SERIOUS ADVERSE EVENT (SAE) FORM

Clinical Trial of Investigational Medicinal Product (CTIMP)

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| **GUIDANCE FOR THE PERSON COMPLETING THIS FORM** |
| 1. Forms must be submitted to ACCORD **within 24 hours** of the site research team becoming aware of the SAE. 2. **Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form. 3. Do not include any supplementary information or documents unless requested by ACCORD. 4. Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available. 5. Any updates should be added to the original form – **DO NOT**create a new form for each update to this SAE. 6. Forms must be submitted via email in a PDF format to [**safety@accord.scot**](mailto:safety@accord.scot) |

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| **1. REPORT DETAILS** | | | | | |
|  |  |  |  |  |  |
| **Trial Name:** |  |  | **Date of Report:** |  |  |
|  |  |  |  |  |  |
| **Sponsor Number:** |  |  | **Centre ID:** |  |  |
|  |  |  |  |  |  |
| **EudraCT or ISRCTN Number:** |  |  | **Centre Name:** |  |  |
|  |  |  |  |  |  |
| **Participant ID:** |  |  | **Centre Country:** |  |  |
|  |  |  |  |  |  |
| **Date PI informed of SAE:** |  |  |  |  |  |
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| **2. EVENT DETAILS** | | | | | |
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| **Date of Onset:** |  |  | **Diagnosis\*:** |  |  |
| **\*The Diagnosis is the Main Event (or symptom) for which the seriousness criteria(s) apply. There should be ONE Main Event per form. If there are two events, please complete two forms** | | | | | |
|  | | | | | |
| **Description**  **of SAE:**  *(1000 character limit)*  **If any event/symptom mentioned in the Description of SAE area meets a seriousness criteria in their own right, a separate SAE form will need to be completed** |  | | | |  |
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| **Seriousness Criteria:**  *(Tick all that apply)* |  | Congenital anomaly/birth defect |  | Inpatient hospitalisation or prolongation  of existing inpatient hospitalisation | |
|  | Involved persistent or significant disability or incapacity |  | Life-threatening | |
|  | Other significant medical event |  | Participant died | |
| **Other SAE Criteria:**  *(To be ticked IF other criteria(s) apply, left blank if not)* |  | New events/reactions likely to affect the safety of participants |  | Post-trial SUSAR | |
|  | Recommendation  of the DMC | |
| **Severity of Event:** | Mild  Moderate  Severe | | | | |
| **Is the event due to progression of underlying disease?** | Yes  No | | | | |
| **Is the event due to lack of efficacy of IMP?** | Yes  No | | **If yes, indicate which IMP(s):** | |  |

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| **3. TRIAL TREATMENT** | | | | | | | | | | | |
| **Did participant receive IMP prior to SAE?** | | | Yes | | | No *if no, please proceed to section 4* | | | | | |
| **Name of trial IMP** | | **Dose/**  **Schedule** | **Route of Administration** | | **Start Date** | | **End Date**  *Tick box if ongoing* | | **Is SAE causally related to IMP?** | | |
| **1** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **2** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **3** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **Rationale for causality assessment:**  **The causality assessment (and expectedness if required) has to be made using the event / symptom mentioned in the Diagnosis box** | |  | | | | | | | | | |
| **The section below must only be completed when the SAE is POSSIBLY RELATED to the IMP** | | | | | | | | | | | |
| **Expectedness:** | | Expected | | *the reaction is consistent with the toxicity of the trial drug as listed in the Reference Safety Information (RSI) contained in the SPC or IB* | | | | | | | |
| Unexpected | | *the reaction is* ***not*** *consistent with the toxicity as listed in the Reference Safety Information (RSI) contained in the SPC or IB* | | | | | | | |
| **Version and/or date\* of IB or SPC containing the RSI used to assess expectedness:** | |  | | | | | | | | | |
| \* for SPCs ‘date’ refers to ‘Date of revision of text’ as indicated near the end of the document | | | | | | | | | |
| **Rationale for expectedness assessment:** | |  | | | | | | | | | |

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| **4. NON-INVESTIGATIONAL MEDICINAL PRODUCTS (NIMPs)** | | | | | | | | | | | |
| **Are there any additional medications used as part of the protocol (e.g. rescue/escape medications)?** | | | Yes | | | No *if no, please proceed to section 5* | | | | | |
| **Name of trial NIMP** | | **Dose/**  **Schedule** | **Route of Administration** | | **Start Date** | | **End Date**  *Tick box if ongoing* | | **Is SAE causally related to NIMP?** | | |
| **1** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **2** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **3** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **Rationale for causality assessment:** | |  | | | | | | | | | |
| **The section below must only be completed when the SAE is POSSIBLY RELATED to the NIMP** | | | | | | | | | | | |
| **Expectedness:** | | Expected | | *the reaction is consistent with the toxicity of the NIMP as listed in the Reference Safety Information (RSI) contained in the SPC* | | | | | | | |
| Unexpected | | *the reaction is not consistent with the toxicity as listed in the Reference Safety Information (RSI) contained in the SPC* | | | | | | | |
| **Version and/or date\* of IB or SPC containing the RSI used to assess expectedness:** | |  | | | | | | | | | |
| \* for SPCs ‘date’ refers to ‘Date of revision of text’ as indicated near the end of the document | | | | | | | | | |
| **Rationale for expectedness assessment:** | |  | | | | | | | | | |

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| **5. CONCOMITANT MEDICATION RELEVANT TO THE SAE** | | | | | | | | | |
| **Do not include therapy used to treat the SAE** | | | | | | | | | |
| **Are there any relevant concomitant medications?** | | | | Yes | | No *if no, please proceed to section 6* | | | |
| **Name of concomitant medication** | | **Dose/**  **Schedule** | **Route of Administration** | | **Reason for Use** | | **Start Date** | **End Date**  *Tick box if ongoing* | |
| **1** |  |  |  | |  | |  |  |  |
| **2** |  |  |  | |  | |  |  |  |
| **3** |  |  |  | |  | |  |  |  |
| **4** |  |  |  | |  | |  |  |  |
| **5** |  |  |  | |  | |  |  |  |
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| **6. MEDICAL HISTORY** | | | | | | | |
| **Is there any relevant medical history?** | | | Yes | | No *if no, please proceed to section 7* | | |
| **Condition** | | **Start Date** | | **End Date** | | **Ongoing?** | **Medication Required?** |
| **1** |  |  | |  | | Yes  No | Yes  No |
| **2** |  |  | |  | | Yes  No | Yes  No |
| **3** |  |  | |  | | Yes  No | Yes  No |
| **4** |  |  | |  | | Yes  No | Yes  No |
| **5** |  |  | |  | | Yes  No | Yes  No |
| **6** |  |  | |  | | Yes  No | Yes  No |

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| **7. RELEVANT TEST /LABORATORY FINDINGS** | | | | | | | | | | |
| **Include only the results relevant to the SAE diagnosis or course of SAE** | | | | | | | | | | |
| **Are there any relevant tests/laboratory findings?** | | | | | Yes | | No *if no, please proceed to section 8* | | | |
| **Test/Lab Finding** | | **Unit** | | **Date** | | **Value** | | **Date** | **Value** | |
| **1** |  |  | |  | |  | |  |  | |
| **2** |  |  | |  | |  | |  |  | |
| **3** |  |  | |  | |  | |  |  | |
| **4** |  |  | |  | |  | |  |  | |
| **5** |  |  | |  | |  | |  |  | |
| **Comment on findings:**  *(or mark Not Applicable)* | |  | | | | | | | | |
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| **8. ACTION TAKEN** | | | |
| **Any follow-up information relevant to this section can be added to existing (e.g. initial) information.**  **DO NOT cross through or otherwise obscure existing information, and do not use a new form for follow-up reports.** | | | |
| **Action** | **Name of IMP(s)** | **Date of Action** | **Initials and Date** |
| **IMP permanently discontinued**  *If multiple IMPs used, please record which IMPs have been discontinued* |  |  |  |
| **IMP dose reduced**  *If multiple IMPs used, please record which IMPs have been reduced* |  |  |  |
| **IMP dose increased**  *If multiple IMPs used, please record which IMPs have been increased* |  |  |  |
| **IMP dose not changed** |  |  |  |
| **Unknown** |  |  |  |
| **Not Applicable** |  |  |  |

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| **9. OUTCOME OF SAE** | | | |
| **Any follow-up information relevant to this section can be added to existing (e.g. initial) information.**  **DO NOT cross through or otherwise obscure existing information, and do not use a new form for follow-up reports.** | | | |
| **Outcome of SAE** | **Additional Information** | | **Initials and Date** |
| *\*\* Ongoing outcomes: \*\** | | | |
| **Condition still present and unchanged** |  | |  |
| **Condition deteriorated** |  | |  |
| **Condition Improving** |  | |  |
| *\*\* Final outcomes: \*\** | | | |
| **Completely Recovered** | **Date Recovered:** | |  |
| **Recovered with sequelae** | **Date Recovered:** | |  |
| **Death** | **Date of Death:**  **Post mortem:**  Yes  No |  |  |

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| **10. ADDITIONAL INFORMATION** |
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| **11. INFORMATION SOURCE FOR INITIAL REPORT** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | **Telephone:** | |  | | |  |
|  | | | | | | | | | | | | |
| **PI Name** |  | | **PI Signature:** | | *Date:* | | | | | | |  |
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| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **12. INFORMATION SOURCE FOR FOLLOW-UP no. 1** | | | | | | | | | | | | |
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| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | | **Telephone:** | |  |  | |
|  | | | | | | | | | | | | |
| **PI Name** |  | | | **PI Signature:** | | *Date:* | | | | |  | |
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| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **13. INFORMATION SOURCE FOR FOLLOW-UP no. 2 (for any additional follow-ups please use form CR005-T06)** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | | **Telephone:** | |  |  | |
|  | | | | | | | | | | | | |
| **PI Name** |  | | | **PI Signature:** | | *Date:* | | | | |  | |
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| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **Original wet signature forms must be filed in the Investigator Site File (ISF).**  **ACCORD will retain a copy on file.** | | | | | | | | | | | | |