SAE / Safety / SUSAR reporting to a Human Research Ethics Committee

Excerpts from the NHMRC Australia Health Ethics Committee (AHEC) Position Statement May 2009 annotated with requirements.

Monitoring and reporting of safety for clinical trials involving therapeutic products

Investigator / Research responsibilities

The investigator/researcher must report all SAEs to the sponsor and reviewing HREC immediately (within 24 hours) in accordance with the study protocol and GCP guidelines as adopted by the TGA.

For individual local SAEs, the Principal Investigator (PI) for the site should send correspondence directly to the reviewing HREC and to the Coordinating Principal Investigator (CPI) if applicable for a multi-centre study. It is the responsibility of the CPI to submit all other Safety Reports for HREC review in multi-centre research.

For each trial, the PI for the monitored site must provide to the Reviewing HREC:

1. SAEs occurring at the site (via Qld Health reporting template) in addition to reporting to sponsor and CPI for multi-centre research; and
2. Information that:
    a. materially impacts the continued ethical acceptability of the trial or
    b. requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the investigator(s) or sponsor

    A justification or opinion should be given to explain this view.

Site specific required information / investigator / sponsor opinion for annual or other summary safety reports, SUSARs and Investigator Brochures:

- for each, include sponsor and also investigator commentary as to whether action is planned for the trial on the basis of the reports;
- for trials that are sponsored by investigator(s) or a collaborative group of clinicians and in which an Investigator Brochure (IB), European Union Annual Safety Report (EU ASR) or Product Information (PI) is unavailable, then a trial update may be submitted that provides appropriate review of safety information in the previous 12 months;
- when sponsors forward safety information to the investigator, sponsors should include clear advice as to whether the information requires, or indicates the need for, a change in the trial protocol including changed safety monitoring;

- to enable investigators to fulfil their responsibilities to institutions, sponsors need to respond to requests from investigators for clarification of such advice or information;
- when investigators report this information to the institution they should provide their own opinion in regard to potential impact on ethical acceptability and need for action;
- the timing of Annual Safety Report (ASR) production by sponsors and the progress report to the ethics committee by an investigator does not need to be simultaneous.

3. Every six-months - listing of all SUSARs, Australian and international, occurring with a compound:
    a. including sponsor and investigator comment as to whether action is planned for the trial on the basis of the reports;
    b. EU format is acceptable.
4. At least annually an updated Investigator Brochure (IB), or
    a. an European Union Annual Safety report (EU ASR) (or similar format report), or
    b. current, approved Product Information (PI), if appropriate (eg in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained);
    c. other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA).

NHMRC Position Statement: http://www.nhmrc.gov.au/guidelines-publications/e112

Central Coordinating Service: https://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp

HMR For Researchers: https://www.health.qld.gov.au/ohmr/html/regu/for_researcher.asp

For further information, please use the contact details below:

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