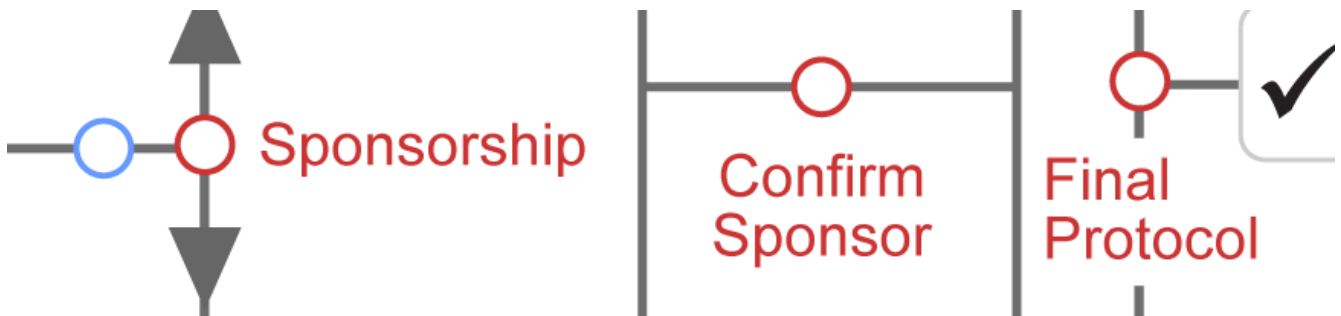


Confirm Sponsor



Trial Planning Phase

The Confirm Sponsor station follows the Trial Registration station and precedes the Feasibility & Investigator Selection station. This process occurs in parallel with Funding Secured, Trial Master File, Trial Registration, and Contract & Agreements. Confirming the Sponsor is a legal requirement which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

For UK trials, the Chief Investigator will approach a potential sponsor (often through a formal registration process) who will assess the operational risk the trial poses before confirming sponsorship. For NHS sponsors, this is usually performed by the NHS R&D office of that organisation. Sponsorship will only be granted once any issues raised by the risk assessment have been addressed. The sponsorship letter should be retained in the Trial Master File.

The sponsor's signature is required on both the application for ethical approval and for MHRA authorisation.

Other parties, including trial funders and host organisations conducting the trial will also require documented assurance that an organisation has accepted the role of sponsor and the obligations and responsibilities of this role.