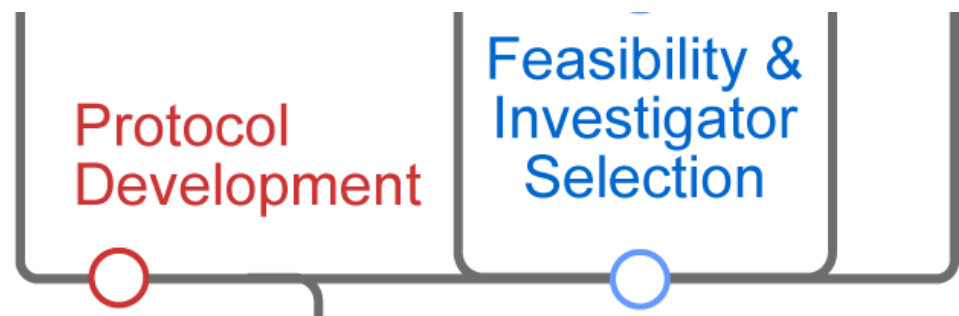


Protocol Development



Trial Planning Phase

The Protocol Development station follows the Sponsorship station and takes place in a parallel process with R&D Consultation, the Funding Proposal, and Peer Review. Protocol Development precedes the Trial Management & Monitoring station. Protocol Development is a legal requirement which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Protocol Development

A protocol is defined in the [amended Clinical Trial Regulations](#) as a *document that describes the objectives, design, methodology, statistical considerations, and organisation of a clinical trial*. The protocol sets out the background and rationale for the study, as well as the detailed study plan.

Protocols should be clear, concise, operationally feasible, and designed to avoid unnecessary complexity. High-quality protocols support the effective conduct, oversight, reporting, and external review of trials.

Involving the public in protocol design can help improve the quality and relevance of a trial by ensuring it considers the needs of participants. [The Health Research Authority \(HRA\)](#) and the [National Institute for Health and Care Research \(NIHR\)](#) have published guidance to support meaningful public involvement in research.

Protocols should outline all operational and ethical trial considerations, including a [definition of the end of study](#) and details on [post-research care](#). As a controlled

document, each protocol should have a version number and date to ensure traceability.

The HRA provides [guidance](#) and a [protocol template](#), now updated to reflect the amended Clinical Trials Regulations. Use of the HRA template is not mandatory, but it covers all key elements typically reviewed by regulatory and ethics bodies to help minimise delays during the review process.

In England, the [NIHR Research Support Service](#) assists non-commercial researchers in developing high-quality protocols.

Non-CTIMPs

For non-CTIMPs, [the SPIRIT template](#) provides a structure for non-CTIMP trials.

Further Reading

- [ICH E8 \(R1\) \(.PDF\)](#): General Considerations for Clinical Studies.
- [COMET database](#): Information on published and ongoing core outcome sets for clinical trials.
- [DIRUM](#): An open-access database of resource-use questionnaires for trial-based. economic evaluations.
- [Modifications](#) station
- [Final Protocol](#) station.