Routemap

Urgent Safety Measures

Recruitment Phase

Urgent Safety Measures follows the Addition of New Sites & Investigators station and precedes the Temporary Halt station. This process occurs in parallel with Safety Reporting, Progress Reporting, Ongoing Management & Monitoring, and GCP & Serious Breach Reporting. It also has the potential to occur simultaneously with an MHRA Inspection, Audit, Substantial Amendments, Addition of New Sites & Investigators, Temporary Halt, and Early Termination. Urgent Safety Measures are a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

The Clinical Trials Regulations make provision for the sponsor and investigator to take appropriate Urgent Safety Measures (USMs) to protect a research participant from an immediate hazard to their health and safety. This measure can be taken before seeking approval from the competent authorities (MHRA in the UK) and ethics committees of all member states concerned.

Any urgent safety measure relating to a CTIMP should be communicated to the MHRA immediately. Sponsors should phone the MHRA Clinical Trial Unit within 24 hours to discuss the event with a medical assessor. The sponsor must then follow-up with notification in writing within three days* of the action being taken. The notification should be in the form of a substantial amendment and should describe the event, the measures taken and justification for the measures taken. Further details can be found on the MHRA webpage.

For trials that have used the combined review process, additional requirements are detailed on the MHRA webpage. The Step by step guide to using IRAS for combined review also provides information in the Reporting section.

The main research ethics committee (REC) must be notified immediately and in any event within three days, that such measures have been taken and the reasons why. NHS R&D offices will require notification in accordance with local policies/procedures.

Where applicable, oversight committees (such as the Data Monitoring Committee) should review information relating to urgent safety measures and report any recommendations to all relevant parties.

If the Principal Investigator (and not the sponsor) has instigated the USM, the sponsor should be notified immediately so that they can assess and report the USM within the timelines required.

For non-CTIMP research, the Chief Investigator must notify the main REC immediately of any USMs and in any event within three days. NHS R&D offices will also require notification in accordance with local policies/procedures.

The funder should be updated on all developments and actions as soon as possible.