58 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 | 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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|----------------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Feb/9/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

6.a

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

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

| | | | | |
|---|-----------------|-------------------------|---|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defin 113 ed Identifier: Test:: Choriogonadotro pin Beta_PX113 Result:: NEGATIVE Not Done:: | Initial Entry |
|---|-----------------|-------------------------|---|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------|---------------|
| Feb-09-2021 10:58:07 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2f96\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: 11951008

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 |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-09-2021 10:58:18 (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-09-2021 10:58:18 (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-09-2021 12:12:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-09-2021 10:58:18 (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-09-2021 10:58:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/9/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Feb-09-2021 12:12:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN8L1D | Initial Entry |

090177e196ae2f96\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: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Feb-09-2021 12:12:18 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN8L1D | Initial Entry |

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

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-09-2021 10:58:42 (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-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-09-2021 10:58:42 (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-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/9/2021 09:25 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-09-2021 10:58:42 (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-09-2021 10:58:42 (UTC+01:00) Sarajevo, | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

Skopje, Warsaw, Zagreb

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

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-09-2021 10:58:42 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2f96\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: 11951008

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-10-2021 08:20:06 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Mar/10/2021 | Initial Entry |

Header Text: C4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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1. Contact Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-10-2021 08:20:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-10-2021 08:20:15 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Mar/10/2021 | Initial Entry |

Header Text: C4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

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 |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-10-2021 08:21:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/10/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-10-2021 08:21:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: OPEN LABEL TREATMENT | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Mar-10-2021 08:21:04 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1195) Medizentrum Essen Borbeck

Subject Initials: ---

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

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Dec-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Oct-15-2020 21:10:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Oct-15-2020 19:34:37 (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 |
|--|-----------------|-------------------------|----------------------------------|--|
| Mar-08-2021 07:39:56 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-04-2021 15:28:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Mar-04-2021 11:41:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2021205401 anal prolapsed (onset date:18Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Dec-02-2020 14:07:25 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Dec/2/2020 | Initial Entry |

090177e196ae2f96\Final\Final On: 01-Apr-2021 03:47 (GMT)

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1195

Subject No: 11951008

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

| | | | | |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-15-2020 21:10:22 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/15/2020 | Initial Entry |
| Oct-15-2020 19:34:37 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/15/2020 | Initial Entry |

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1195

Site Name: (1195) Medizentrum Essen Borbeck

Subject No: 11951008

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-03-2020 18:59:19 (UTC+01:00) Sarajevo, Skopje, Warsaw, Zagreb | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |