

Trial Registration



Trial Planning Phase

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

Trial Registration

Registering clinical trials in a public registry promotes transparency and accountability in research. It helps prevent selective reporting and enables the public, participants, and researchers to access information about the study's purpose, design, and outcomes.

The [amended Clinical Trial Regulations](#) mandate the registration of a trial on a public registry, while providing deferrals that permit only a minimal record of the trial to be published. The [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) and the [Health Research Authority \(HRA\)](#) provide further guidance.

To promote transparency, the National Institute for Health and Care Research (NIHR) has developed [a policy](#) on clinical trial registration and the disclosure of results.

Trial registration is also a condition for a favourable ethics opinion, unless a deferral of registration has been granted, which includes [automatic deferrals for all Phase I trials](#). Many publishers, including the International Committee of Medical Journal Editors (ICMJE), require registration as a precondition for publication.

The requirements sponsors and researchers must meet depend on the status of their study, and this [HRA Blog](#) provides information on the transitional arrangements for trial registration.

Automatic Registration

All Clinical Trials of Investigational Medicinal Products (CTIMPs) and combined trials of an investigational medicinal product and an investigational medical device, submitted for combined review in the new part of IRAS, are automatically registered* on the ISRCTN Registry. Further information, including guidance for deferring registration, is available on the [HRA](#) and the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) websites.

* Unless the HRA is notified that the trial will be registered on a publicly accessible registry on the [World Health Organisation](#) list of primary registries or the [International Committee of Medical Journal Editors](#) list of public registries.

Non-CTIMPs

The HRA has published [guidance](#) for non- CTIMP trials, which includes the requirement for trial registration.

Further Reading

- [HRA](#): Make it Public: transparency and openness in health and social care research
- [ISRCTN](#): Guidance for applicants using the deferral process for registration of UK Phase I clinical trials in ISRCTN.
- [MHRA](#): Transitional arrangement for transparency regulations.