UNIVERSITY OF LEICESTER

Serious Adverse Event Report Form A

For UoL sponsored clinical trials of investigational medicinal products

Guidance document

This form is for the reporting of serious adverse events in trials **involving** investigational medicinal products. If your study **does not** involve investigational medicinal products you must use SAE report form B.

All Serious Adverse Events **must** be reported to rgosponsor@le.ac.uk within **24 hours** of the research team becoming aware of the event.

Prior to completing SAE Reporting Form A please refer to the SAE reporting/pharmacovigilance section of the trial specific protocol, the SIV documents of the trial manager for any trial specific reporting requirements and guidance.

The initial report may be submitted without causality/expectedness section completed or a PI/delegated medic signature, but this **must be** followed up with a signed copy reporting expectedness and causality within 7 days.

Once a signed initial report is received, a follow up or final report should be submitted within 28 days. The reporting person(s) will receive an 'acknowledgment of receipt' email from the Sponsor following the submission of each report. This will contain the date by which a follow-up or final report should be submitted, and details of any additional queries raised. Response to the request is required as per the timelines dictated in the email. If the participant is still an inpatient, or there is an unavoidable delay in the provision of further information, inform the sponsor at the Research Governance Office.

Please return the completed form and any anonymised copies of supporting documents to rgosponsor@leicester.ac.uk

Area of report	Information Required
1. Study details	
SAE ID	This number is allocated by the Sponsor following the submission of an initial report to be added to the header of follow-up or final reports
Sponsor reference number	Study identifier given by the Sponsor. This can be found on the Sponsor green light letter and is usually four numbers. This **must** be given to enable sponsor to identify the trial.
Study title/Acronym	Full or short version of the study title as entered on the IRAS form.
Centre name or number	Centre name and/or number. (If numbers are utilised please ensure that the Sponsor is provided with a listing of corresponding centre names)
EudraCT number	EudraCT registration number
Chief Investigator	Name of chief investigator
Principal Investigator	Name of principal investigator
2. Participant Details	
Participant ID	Unique subject identifier
Participant Initials	Participant initials
Participant year of birth	Enter **year** of birth only. Please note **full date of birth must not be included**. **No other patient identifiable data must be entered on this form**
3. Report /event overview	
Type of report	Select one option from the list below **Initial report** The first time you are reporting an event, this may be a signed or unsigned report. At this time point either not all details are available, the form is unsigned, or the event is marked as ongoing. **Initial and final report** The first time you are reporting an event, however all information about the SAE is available and the outcome of the event is known. The SAE is therefore considered to be complete on the submission of the initial report. **Follow-up report** Follow-up information to an initial report is being provided. The event may still be ongoing or even resolved and further information relating to the event is still required. Further reports must be submitted until the resolution of the event or all information has been provided. Please enter the number of the follow-up report e.g. if an initial report has been submitted and this is the first follow-up report put '1' in the box. If an initial and a follow-up report has previously been submitted and this is a further follow-up, please put a '2' in the box etc. **Final report** When all follow-up information is available for this serious adverse event and the outcome for the event has been completed.
Date of report	Date you are completing this specific SAE report. This should be updated each time an additional report e.g. follow-up, final or amended report is submitted.

Title of serious adverse event	Enter keywords that best summarise the event e.g. chest pain. **Multiple serious adverse events must be reported on individual forms.**
Is the event an Adverse Event of Special Interest (AESI)?	Answer Yes or No
Has the title been updated since the initial report?	Answer Yes (and provide additional detail) or No
Date of onset of symptoms	This should be the date of onset of the initial symptoms which may be prior to the event becoming an SAE e.g. if a person suffers for three days with abdominal pain prior to being hospitalised. The onset date should be the date when they first started experiencing abdominal pain. If a full date is not known then UKN/MM/YYYY should be completed.
Date event became serious	Date that the event met the criteria listed in section 4
Date study team became aware	The date that the event was reported to/or the study team became aware of the event. **The SAE must be submitted within 24 hours of this date.**
4. Serious criteria	
Criteria for definition of SAE	Select one option from the list. If the event fits more than one criteria, choose the **most significant** one. Multiple Serious Adverse Events **must** be reported on individual forms. If 'other' is selected, please specify e.g. adverse event of special interest. If for example an event has led to an individual being hospitalised and later dying. The serious criteria should be marked as inpatient hospitalisation and the death will be captured in the outcome section of the report. Serious criteria of death should not be selected in this instance.
5. Narrative	
Was the participant admitted to hospital?	Answer yes or no. If yes, provide dates of admission and discharge
Describe the event. Add continuation pages if needed)	In the narrative box, provide an account of the event, similar to that of a discharge summary. The description must have sufficient details for evaluation by the individual(s) reviewing the SAE, who may not be experts in the disease area or investigational medicinal product(s). Abbreviations of clinical conditions **should not** be used. Summarise any relevant laboratory or diagnostic tests. Include details of discharge if appropriate. Please provide any anonymised supporting documents as appropriate e.g. copies of CT scans/blood results. If extra space is required for the narrative section, please use a separate continuation sheet and submit alongside the SAE report.
Treatment given for the SAE	List any relevant information
Relevant medical history	List any relevant information
5.1 Concomitant medication at the time of the event	Provide relevant details of all concomitant medication
6. Event severity	
Severity of the event	Select the most appropriate option from mild, moderate, severe.
7. Blinding information	

Is the IMP blinded or un-blinded?	Detail if the study drug(s) the participants are receiving are known to the investigating team or are blinded. **If a SUSAR has been reported blinded studies must be un-blinded as per un-blinding procedure.**
8. Medication Overview	If the study involves more than one drug, the 'additional drug sheet' should be used to capture the information for the different IMPs. Use as many additional drug sheets as required. Select the check box if an additional drug sheet has been completed.
Has the participant been administered the study drug	Answer Yes or No. If yes, complete section 8.1 If No, please provide a reason and move on to section 9
8.1 Study medication Information	Update table based on study IMP
9. Action taken with IMP due to the event	Select one option from the list. Provide additional details as necessary e.g. dates/dosages If participant not taking IMP at time of event mark as not applicable.
10. Causality and expectedness	**This section must be completed by the Chief/Principal Investigator or other medically qualified investigator, as agreed by the Sponsor, and delegated this role on the Delegation of Authority and signature log by the Principal Investigator.**
10.1 Evaluation of Causal relationship to IMP	Answer related or unrelated The causal relationship of the study drug to the event **must** be reported. ****Related** – if there is at least a reasonable possibility of a causal relationship between the IMP and the SAE i.e. the relationship cannot be ruled out. If related please specify whether this is a possible, probable or definite relationship. **Not Related** – If there is no causal relationship between the IMP and the SAE i.e. the event is caused by something other than the IMP e.g. underlying disease, a concomitant medication.
10.2 Expectedness	If the event is considered related to the IMP, the expectedness **must** be reported. **The assessment of expectedness must be based only on the information contained in the approved Reference Safety Information (RSI) i.e. Investigator Brochure and/or the Summary of Product Characteristics.** **Expected** – The event is an expected reaction based on the information contained in the Investigator Brochure and/or Summary of Product Characteristics. ****Unexpected** – The event is unexpected based on the information contained in the Investigator Brochure and/or Summary of Product Characteristics. ****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**

	If the trial involves more than one IMP then complete an additional drug form and mark the checkbox on the SAE report.
RSI version and date used	The RSI approved at the event that the time occurred should be used. Please list the RSI date and version used to determine the expectedness assessment.
10.3 Was the event related to a study procedure or intervention other than the IMP?	Select Yes† or No box as appropriate. If yes, please complete the further information requested. †**If the SAE is related to the research procedure(s) and is unexpected (i.e. it is not listed in the protocol as expected) a HRA Serious Adverse Event form must be submitted to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event**. The form can be accessed via the HRA website
11. Protocol deviation	
Was the event related to protocol deviation	Answer Yes or No. If Yes - Further information should be supplied on a separate protocol deviation form.
12. Participant Withdrawal	
Was the participant withdrawn?	Answer Yes or No
11. Outcome	
What is the outcome of the event?	Select one option from the list. **Resolved** - The serious adverse event has resolved e.g. patient has been hospitalised, received treatment and the event has resolved. Provide details of the date of resolution of the SAE. **Resolved with sequelae** – The serious adverse event has resolved but there are still some residual problems as a result of the SAE e.g. the patient hospitalised for DVT and then discharged on warfarin. The patient no longer requires hospital treatment but the pre-existing symptoms persist. **Ongoing** – The serious adverse event has not resolved at this time. This will require follow up until resolution of event. **Unknown at present** - Information is not available at the present time. Further information **must** be supplied until resolution of event. **Fatal** - Where the event is fatal details of the date of death and the cause of death **MUST** be obtained.
13.1 Fatal details	
Date of death	Provide date of death
Cause of death	Name the cause of death
Cause of death obtained from	Select where the information was obtained to support cause of death. Supporting documents* to be supplied with SAE. ***Note all supporting documentation must have all patient identifiable data removed. The documents must only be identified with the addition of the patient study ID and initials.**
14. Reporting persons	
Reporting Person	Supply full details as indicated of the person reporting the event. Please ensure contact phone number and/or email address are complete. The signature should be 'wet ink' or if electronic needs to be an approved/verifiable eSignature e.g. via Adobe Sign.

	If the reporting person is also the Principal investigator/delegated medically qualified individual. Details should be repeated across the table.
Principal investigator/delegated medically qualified individual	Supply full details as indicated. Please note the person signing this section must be either the Principal Investigator or a medically qualified individual as agreed by Sponsor to undertake this role. The person must be named and delegated the duty on the delegation of authority log. The signature should be 'wet ink' or if electronic needs to be an approved/verifiable eSignature e.g. via Adobe Sign.
15. Causality/expectedness sign off	To be signed by the delegated individual who conducted the causality/expectedness section of the reporting form.

Reporting and completion of SAEs involving investigational medicinal products must be undertaken in accordance with Sponsor SOP S-1009 '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'.