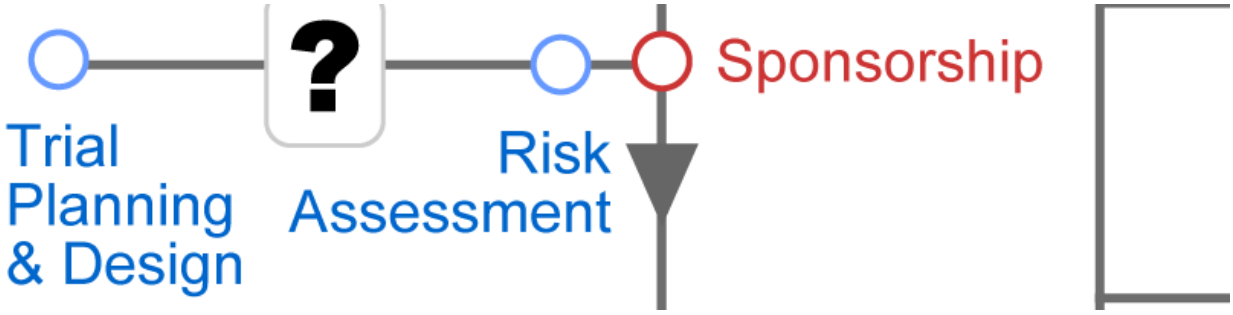
Routemap

Risk Assessment



Trial Planning Phase

The Risk Assessment station follows the Trial Planning and Design station, and confirming whether a trial falls within the scope of the Clinical Trial Regulations. Risk Assessment is good practice and is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Some host organisations may not be in a position to undertake the role of sponsor for Clinical Trials of Investigational Medicinal Products (CTIMPs) or may only sponsor trials of a certain risk level. It is essential therefore that they are involved at an early stage and that a risk assessment is undertaken at the very start. The process could be defined such that the risk assessment is undertaken on the research proposal and then further refined once the protocol has been drafted.

Risk Adaptation

The MHRA have implemented a scheme for defining the risks associated with each clinical trial by adopting a dual strategy:

1. Defining the risks of the IMP using a simple IMP risk categorisation (Type A,B and C) based on marketing status and standard medical care
2. Defining the risks associated with trial conduct by examining the trial design, population and procedures to identify specific areas of vulnerability and to determine how any risks can be mitigated.

The Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (.PDF) has been published as part of the MHRA Good Clinical Practice Forum to help sponsors undertake this process.

The MHRA web site gives further information with a 'Frequently Asked Questions' thread on the MHRA GCP forum relating to risk adaptation.

Further reading & Workstream Documents:

- Sponsorship station.
- Trials Management & Monitoring station.
- Joint Project Pharmacovigilance Document (pdf, 344.05 KB).
- Trials Supplies station.