**Serious Adverse Event (SAE) /Suspected Unexpected Serious Adverse Reaction (SUSAR) FOLLOW UP REPORT FORM**

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| **1. Further details of SAE/SUSAR** | | | | | | |
| **Primary event name** **used on initial form:** | |  | | | | |
| **Updated event name (if applicable):** | |  | | | | |
| **MedDRA Preferred Term for updated event name (if applicable):** | |  | | | | |
| **Any changes or additional details of event/reaction**, i.e. body site, reported signs and symptoms and diagnosis where possible since initial report including missing data relevant to assessment of case e.g. medical history, family history, test results and any actions taken: | |  | | | | |
| **Have there been any changes to the *maximum* severity of event since the initial report?** | | Yes | | | No | |
| **If yes, please provide maximum severity of event:** | | Mild | Moderate | | | Severe |
| **2. Outcome** | | | | | | |
| **Outcome of event:** | Resolved  Resolved with sequelae  Ongoing  Died (give cause and post-mortem details if available)  Unknown | | | | | |
| **Further details regarding the outcome**: |  | | | | | |
| **End date and time (where applicable):** |  | | | | | |
| **Was the patient withdrawn from study treatment?** | Yes | | | No | | |

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| **3. Causality assessment** | | |
| **Any changes required to causality assessment since initial report form**: | Yes | No |
| **If Yes detail below:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **List IMP/device/intervention below**  (add new rows as needed)  (For blinded studies all IMPs/devices/interventions should be listed and assessed for causality) |  | | | | | |  | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related | |  | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related | |  | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |  |  |  | | --- | --- | | **Is this event expected of the IMP/device/study intervention**  (note only required where ‘possibly, probably or definitely related’) | Expected  Unexpected | | **Name of person making causality assessment:**  This must be a delegated medically qualified individual if a CTIMP or interventional surgical study, or device study |  | | **Role in study:** |  | | **If not related to study IMP/device/intervention(s) what is the possible cause of the event?** |  |   Note: sponsor representative will re-assess expectedness of the event against the relevant Reference Safety Information on receipt of an updated event name and will inform site and CI if event is a SUSAR | | |

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| **4. Chief/Principal Investigator or delegated appropriately qualified individual\* (at this site)** | | |
| **Name (please print):** |  | |
| **Job title/role in study:** |  | |
| **Contact details:** |  | |
| **Signature:** |  | **Date:** |
| **I confirm that the contents of this form** (pages 1, 2 ± 3)  **are accurate and complete** | | |

**\* This must be a medically qualified individual if a CTIMP or interventional surgical study**

|  |  |  |
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| **5. Details of person completing this report (if different to CI/PI/delegated other above)** | | |
| **Name (please print):** |  | |
| **Job title/role in study:** |  | |
| **Contact details:** |  | |
| **Signature:** |  | **Date:** |
| **I confirm that the contents of this form** (pages 1, 2 ± 3)  **are accurate and complete** | | |

**Continue on new sheet if necessary; please identify how many sheets have been used.**

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| **Any changes to IMP since initial report form** Yes  No  **If Yes update table below** |

**SAE/SUSAR FOLLOW UP REPORT FORM**

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| **7. STUDY IMP** – details of administration. **NB complete for IMP studies only** | | | | | | | | | | | | | |
| Brand name: | Indication | | Batch no. | Route  (e.g. oral) | Form  (e.g. tablet) | | Total dose/24h  (specify units) | | Regimen (e.g. BD) | | Start date  & time | Stop date  & time | *Or* duration of treatment |
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| For blinded studies, was the randomisation code broken? | | | | | | \*Yes | | No | | N/A | | | |
| \*If yes, give details: | |  | | | | | | | | | | | |

**Continue on new sheet if necessary; please identify how many sheets have been used.**