**Serious Adverse Events Reporting Form**

*The safety reporting contact details below are for use by trials that are required by their protocol to report SAEs to the Joint Oxford University Hospitals NHS Foundation Trust/University of Oxford Trial Safety Group for review.*

*Other University of Oxford sponsored trials using the template should amend the safety reporting contact details in line with the trial protocol.*

Clinical Trials & Research Governance, Joint research Office, Block 60, Churchill Hospital, Headington, Oxford, OX3 7LE

**Tel: 01865 572221; Email:** **safetyreportingctrg@admin.ox.ac.uk**

* *Please complete the form, sign and email a scanned copy to (****safetyreportingctrg@admin.ox.ac.uk)****, within* ***24 hours*** *of awareness****.***
* *Refer to the safety reporting form completion guidelines for guidance.*
* *The original should be filed in the Trial Master File or Investigator Site File. Please ensure that the event is recorded in patient hospital notes and case report form, where applicable.*

**1. Summary**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Report Type (Tick ONE)** |  | Initial Report |  | Follow-Up |

**Criteria for definition of SAE (Tick ONE)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Subject died |  | Life Threatening |
|  | In-Patient hospitalisation or prolongation |  | Persistent or significant disability |
|  | Congenital anomaly/birth defect |  | Medically Important event |

|  |  |
| --- | --- |
| Chief Investigator‘s Name |  |
| Study Number |  |
| Date of SAE Awareness |  |
| Start date of SAE |  |
| Stop date of SAE (or state if ongoing) |  |
| Keywords (SAE Diagnosis or main symptoms) |  |
| Subject Initials |  |
| Subject ID |  |

**2. Narrative**

|  |
| --- |
| *Please provide an account of the event, similar in format to that of a discharge summary. Mention any relevant lab data or diagnostic tests.* |
|  |

**3. Evaluation of event**

**Outcomes (Tick ONE)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Recovered | | |  | Change in SAE | | |
|  | Recovered with sequelae | | |  | Patient died | | |
|  | Continuing | | |  | Unknown | | |
| **Severity (Tick ONE)** | | | | | | | |
|  | Mild |  | Moderate | | |  | Severe |

|  |  |  |  |
| --- | --- | --- | --- |
| **Action taken with study drug (Tick ONE)** | | | |
|  | None |  | Dose temporarily reduced |
|  | Dose reduced |  | Discontinued temporarily |
|  | Discontinued |  |  |
| **Other Action (Tick ONE)** | | | |
|  | None |  | Treated with medication |
|  | Other |  |  |
| **Withdrawn due to SAE (Tick ONE)** | | | |
|  | No |  | Yes |

**4. Subject Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Subject DOB | |  | |
| Age | |  | |
| **Sex** | | | |
|  | Male |  | Female |
| Height (cm) | |  | |
| Weight (Kg) | |  | |

**5. Study Drug (s)**

|  |  |
| --- | --- |
| ***Study Drug 1*** |  |
| Drug |  |
| Route |  |
| Dose Details |  |
| Indication |  |
| Batch number |  |
| Expiry date |  |
| Start date of drug |  |
| Stop date or state if ongoing |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| If stopped/lowered dose, did the event resolve after this? (Tick ONE) | | | | | |
|  | Yes |  | No |  | N/A |
| If reintroduced did the event reappear? (Tick ONE) | | | | | |
|  | Yes |  | No |  | N/A |
|  |  |  |  |  |  |

|  |  |
| --- | --- |
| ***Study Drug 2:*** |  |
| Drug |  |
| Route |  |
| Dose Details |  |
| Indication |  |
| Batch number |  |
| Expiry date |  |
| Start date of drug |  |
| Stop date or state if ongoing |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| If stopped/lowered dose, did the event resolve after this? (Tick ONE) | | | | | |
|  | Yes |  | No |  | N/A |
| If reintroduced did the event reappear? (Tick ONE) | | | | | |
|  | Yes |  | No |  | N/A |
| *Attach supplemental pages if there are more than 2 study drugs* | | | | | |

**6. Death Details (If applicable)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date of death | |  | | | | |
| Cause of death | |  | | | | |
| **Cause of death obtained from (Tick ONE)** | | | | | | |
|  | Working diagnosis | |  | Coroners inquest |  | Death Certificate |

**7. Relevant medical/surgical history**

|  |
| --- |
| No. of medical/surgical history CRF pages attached:  *If no CRF pages attached, describe details of medical history :* |
|  |

**8. Concomitant Medication**

|  |
| --- |
| No. of concomitant CRF pages attached:  *If no CRF pages attached, describe details of conc. meds :* |
|  |

**9. Study Details**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study title | |  | | | | |
| Protocol Version or date | |  | | | | |
| Eudract No. | |  | | | | |
| **Study Design** | | | | | | |
|  | Open label | |  | Single blind |  | Double blind |
| If blinded, blind broken? (Tick ONE) *Consider unblinding if SUSAR* | | | | | | |
|  | Yes | |  | No |  | N/A |

**10. Principal Investigator Details (site specific, and if different from Chief Investigator**

|  |  |
| --- | --- |
| Name of PI |  |
| Address |  |
|  |
|  |
|  |
| Telephone |  |
| Fax |  |
| Email Address |  |

**11. Reporter Details**

|  |  |
| --- | --- |
| Signature of reporter |  |
| Date of signing |  |
| Full Name |  |
| Designation |  |
| Contact telephone |  |
| Email address |  |

**This section is to be completed by a medically qualified investigator**

**12. Causality and expectedness**

|  |  |  |
| --- | --- | --- |
| **Evaluation of causal relationship with study drug 1 (Tick ONE )** |  | Related |
|  |  | Unrelated |
| If the causal relationship is not clear, please indicate how you came to your decision | | |
|  | | |
| If causal relationship is **‘related ‘,** was the event **‘expected’**? Your assessment of expectedness must be based on the investigator brochure &/or summary of product characteristics. **If the event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) it requires expedited reporting within the regulatory timelines.** |  | Yes (Expected) |
|  | No (Unexpected) |
|  |  |

|  |  |  |
| --- | --- | --- |
| **Evaluation of causal relationship with study drug 2 (*if applicable)* (Tick ONE )** |  | Related |
|  |  | Unrelated |
| If the causal relationship is not clear, please indicate how you came to your decision | | |
|  | | |
| If causal relationship is **‘related ‘,** was the event **‘expected’**? Your assessment of expectedness must be based in the investigator brochure &/or summary of product characteristics. **If the event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) it requires expedited reporting within the regulatory timelines.** |  | Yes (Expected) |
|  | No (Unexpected) |
|  |  |

|  |  |
| --- | --- |
| Signature of Medically Qualified Investigator |  |
| Date of signing |  |
| Full Name |  |
| Designation |  |
| Contact Telephone |  |
| Email Address |  |