# 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 | |

**SAE/SUSAR INITIAL REPORT FORM**

Sheet number:      of

**Complete Table 4 - if applicable**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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.**

**SAE/SUSAR INITIAL REPORT FORM**

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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**

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

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