**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| Was the patient withdrawn from the study?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 |

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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**

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.**