Southampton Clinical Trials Unit

Instructions for Serious Adverse Event Reporting – Non-CTIMP

Use the Serious/ Adverse Event Reporting Flowchart (overleaf) to identify the actions required for each event (unless otherwise specified in the trial protocol).

- All Adverse Events relating to the trial medication should be input onto the trial database as per the trial-specific reporting requirements.
- If you are required to complete an SAE Report Form, it should be sent immediately, but certainly **within 24 hours** of you becoming aware of the event, to the SCTU. **Originals of the SAE/SUSAR form should be kept in the Investigator Site File (ISF) with only copies sent to SCTU.**

Fax: **0844 7740621**
Email: **ctu@soton.ac.uk**

New SAE

1. Download a copy of the SAE Report Form from the EXCALIBUR section of the CTU website: www.southampton.ac.uk/ctu (click on 'Trial portfolio', then 'List of trials').
2. Complete as much of the report form as possible (some sections should only be completed by the Principal Investigator (PI) or their delegate – this is indicated on the report form). Even if you are unable to complete the report in full, please still submit within the 24 hour period and send follow up information as soon as it becomes available. The SCTU will advise what is needed in terms of missing information, typically within a confirmation email.
3. Please keep the original SAE Report Form in the ISF. An emailed/faxed copy is the only copy that the SCTU need.

SAE Updates & Case Closure

- If further information is required, please update the original SAE Report Form and email/fax it to SCTU. Send all updates and additional information to SCTU as it becomes available.
- SCTU will acknowledge receipt of all updates and will advise what information is outstanding. Once SCTU have all required details, an email will be sent stating that no further information is required and that the case is closed.

Important

- If the initial report is considered a **related and unexpected SAE**, the SCTU must receive all additional information as soon as possible, but certainly within **14 days following the initial report to SCTU.** This is because **related and unexpected SAEs** must be **reported to REC within 15 days** of SCTU becoming aware of the event.
- **Report related and unexpected SAEs** via Yellow Card to the MHRA.
- All **changes** to report forms should be **initialled and dated**, ensuring that the **original entry is not obscured** (strike through with a single line; as per ICH-GCP guidelines).
- Non-serious adverse events will only be recorded if due to any medical encounters related to the following:
    - **Medication:** any events relating to study medication
- The practitioners providing care for the patient are advised to record any event for which there is uncertainty as to whether it is study related or not, and to discuss with the CI.

- A medically significant pre-existing condition (prior to informed consent) should not be reported as an AE unless the condition worsens during the trial, and this worsening is either deemed related to the trial treatment or is deemed an SAE. The condition, however, must be reported on the Medical History eCRF.

Serious/Adverse Event Reporting Flowchart – Non-CTIMP

If an Adverse Event occurs, what do I do next?

Is the event serious?

An Adverse Event is considered serious if the event:

- Results in death;
- Is life-threatening;
- Requires hospitalisation or prolongation of hospitalisation;
- Results in persistent or significant disability or incapacity;
- Consists of a congenital anomaly or birth defect; or
- Is considered medically significant by the PI/delegate.

Note : For EXCALIBUR, Hospitalisations for elective treatment of a pre-existing condition do not require reporting as an SAE

No

Record Adverse Event (AE) (if related to trial medication as specified in the protocol) electronically on the study database and follow up adverse event until resolved (if applicable).

Yes

Is the event considered related to the Shufeng Jiedu capsules?

No

SAE

Complete the EXCALIBUR SAE&SUSAR reporting form with as much detail as possible Fax or email this form to SCTU on 0844 7740621 or ctu@soton.ac.uk **immediately but at least within 24 hours**

- Follow up the event and report any additional information to the SCTU.
- File SAE originals in Investigator Site File.
- All SAEs should be recorded as a corresponding AE
- You will be prompted to complete a corresponding AE form in the study database for this event.

Yes

Is the event considered expected in reference to section 4.8 of the SmPCs listed in the protocol?

Yes

'Expected' drug related SAEs (as per the IMPD) should be reported as Adverse Events on the adverse event form on the study database

No

Related and unexpected SAE (SUSAR)

Complete the HATRIC SAE reporting form with as much detail as possible. Fax or email this form to SCTU on 0844 7740621 or ctu@soton.ac.uk **immediately but least within 24 hours**

- Follow up the event and report any additional information to the SCTU.
- File SAE original in Investigator Site File.
- All SAEs should be recorded as a corresponding AE
- You will be prompted to complete a corresponding AE form in the study database for this event.
- Report event to the MHRA via Yellow Card.

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If the event is considered a **related and unexpected SAE**, SCTU must report to REC within 15 days of becoming aware of the event.
If the event is considered a **related and unexpected SAE**, report event to the MHRA via Yellow Card.