#  TMPL\_025 SAE/SUSAR INITIAL REPORT FORM

Please refer to the Work Instructions document (WI\_002) for details on how to complete this form

|  |  |
| --- | --- |
| **IRAS number** |  |
| **R&D ref** |  |
| **Current protocol version** |  |
| **1. Study Title (use short title where available):** |
|  |
| **2. Details of subject affected by SAE/SUSAR** |
| Subject study ID:      Year of Birth:       |
| **3. Details of SAE/SUSAR** (further space available in section 10) |
| **Event name****This should be the diagnosis (or main symptom if diagnosis not known) (to be used as quick reference of event):** |  |
| **Onset Date** **(**when event became serious) | **Date investigator/research team became aware of event**  | **End date and time (if applicable)** |  |
| Full description of event/reaction, including body site, reported signs and symptoms:       |
| Event is defined as serious because it (tick as many as apply):[ ]  resulted in death [ ]  is/was life-threatening[ ]  resulted in persistent or significant disability/incapacity[ ]  required hospitalisation[ ]  prolonged an ongoing hospitalisation[ ]  resulted in a congenital anomaly or birth defect[ ]  other – please specify\* **Please give further details in Section 5 ‘Outcome’** | \*Specify:      |
| **Maximum intensity if not life threatening or results in death (up until time of initial report)** | Mild [ ]  | Moderate [ ]  | Severe [ ]  |

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Sheet number:      of

**Complete Table 4 - if applicable**

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| **4. Details of IMP/device/intervention(s) if applicable**  |
| 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 | Suspected cause of SAE /SUSAR? (Y/N) |
|       |       |       |       |       |       |       |       |       |       |
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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.**

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| **5. Outcome** (*further space available in section 10)* |
| [ ] Resolved\* | [ ]  Resolved with sequelae\* | [ ]  Ongoing\* | [ ]  Died\* (give cause and post-mortem details if available) | [ ]  Unknown |
| \*Give details:       |
| Was the patient withdrawn from the study? | Yes [ ]  | No [ ]  |
|  |
|  |
|  |
| **6. Action taken and further information** *(further space available in section 10)* |
| Please describe action taken (including details of IMP where applicable e.g. drug withdrawn, clinical investigations, treatment received etc…):       |
| Other information relevant to assessment of case e.g. medical history, family history, test results, concomitant medication.      |
| **7. Causality and Expectedness (to be completed by delegated appropriately qualified**  **individual\*)** |
| **Is the SAE related to the drug/device/intervention?**[ ] Not related[ ]  Unlikely to be related |  | ***In addition to this form, and within 5 days:***1**For unexpected SAEs, if event ongoing, please complete and return all sections of the follow up report form.**2**For expected SAEs, if event ongoing, please complete and return sections 1, 2 and 3 of the follow up report form.** |
| [ ]  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 |
|  |

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

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| **8. Additional information (refer to section number)** |
| Section no. | Further information |
|       |       |
|       |       |
|       |       |
| **9. Chief/Principal Investigator or delegated appropriately qualified individual\* (at this site)** |
| Name: (please print) |       |
| Job title/role in study: |       |
| Email address: |       |
| Telephone No: |       |
| Signature: |  | Date:  |
| I confirm that the contents of this form (pages 1, 2, 3, 4) are accurate and complete |

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

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| **10. Details of person completing this report (if different to CI/PI/delegated other above)** |
| **Name** (please print) |  |
| **Job title/role in study:** |  |
| **Contact details (email and telephone number)** |  |
| **Signature** |  | **Date:** |
| **I confirm that the contents of this form** (pages 1, 2, 3, 4)  **are accurate and complete** |

**Please tick this box if additional pages have been used: [ ]**

#  Number of additional pages used (if applicable):

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