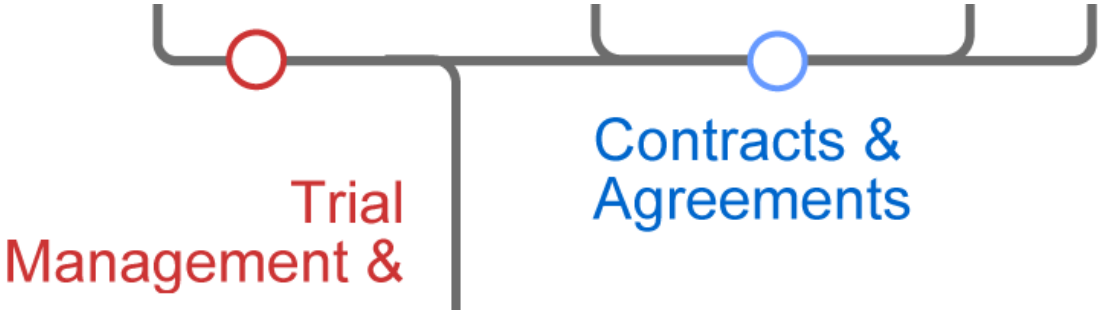
Routemap

Contracts & Agreements



Trial Planning Phase

Contracts & Agreements follows the Feasibility & Investigator Selection station and precedes the Final Protocol station. This process occurs in parallel with Funding Secured, Trial Master File, Trial Registration, and Confirm Sponsor. Contracts & Agreements is good practice and is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Many parties may be involved in the conduct and management of a clinical trial and it is important that each party has a clear reference of what is expected of them.

Contracts and agreements should be in place prior to the initiation of any trial and should be subject to periodic review to ensure that they remain up to date and relevant.

The content of contracts and agreements should include:

- The standards that are applicable (for Clinical Trials of Investigational Medicinal Product (CTIMPs) this would include the Clinical Trials Regulations)
- The roles and responsibilities of various parties
- The procedures to be undertaken
- The lines of communication.

Contracts and agreements can be formed at many levels; internal or external and both legal or non-legal. Examples include but are not limited to:

- Co-Sponsorship Agreements (defining the legal responsibilities taken on by parties under the Clinical Trials Regulations)
- Funding Agreements (terms and conditions related to any funding granted)
- Clinical Trial Agreement/Site Agreements (see UKCRC web pages and NIHR web pages)
- Collaboration Agreements
- Intellectual property Agreements
- Commercialisation Agreements
- Service Level Agreements (with external suppliers such as central laboratories, external statisticians)
- Material Transfer Agreements (handling requirements for material, such as tissue samples, transferred from one organisation to another)
- Pharmacy Technical Agreements (to cover processes applied to the IMP such as packaging, manufacture and radiolabelling) - See Trial Supplies station.

For non-commercial trials conducted in the UK, the Organisation Information Document may be used as the agreements between the sponsor and a participating for non-commercial research projects. This can be found on the HRA website.

At the site level, the roles and responsibilities of the Chief investigator, particularly if they are delegated sponsor tasks, should be documented and agreed (see Sponsorship station).