Serious Adverse Event - narrative continuation sheet

# Event overview

| **Information Requested** | **Response** |
| --- | --- |
| Sponsor reference number |  |
| Study title or Acronym |  |
| Centre name or number |  |
| EudraCT number |  |
| Participant ID: |  |
| Participant initials |  |
| Date of report: *(dd/mm/yyyy)* |  |
| Title of Serious Adverse Event: |  |

* **If this continuation sheet is completed in addition to the SAE form, please submit both forms together to** [**RGOSponsor@le.ac.uk**](mailto:RGOSponsor@le.ac.uk)
* **If this form is required, please refer to it on the relevant SAE report e.g. within the narrative section state ‘please see the continuation sheet for further information’.**
* **If you have queries regarding your SAE submission, please contact the Sponsor via** [**RGOSponsor@le.ac.uk**](mailto:RGOSponsor@le.ac.uk)

# Narrative

| **Information Requested** | **Response** |
| --- | --- |
| Describe the event (please include information about how and when the research team became aware of the event, any sequelae and attach any relevant **anonymised** supporting documentation such as medical reports, lab results and discharge summaries. Add continuation pages if needed) |  |
| Please list any treatment given |  |
| Please provide any relevant medical history |  |