UNIVERSITY OF LEICESTER

Serious Adverse Event Reporting Form Guidance

SAE Forms and any redacted documentation must be sent to the Sponsor within 24 hours of becoming aware of the event/receiving updated information

Email SAE Forms to: rgosponsor@le.ac.uk

General considerations

1. Prior to completing and submitting an SAE, you must refer to the SAE reporting/pharmacovigilance section of the approved protocol for specific reporting requirements and guidance.
2. For each SAE, and each follow-up report, a completely new report must be completed. Do not re-use or type over a previously submitted report unless specifically requested to do so by the Sponsor. Sponsor requested amendments to a report should be made in a GCP compliant manner.
3. Refer to SOP S-1009 for information about the reporting process and/or reporting timelines.

1. Trial Identifiers	
Sponsor reference number	4 digit reference number found on trial protocol
Trial Title	Full or short trial title/acronym
Centre name or number	Full name (and/or number) of reporting location/site
Principal Investigator	Full name of reporting location/site Principal Investigator
Trial design	Select one option only, as per the protocol
2. Participant Identifiers	
Participant ID	Unique participant identification number
Participant Initials	Participant initials, typically expressed as ABC, or A-C
Participant year of birth	Year of birth (yyyy)
Participant age at time of onset of SAE (years)	How old (in years) the participant was when the SAE began
3. Report Overview	
Name of person completing and submitting this report	Full name of person at the reporting location responsible for completing and submitting the report to the Sponsor
Date research team made aware of the event	Date the person at the reporting location became aware of the event (dd/mm/yyyy)
Date of this report	Date that the report is prepared (dd/mm/yyyy)

Type of report	Select one option only; **Initial** = first time reporting the event, not all information is known or the event is ongoing **Follow-up #__** = new or further information is available, the event is ongoing or further information is still required. Add what number follow-up report this is (i.e., #4) **Final** = all information about the event is now known and available, all queries have been resolved, and the outcome is known **Initial + Final** = first time reporting the event and all information about the event and outcome is known and available.
Sponsor SAE ID	Unique SAE reference ID issued by the Sponsor following receipt of the first report. The SAE ID must be included on all subsequent SAE reports to facilitate SAE tracking
4. Event Overview	
Title of SAE	Include the diagnosis (if known) or list symptoms of the event Report only one SAE per form
Date of onset of symptoms	Date that the symptoms/adverse event first started (dd/mm/yyyy)
Date event became serious	Date that the symptoms/adverse event first met the seriousness criteria (dd/mm/yyyy; i.e., the date that hospitalisation happened)
Select the **most significant criteria** that classifies this event as serious	Select one option only. If the event fits more than one criteria, choose the **most significant** one. E.g. if an event begins as a hospitalisation and a participant subsequently dies, the seriousness would be classified as death, the earlier hospitalisation should still be documented in the event narrative and timeline. If 'other serious important medical event' is selected, please specify what has happened

What is the severity of the event?	Select one option only
Was the participant admitted to hospital?	Select one option only, include dates when available (dd/mm/yyyy)
Event narrative	This should be a chronological, medically coherent, and objective account of the event that facilitates accurate reconstruction, and the review of the information by those who may not be experts in the disease area or investigational medicinal product(s). Abbreviations of clinical conditions should not be used. Supporting documentation (i.e., lab reports) must be pseudonymised with Participant ID and Initials prior to submission
Relevant medical history, baseline characteristics, underlying conditions	Provide an overview of relevant information
Interventions/treatments performed and clinical response relating to this event	Provide an overview of relevant information
Is the event is related to a protocol deviation.	Select yes or no and ensure detail is added to the narrative as appropriate.
What is the outcome of the event?	Select one option only, provide dates where applicable (dd/mm/yyyy). It is expected that this will change in subsequent reports. **Resolved/Recovered** = the event has completely ended and the participant has returned to their usual health with no remaining symptoms of the SAE. **Resolved/Recovered with sequelae** = the event has ended but the participant has persistent after-effects (i.e., reduced mobility, ongoing mild symptoms, lasting impairment) and they have not returned to their usual health. **Ongoing*** = the event is still occurring at the time of reporting (i.e., symptoms or clinical findings have not resolved).

	Unknown at present = it is not yet clear whether the event has resolved (i.e., information is incomplete/pending, the participant cannot be assessed). **Fatal** = the event resulted in the participant's death. Add date of death. *In exceptional circumstances an event may be closed out with an on-going outcome where the event has not resolved but is stable and a resolution is unlikely and continuing to keep the SAE open would not add meaningful clinical or safety information. This applies to long-term or permanent conditions where "resolution" is not realistic, such as a new cancer diagnosis, chronic disability, or irreversible organ damage.
If fatal, primary cause of death (if known)	Where available, the main medical condition or event that directly led to the participant's death; this should be one single cause even when multiple SAEs may have contributed
Where was the cause of death obtained from?	Select one option only; evidence does <u>not</u> need to be routinely provided unless specifically requested by the Sponsor. Where the cause is based on a provisional/working diagnosis, a final confirmation from a corners inquest or death certificate will be requested.
Autopsy performed?	Select one option only; evidence does <u>not</u> need to be routinely provided unless specifically requested by the Sponsor
5. IMP and Medication Overview - If the study involves more than one IMP, select the check box and complete an 'additional drug sheet' for each IMPs.	
Has the participant been administered IMP?	Select one option only; **Yes** = complete the remainder of Section 5 **No/Not Applicable** = Move to section 6
Name of IMP	As per the protocol, provide the name of the active IMP

	For blinded trials, the active IMP should be recorded for SAE reporting, regardless of the participant's actual allocation
Dose (units) and Frequency	As per the protocol
Batch/bottle number	Where available and where this will not risk unblinding the research team. Participant-specific, or central pharmacy records may be used to obtain this information
Route of administration	As per the protocol
Date of first administration	Provide date (dd/mm/yyyy)
Date of last administration prior to SAE onset, if stopped	If the IMP was stopped, provide date of last dose/administration, where available (dd/mm/yyyy) Leave blank if date is unknown or IMP was ongoing at the time of the event.
Action taken with IMP due to event	Select one option only; provide dates where applicable (dd/mm/yyyy)
6. Causality	
****The Causality Assessment MUST only be completed by the Principal Investigator or other delegated medically qualified individual****	
Source of Causality Assessment	Select one option only
Is the event causally related to IMP?	Causality assessment determines whether there is a **reasonable possibility** that the IMP contributed to the SAE. This is a regulatory expectation and must be based on clinical judgement Select one option/sub-option only; **Related** = when there is **any reasonable possibility** that the IMP contributed to the SAE. This includes a broad range of certainty from tentative suspicion to clear evidence of causation; • **Possibly related:** A causal link cannot be ruled out • **Probably related:** Evidence leans toward a causal link • **Definitely related:** Strong, clear evidence supports the IMP as the cause

	Where an event is considered related, Sponsor will complete an expectedness assessment against the approved RSI. This will help the Sponsor determine whether or not the event needs any further onward reporting. **Unrelated** = when there is **clear clinical evidence** that the event is most likely due to causes **other than** the IMP For a non CTIMP study select Not Applicable
Is the event causally related to Trial intervention/ assessment/procedure (other than an IMP)?	Causality assessment determines whether there is a **reasonable possibility** that the Trial intervention/assessment/procedure contributed to the SAE. This is a regulatory expectation and must be based on clinical judgement. If an event is considered related, its expectedness must be confirmed against the safety/pharmacovigilance section of the protocol This will help the Sponsor determine whether or not the event needs any further onward reporting.
Name of Causality Assessor	Full name of Principal Investigator or other delegated medically qualified individual (i.e., sub-investigator)
Signature of Causality Assessor	Wet ink signature must be supplied, or this can be left blank and the Sponsor will request the Causality Assessor's signature via AdobeSign
Email of Causality Assessor	Contact email for the Causality Assessor
Date of Causality Assessment	Date causality assessment made (dd/mm/yyyy)
7. Concomitant Medications – update the table based on the information requested, or select the box if not applicable because there are no concomitant medications being taken.	