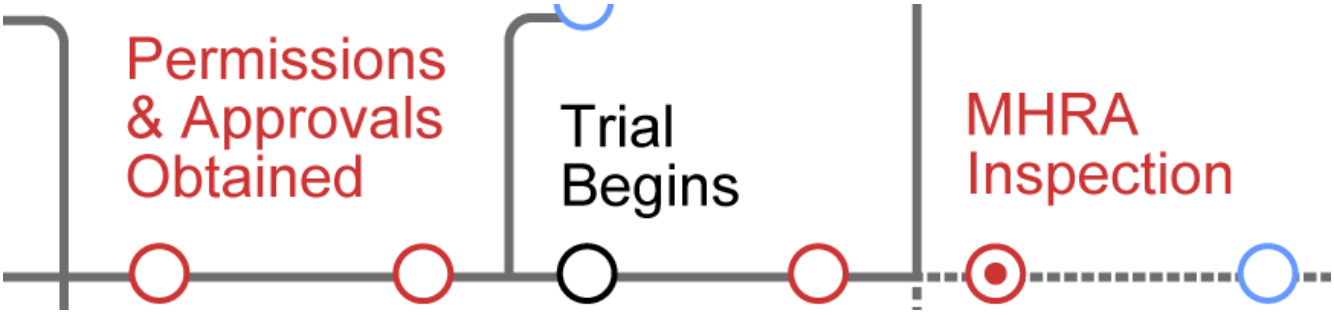
Routemap

Trial Begins



Trial Recruitment Phase

The Trial Begins station follows the Final Trial Management Documentation process. It occurs in the routemap after the Trial is Abandoned station to show that this step is considered before the trial commences. The Trial Begins station precedes the Informed Consent station and is a standard process which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

Once all of the relevant approvals are in place, all documentation has been finalised, and all participating sites have the information they need, the trial can begin.

This process is often achieved by a holding start-up meeting at each site (site visit or teleconference). The Chief Investigator is then able to satisfy him/herself that all technical aspects of a trial and protocol requirements are fully understood by all relevant site staff. Trial specific training (protocol and trial-specific procedures) as well as training on aspects of trial conduct such as Case Report Form (CRF) completion and safety reporting requirements is often undertaken at this stage. The site also has an opportunity to ask questions and clarify misunderstandings.

For Clinical Trials of Investigational Medicinal Products (CTIMPs), this communication should also include pharmacy (where applicable) so that they can confirm that all requirements are in place before dispensing Investigational Medicinal Products (IMPs) to subjects (see Trial Supplies station).

Generally, there is an expectation that a trial should start (recruitment activities) within a specified time period. For example, the ethics committee will assume that the research will commence within 12 months of the date of favourable ethical opinion and may review its opinion if the trial does not start with 24 months of receipt of the final opinion letter.