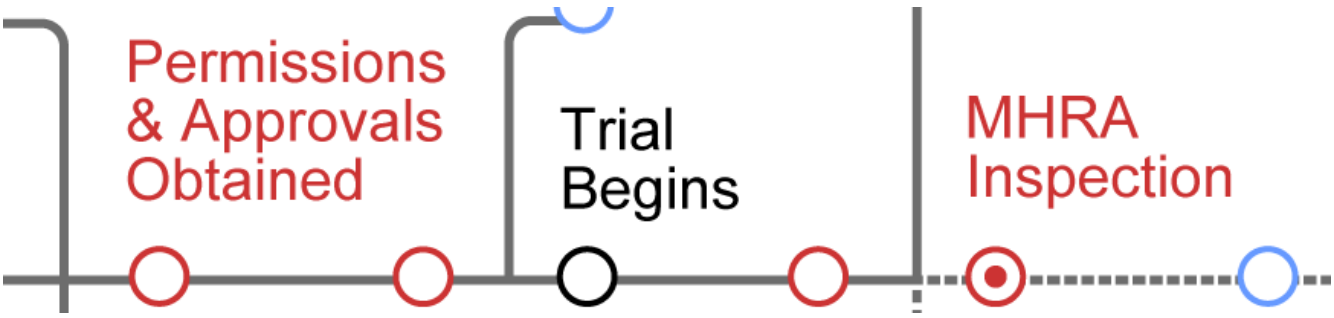
Trial Begins



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.

Trial Begins

Once all 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 through a start-up meeting at each site. During this meeting, the Chief Investigator confirms that site staff fully understand all technical aspects of the trial and protocol requirements relevant to their role. Trial-specific training is often undertaken, for example, covering the protocol, trial procedures, case report form completion, and safety and serious breach reporting requirements. These meetings also provide the opportunity for site staff to ask questions and clarify any misunderstandings.

For Clinical Trials of Investigational Medicinal Products (CTIMPs), this communication should include the pharmacy team to confirm that all requirements are met before dispensing IMP to participants (see Trial Supplies station).

The amended Clinical Trials Regulations require that trials that fail to recruit a single participant within two years of opening either close the trial or request an extension, which the Medicines and Healthcare products Regulatory Agency (MHRA) may grant if justified.

Non-CTIMPs

The HRA has published guidance which includes the requirement for commencing research and actions taken should a trial not commence within 12 months.