**Fax within 24 hours after awareness of SAE to KKS Marburg: 06421 28 66 517**

| **EudraCT-No.:** 2012-004074-25 | **SAE-REPORT** | **SPONSOR:** Ruhr-Universität Bochum |
|---|---|---|
| **STUDY IDENTIFICATION:** CORRA | **SAE-ID:** (to be completed by Sponsor) | |

**1. PATIENT CHARACTERISTICS**

| Patient No.: | Sex: ☐ M ☐ F | Age (years): | Height (cm): | Weight (kg): |
|---|---|---|---|---|

**2. REPORT INFORMATION**

| ☐ INITIALREPORT | Date: (dd.mm.yyyy) | Date of notice at site: (dd.mm.yyyy) |
|---|---|---|
| ☐ FOLLOW-UP REPORT No. _____ | Date: (dd.mm.yyyy) | To Initial Report dated: (dd.mm.yyyy) |

| Name of investigator: | Site No.: |
|---|---|
| Address Institution: | Country: _____<br>Telephone: _____<br>Fax: _____<br>E-Mail: |

**3. SERIOUSNESS CRITERIA OR REPORTABLE REASON**

| | |
|---|---|
| ☐ Results in death | ☐ Results in persistent or significant disability / incapacity |
| ☐ Life-threatening | ☐ Congenital anomaly / birth defect |
| ☐ Requires in-patient hospitalisation or prolongation of existing hospitalisation | ☐ Other medically important condition |

**4. SERIOUS ADVERSE EVENT (SAE)**

**Please enter only ONE Reaction/Event or Diagnosis !**

**If more than one Reaction/Event is to be reported for the same patient, complete a separate Form for each SAE.**

**Reaction/Event or Diagnosis**:_____

| Onset date of SAE: (dd.mm.yyyy) | Date of resolution: (dd.mm.yyyy) |
|---|---|

**5. DESCRIPTION OF SAE:** (Summarize history of the event chronologically; outcome of hospitalization, and any other relevant information. Include signs and symptoms **referring to specified Reaction/Event or Diagnosis in section 4.**)

**6. SEVERITY / INTENSITY**

| ☐ Mild / CTCAE Grade 1 | ☐ Moderate / CTCAE Grade 2 | ☐ Severe / CTCAE Grade 3 | ☐ Life-threatening / CTCAE Grade 4 | ☐ Death / CTCAE Grade 5 |
|---|---|---|---|---|

| **EudraCT-No.:** 2012-004074-25 | **SAE-REPORT** | **SPONSOR:** Ruhr-Universität Bochum |
|---|---|---|
| **STUDY IDENTIFICATION:** CORRA | **SAE-ID:** (to be completed by Sponsor) | |

**7. DRUG INFORMATION – BLINDED IMP: PREDNISOLON vs. PLACEBO**

**UNBLINDING**: ☐ not applicable ☐ no ☐ yes

| Drug name: | Dose: | Unit: | Frequency: | Route: | Dosage Form: |
|---|---|---|---|---|---|
| PredniHexal / Placebo | | | | | |

| Start date (dd.mm.yyyy) | Date of last dose prior to SAE (dd.mm.yyyy): | Batch-No.: |
|---|---|---|
| | | |

**Relatedness:** ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related ☐ Not assessable ☐ Not applicable ☐ Unknown

Drug administration altered in response to the Adverse Event? ☐ no ☐ yes
(If 'yes' specify)

Dates when drug administration altered:

| | | dd | mm | yyyy |
|---|---|---|---|---|
| ☐ | Reduced: | | | |
| ☐ | Increased: | | | |
| ☐ | Stopped: | | | |
| ☐ | Restarted: | | | |
| ☐ | Withdrawn: | | | |

If applicable, details of new dose:

| New. dose: | Unit: | Frequency: |
|---|---|---|
| | | |

If applicable:

| | | | |
|---|---|---|---|
| Did reaction abate after stopping drug? | yes ☐ | no ☐ | un-known ☐ |
| Did reaction recur on readministration? | yes ☐ | no ☐ | un-known ☐ |

**7. DRUG INFORMATION – DMARDs (Disease-Modifying Antirheumatic Drugs)**

**UNBLINDING:** ☐ not applicable ☐ no ☐ yes

| Drug name: | Dose: | Unit: | Frequency: | Route: | Dosage Form: |
|---|---|---|---|---|---|
| | | | | | |

| Start date (dd.mm.yyyy) | Date of last dose prior to SAE (dd.mm.yyyy): | Batch-No.: |
|---|---|---|
| | | |

**Relatedness:** ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related ☐ Not assessable ☐ Not applicable ☐ Unknown

Drug administration altered in response to the Adverse Event? ☐ no ☐ yes
(If 'yes' specify)

Dates when drug administration altered:

| | | dd | mm | yyyy |
|---|---|---|---|---|
| ☐ | Reduced: | | | |
| ☐ | Increased: | | | |
| ☐ | Stopped: | | | |
| ☐ | Restarted: | | | |
| ☐ | Withdrawn: | | | |

If applicable, details of new dose:

| New. dose: | Unit: | Frequency: |
|---|---|---|
| | | |

If applicable:

| | | | |
|---|---|---|---|
| Did reaction abate after stopping drug? | yes ☐ | no ☐ | un-known ☐ |
| Did reaction recur on readministration? | yes ☐ | no ☐ | un-known ☐ |

| **EudraCT-No.:** 2012-004074-25 | **SAE-REPORT** | **SPONSOR:** Ruhr-Universität Bochum |
|---|---|---|
| **STUDY IDENTIFICATION:** CORRA | **SAE-ID:** (to be completed by Sponsor) | |

**7. DRUG INFORMATION – DMARDs (Disease-Modifying Antirheumatic Drugs)**

**UNBLINDING**: ☐ not applicable ☐ no ☐ yes

| Drug name: | Dose: | Unit: | Frequency: | Route: | Dosage Form: |
|---|---|---|---|---|---|
| | | | | | |

| Start date (dd.mm.yyyy) | Date of last dose prior to SAE (dd.mm.yyyy): | Batch-No.: |
|---|---|---|
| | | |

**Relatedness:** ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related ☐ Not assessable ☐ Not applicable ☐ Unknown

Drug administration altered in response to the Adverse Event? ☐ no ☐ yes
(If 'yes' specify)

Dates when drug administration altered:

| | | dd | mm | yyyy |
|---|---|---|---|---|
| ☐ | Reduced: | | | |
| ☐ | Increased: | | | |
| ☐ | Stopped: | | | |
| ☐ | Restarted: | | | |
| ☐ | Withdrawn: | | | |

If applicable, details of new dose:

| New. dose: | Unit: | Frequency: |
|---|---|---|
| | | |

If applicable:

| | | | |
|---|---|---|---|
| Did reaction abate after stopping drug? | yes ☐ | no ☐ | un-known ☐ |
| Did reaction recur on readministration? | yes ☐ | no ☐ | un-known ☐ |

**7. DRUG INFORMATION – DMARDs (Disease-Modifying Antirheumatic Drugs)**

**UNBLINDING:** ☐ not applicable ☐ no ☐ yes

| Drug name: | Dose: | Unit: | Frequency: | Route: | Dosage Form: |
|---|---|---|---|---|---|
| | | | | | |

| Start date (dd.mm.yyyy) | Date of last dose prior to SAE (dd.mm.yyyy): | Batch-No.: |
|---|---|---|
| | | |

**Relatedness:** ☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Not related ☐ Not assessable ☐ Not applicable ☐ Unknown

Drug administration altered in response to the Adverse Event? ☐ no ☐ yes
(If 'yes' specify)

Dates when drug administration altered:

| | | dd | mm | yyyy |
|---|---|---|---|---|
| ☐ | Reduced: | | | |
| ☐ | Increased: | | | |
| ☐ | Stopped: | | | |
| ☐ | Restarted: | | | |
| ☐ | Withdrawn: | | | |

If applicable, details of new dose:

| New. dose: | Unit: | Frequency: |
|---|---|---|
| | | |

If applicable:

| | | | |
|---|---|---|---|
| Did reaction abate after stopping drug? | yes ☐ | no ☐ | un-known ☐ |
| Did reaction recur on readministration? | yes ☐ | no ☐ | un-known ☐ |

| **EudraCT-No.:** 2012-004074-25 | **SAE-REPORT** | **SPONSOR:** Ruhr-Universität Bochum |
|---|---|---|
| **STUDY IDENTIFICATION:** CORRA | **SAE-ID:** (to be completed by Sponsor) | |

| **8. RELEVANT MEDICAL HISTORY (pre-existing / concurrent conditions)** ☐ None | Start date (dd.mm.yyyy) | Stop date (dd.mm.yyyy) |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |

**9. RELEVANT CONCOMITANT MEDICATION** ☐ none

| Drug name: | **Dose** (e.g.1-0-1) | **Unit** (e.g.mg, µg, ml) | **Form** (e.g. tablet, capsule ….) | **Route** (oral, iv) | **Indication** | **Start date** (dd.mm.yyyy) | **End date** (dd.mm.yyyy) |
|---|---|---|---|---|---|---|---|
| 1. | | | | | | | |
| 2. | | | | | | | |
| 3. | | | | | | | |
| 4. | | | | | | | |
| 5. | | | | | | | |
| 6. | | | | | | | |
| 7. | | | | | | | |
| 8. | | | | | | | |
| 9. | | | | | | | |

**10. RELEVANT LAB FINDINGS OR INVESTIGATIONS FOR DIAGNOSIS OF EVENT** ☐ none

| | Normal range (low/high) | Date (dd.mm.yyyy) | Result, Unit |
|---|---|---|---|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |
| 9. | | | |

**11. SAE OUTCOME:**

☐ Recovered / Resolved ☐ unknown

☐ Recovering / Resolving

☐ Not recovered / Not resolved

☐ Recovered / Resolved with sequelae

☐ fatal

Date of death:_____ (dd.mm.yyyy)

Cause of death:_____

Autopsy: ☐ yes ☐ no ☐ unknown

**12. SAE TREATMENT:**

☐ None

☐ Drug treatment ➔ specify:

☐ Others ➔ specify:

**13. ATTACHMENTS:** ☐ no ☐ yes. If yes, please specify:

**14. INVESTIGATOR SIGNATURE :**

| Name | Signature | Date (dd/mm/yyyy) |
|---|---|---|