

Please reply to this email using rgosponsot@le.ac.uk and ensuring that the email trail is maintained.

Dear Study Team

Thank you for submitting the following SAE/SADE to the Research Governance Office:

Patient ID	
Centre	
Study	
Sponsor Ref	
Onset date	
Event	
Type of Report	
Date of Report	

<Delete as appropriate>

Further clarification/action is required as indicated below. Please amend/provide further information within the requested timeframe. Please be aware that where changes are made to the form after original PI signature, the PI will be required to review and resign and date the form.

Should you have any queries with regards to the request/s please feel free to contact me:

- An Initial unsigned report has been received. **Please forward a signed copy of either the initial report or where available the final report within 7 days.**
- An initial signed report has been received. **Please forward a signed follow up report within 28 days.**
- The type of report (SAE/SADE/USADE) field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'serious criteria' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'device information' field is incomplete **Please review/revise and return updated form within 7 Days**
- The 'causality assessment' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'event expectedness' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'study blinded/unblinded field' is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'relationship to protocol violation' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'action taken with regards to device' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'patient withdrawn as a result of this event' is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'outcome of the event' field is incomplete. **Please review/revise and return updated form within 7 Days**
- The 'cause of death' field is incomplete. **Please review/revise and return updated form within 7 Days**
- Please provide evidence of submission to MHRA/REC within XX days.
- Other/comment. **Return within xx days.**

<Or delete as appropriate>

We have marked this SAE/SADE/USADE as COMPLETE and no further follow-up is necessary.

Please file this acknowledgement in your site file along with a copy of the report(s). Please updated the SAE log as appropriate

Many thanks.