

Sponsor SAE Email

Dear Study Team

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

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

<Delete as appropriate>

The SAE requires amendment/further information or signature as indicated below sent to UOLSPONSOR@le.ac.uk:

- The SAE has been submitted on the incorrect form. **Please resubmit on the correct attached version XXX from within 7 days.**
- Initial unsigned report received. **A signed copy of the either in the initial report of the final report is required within 7 days.**
- An initial signed report received. **A signed follow up report is required within 28 days.**
- Serious Criteria not completed. **Return within 7 days.**
- Causality assessment incomplete. **Return within 7 days.**
- Event expectedness incomplete. **Return within 7 days**
- Relationship to study procedure incomplete. **Return within 7 days.**
- Relationship to protocol violation incomplete. **Return within 7 days.**
- Study medication information incomplete. **Return within 7 days.**
- Action taken with regards to IMP incomplete. **Return within 7 days.**
- Was patient withdrawn as a result of this event incomplete. **Return within 7 days.**
- Outcome of the event incomplete. **Return within 7 days.**
- Other/comment. **Return within X days.**

<Or delete as appropriate>

We have marked this SAE as COMPLETE and no further follow up is necessary.

Please file this acknowledgement in your site file.

Many thanks.