

SAE/SAR Query Form

Cambridge Clinical Trials Unit

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Please fax or email a completed copy of this form to the Clinical Trials Unit **within 7 days of receiving the queries.**

Grey sections for R&D Clinical Trials Unit Use only.

Query details

Field Name from SAE form:

Query details:

Query response:

Page no in SAE form:

Query resolved? Yes No

Date of Resolution: / /

Entered into PV database? Yes No

CCTU Staff Initials:

Query details

Field Name from SAE form:

Query details:

Query response:

Page no in SAE form:

Query resolved? Yes No

Date of Resolution: / /

Entered into PV database? Yes No

CCTU Staff Initials:

CTO Staff details

If you would like more guidance on either responding to a query on this form please contact the member of staff who generated the query. Please have your SAE and Query paperwork available when contacting the CCTU for assistance. **Investigator sites please contact your lead site primary contact, please do not contact the CCTU office directly unless this is arranged via your primary contact.** CCTU Direct contact details are as follows:

Staff Member Name:

Direct Tel:

Email:

Please ensure you are using the current version of this document. Please notify any changes required to the relevant QA Manager

This document is reviewed and updated in line with emerging evidence or local requirements at least every two years