Routemap

Safety Reporting

Recruitment Phase

Safety Reporting follows the GCP & Serious Breach Reporting Station and precedes the Progress Reporting station. This process occurs in parallel with 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, Urgent Safety Measures, Temporary Halt, and Early Termination. Safety Reporting is a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

Sponsor Responsibilities

The sponsor is responsible for the ongoing safety evaluation of the Investigational Medicinal Product(s) used in a Clinical Trial of Investigational Medicinal Products (CTIMPs). Part 5 of the Medicines for Human Use (Clinical Trials) Regulations (SI 1031) as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019) that defines the sponsor's responsibilities for safety reporting following the UK's exit from the European Union.

Sponsors should develop formal, written processes for the management of adverse events and safety reports, including the handling of both expedited reports and annual safety reporting.

Expedited Safety Reporting

A clinical-trial sponsor must report all UK-relevant suspected, unexpected, serious, adverse reactions (SUSARs) that occur during a clinical trial and the MHRA has published guidance on submitting clinical trials safety reports. Sponsors may use the current eSUSAR portal to submit single SUSAR reports. Sponsors may register to either the ICSR Submissions portal (which replaces the Eudravigilance website (EVWEB)) or the MHRA Gateway (which replaces the Eudravigilance Gateway) to submit SUSAR reports in bulk). Further information, including reporting timelines, can be found on the MHRA webpages). Information on how to send safety reports to the ethics committee can be found on the HRA website.

Annual Safety Reporting

The annual safety report sent to the MHRA depends on the type of CTIMP.

- Trials with a Clinical Trial Authorisation will need to complete a Development Safety Update Report (DSUR) as outlined in the ICH E2F Guidelines.
- Trials approved under the Clinical Trial Notification Scheme (see CTA Station) can submit a shortened DSUR.

The MHRA provides further guidance for submitting DSURs and shortened DSURs.

Investigator Responsibilities

The MHRA GCP Guide provides comprehensive guidance on the safety reporting responsibilities of the Principal Investigator. A Safety Reporting flowchart (pdf, 129.26 KB) has been developed giving an overview of the expedited safety reporting requirements to the sponsor for a UK open label trial.

For non-CTIMP research, safety reporting requirements are described on the HRA web pages.

Further reading:

- Pharmacovigilance station.