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.

Safety Reporting

The sponsor is responsible for the ongoing safety evaluation of a trial. Sponsors should establish formal, written procedures for managing adverse events and other safety reports, including handling both expedited reports and periodic safety reporting.

For Clinical Trials of Investigational Medicinal Products, the amended Clinical Trials Regulations require sponsors to:

- Keeping detailed records of adverse events reported by investigator(s) and continuously assessing the trial’s risk-benefit balance, usually through aggregate analyses of accumulating safety data.

- Reporting suspected unexpected serious adverse reactions (SUSARs) to the MHRA as follows:
- Fatal and life-threatening SUSARs no later than 7 days after the sponsor was first aware of the reaction.
- All other SUSARs within the time period specified in the protocol.
- Reporting Urgent Safety Measures to the Medicines and Healthcare products Regulatory Agency (MHRA) and the Research Ethics Committee as soon as possible, and no later than 7 days from the date the measures are taken.
- Sending an annual safety report (Development Safety Update Report) to the MHRA.

For combined IMP/medical device trials, the sponsor must also comply with the safety reporting requirements outlined in ISO 14155 (2026). The MHRA provides guidance on reporting requirements.

Safety Reporting: NIMPs

The amended Clinical Trials Regulations define a NIMP as: *A medicinal product used in a clinical trial as described in the protocol, but not as an IMP*. Examples include challenge agents, rescue medications, or background treatments. The MHRA has published guidance on using NIMPs in clinical trials, including safety reporting in relation to NIMPs.

Investigator Responsibilities

Investigator responsibilities for reporting adverse events (AEs) and serious adverse events (SAEs) are detailed on the MHRA website, and a Safety Reporting Flowchart (pdf, 129.26 KB) provides an overview of the expedited safety reporting requirements to the sponsor for a UK open-label trial.

Selective Safety Data Collection

The ICH E6 (R3) Guidelines permit selective safety reporting by referencing ICH E19, which provides guidance on when a targeted approach to safety data collection is acceptable in certain late-stage pre-marketing or post-marketing studies and on how to implement it.

Non-CTIMPs

The HRA has published guidance on safety reporting, including the reporting of non- CTIMPs safety events, reporting timelines and a procedural table.

Further Reading

- Pharmacovigilance station.
- ICH E2F Guidelines (.PDF): Reporting of DSURs
- HRA: Safety and progress reports (CTIMPs) procedural table.
- MHRA: Transitional arrangements for pharmacovigilance.