Routemap

Pharmacovigilance

Trial Planning Phase

The Pharmacovigilance station follows the Trial Supplies station and precedes the R&D Consultation station. Pharmacovigilance is a legal requirement and is specific for trials within the Clinical Trial Regulations scope. This station is part of the 'trial planning phase' group of stations.

Pharmacovigilance (PV) is the science relating to the detection, assessment, understanding and prevention of the adverse effects of medicines. Systems must be in place to enable the identification, recording, reporting and analysis of safety information so that any safety signals that arise during a trial are quickly identified and acted upon.

For Clinical Trials of Investigational Medicinal Products (CTIMPs), the sponsor's responsibilities for PV are outlined in Part 5 of the Clinical Trial Regulations). The terminology associated with PV is based on the assessment of seriousness, causality and expectedness of an adverse event. An Adverse Event flowchart (pdf, 180.98 KB) has been developed as part of the Toolkit to provide an overview of the assessments required.

Safety Reporting

The MHRA website provides guidance on reporting safety issues including the expedited reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) and Urgent Safety Measures (USMs) and the periodic reporting of

Developmental Safety Update Reports (DSURs).

The Investigational Site

For all trials, the investigator should make all staff aware of any safety reporting requirements and have systems to ensure all relevant events are detected, recorded and notified in accordance with the protocol (see Safety Reporting station).

Staff should be made aware of these requirements through GCP training and/or knowledge of local procedures or policies.

Further reading & Workstream Documents:

- Safety Reporting station: Outlines the safety reporting requirements once a trial has commenced
- Trial Supplies station: For information on requirements for the Investigators Brochure
- The MHRA Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (.PDF): Appendix 1, Section 4 - Risk adaptation relating to safety surveillance.