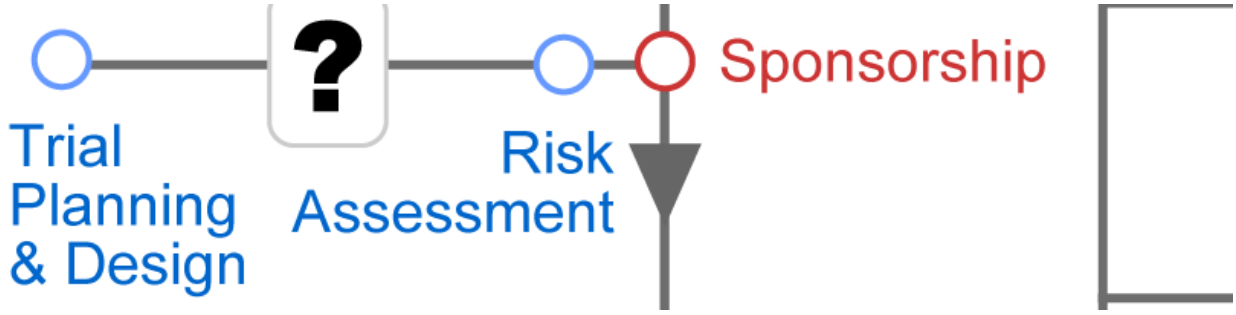
Risk Assessment



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.

Risk Assessment

Some organisations may not be equipped to undertake the role of sponsor for Clinical Trials of Investigational Medicinal Products (CTIMPs) or may choose to sponsor only trials below a specific risk threshold. Many sponsors will expect a risk assessment to be conducted at the outset. This process can be organised so that an initial risk assessment is carried out on the research proposal, further refined once the protocol has been developed and amended if new risks are identified as the trial progresses.

For CTIMPs, the Risk-Adapted Approaches to the Management of CTIMPs provides a framework for defining and managing the risks associated with the trial. This process of risk assessment includes:

- Categorising the IMP’s risks into three levels (Type A, B, and C) based on its marketing status and alignment with standard medical care.
- Assessing the risks related to trial design, study population, and procedures to identify areas of vulnerability and determine appropriate risk mitigation

strategies.

The risk assessment should focus on identifying and mitigating risks that threaten a trial's critical-to-quality factors, as described in resources provided by the Clinical Trials Transformation Initiative (CTTI).

Risk Assessment Examples and Forms

Examples of Type A, B, and C trials, along with their corresponding risk assessment forms, are available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

New Clinical Trials Regulations

On 28 April 2026, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations (SI 2025/538) will come into force, introducing risk-adapted approaches for certain lower-risk trials.

The Health Research Authority (HRA) has published guidance to help prepare for these upcoming changes. The MHRA has also published guidance on the new Regulations setting out certain requirements that should be followed before 28 April 2026, and those that will take effect from 28 April 2026 onwards.

Further Reading

- MHRA-Accredited Phase 1 Units (.PDF): Units accredited under the MHRA Phase 1 Accreditation Scheme with standards that exceed the basic regulatory GCP standards to mitigate the risk of harm.
- Sponsorship station.
- Trials Management & Monitoring station.
- Trials Supplies station.