Serious Adverse Event – additional drug sheet

(For UoL sponsored clinical trials of investigational medicinal products)

# 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 ensure this is reference on the relevant SAE reporting form by selecting the relevant box under within the Causality & Expectedness section.**
* **If you have queries regarding your SAE submission, please contact the Sponsor via** [**RGOSponsor@le.ac.uk**](mailto:RGOSponsor@le.ac.uk)

# Medication Overview

| **Information Requested** | **Response** |
| --- | --- |
| Has the participant been administered IMP? | Yes – complete section 2.1  No – provide reason and move on to section 9 (e.g. participant is still at the screening phase/they are in the standard of care arm): |

## 2.1 Study medication information

| **Information Requested** | **Response** |
| --- | --- |
| Name of IMP |  |
| Indication(s) for use |  |
| Dose (units) |  |
| Route of administration |  |
| Date of first administration |  |
| Date of last administration |  |
| Batch/bottle number |  |

# Action taken with IMP due to event:

| **Information Requested** | **Response** |
| --- | --- |
| Action taken with IMP due to event | Dose not changed  Temporarily discontinued  Date discontinued *(dd/mm/yyyy)*:  Date restarted *(dd/mm/yyyy)*:  Permanently discontinued  Date discontinued *(dd/mm/yyyy)*:  Dose reduced  Provide details:  Unknown at present  Other  Provide details:  Not applicable (e.g. participant is still at the screening phase/they are in the standard of care arm)  Provide details: |

# Causality and Expectedness

**\*\*The following section MUST be completed by the Chief/Principal Investigator or other delegated medically qualified Investigator as agreed by the Sponsor\*\***

## 4.1 Evaluation of a causal relationship with IMP

**Related** – If the causal relationship between the IMP and the SAE is at least a reasonable possibility

**Un-related** – If there is no causal relationship between the IMP and the SAE

| **Information Requested** | **Response** |
| --- | --- |
| Was the event related to the IMP? | Yes \*\***Related** – complete the options below and move to section 4.2  Possibly  Probably  Definitely  No Unrelated - move to section 10.3 |

## 4.2 Expectedness - to be completed if the study drug is considered related to the SAE

| **Information Requested** | **Response** |
| --- | --- |
| Was the event expected **as per the information contained within the approved reference safety information?** | Yes- Expected  No - \*\***Unexpected** |
| Please detail the RSI Version and date used. *Note this should be the approved RSI at the time that the event occurred.* |  |

\*\*If the event is **related and unexpected** it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting. **Inform the Sponsor immediately via** [**rgosponsor@le.ac.uk**](mailto:rgosponsor@le.ac.uk)

# Reporting persons

**\*Signatures should be ‘wet ink’ or, if electronic, needs to be an approved/verifiable eSignature e.g. via Adobe Sign or DocuSign. We cannot accept unverifiable electronic signatures on SAE reports for inspection purposes. If Adobe Sign or DocuSign are not available and the form has been completed electronically, please print a copy prior to signing. If it is not possible to obtain a ‘wet ink’ signature please send an unsigned document to** [**rgosposnor@le.ac.uk**](mailto:rgosposnor@le.ac.uk) **and we can facilitate digital signatures via Adobe Sign.**

| **Information Requested** | **Reporting person** | **Principal Investigator/delegated medically qualified individual as agreed by the Sponsor** |
| --- | --- | --- |
| Name |  |  |
| Role |  |  |
| Signature**\*** |  |  |
| Date |  |  |
| Contact Number or email |  |  |

# Assessment of relatedness of event

To be completed by the PI or delegated individual who assessed the relatedness of the event to the study procedure or intervention.

*I confirm that the causality/expectedness of this event was assessed by myself and I have been delegated this task as per the Delegation of Authority Log. Where the event was considered related to the IMP, the expectedness has been assessed against the approved reference safety information listed above.*

| **Information Requested** | **Response** |
| --- | --- |
| **Name** |  |
| **Signature\*** |  |

Please return the completed form and copies of any additional anonymised documents to the Research Governance Office, by email via [rgosponsor@le.ac.uk](mailto:rgosponsor@le.ac.uk)

Reporting of SUSARs to the Research Ethics Committee and Regulatory Authority for UoL sponsored studies will be undertaken in accordance with Sponsor SOP ‘Processing and reporting of serious adverse events, serious adverse reactions and suspected unexpected serious adverse reactions for all research sponsored by the University of Leicester’.

Reporting and completion of SAEs not involving investigational medicinal products must be undertaken in accordance with SOP S-1009 UoL Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions for all Research Sponsored by the University of Leicester