**TMPL\_026 SAE/SUSAR FOLLOW UP REPORT FORM**

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| **1. Further details of SAE/SUSAR** | | | | | | | | | | | | |
| **Event name/ summary (to be used as quick reference of event):** | | | |  | | | | | | | | |
| 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. | | | | | | | | | | | | |
| **Current maximum intensity** | | | | | | Mild | | Moderate | | Severe | | |  | |
| **2. Outcome** | | | | | | | | | | | | |
| Resolved\* | Resolved with sequelae\* | | Ongoing\* | | | | | Patient Died (give cause and post-mortem details if available) | | | Unknown | |
| \*Give details: | | | | | | | | | | | | |
| End date and time (where applicable) | |  | | | |  | | | |  | | |
| Was the patient withdrawn from the study? | | | | | | Yes | | | | No | | |

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| **3. Additional action taken and further information since initial report** |
| Please describe further action taken: |
|  |

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| Any changes required to causality assessment since initial report form: Yes  No |
| If Yes please note changes below:   |  |  | | --- | --- | | **Is the SAE related to the drug/device/intervention?**  Not related  Unlikely to be related |  | | Possibly related\*  Probably related\*  Definitely related\* | **\***If possibly, probably or definitely related, was the SAE unexpected?  Yes1  No2  (Unexpected means not described in the Reference Safety Information | |

|  |  |  |
| --- | --- | --- |
| **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**

|  |  |  |
| --- | --- | --- |
| **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**

Sheet number:      of

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| **6. 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.**