Routemap

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:

Each clinical trial must have a unique trial number and be registered on a publicly accessible database. Trial registration helps researchers fulfil research transparency and result dissemination requirements and is a condition of favourable ethics opinion (unless a deferral of registration (.PDF) has been granted). Many publishers, including the International Committee of Medical Journal Editors (ICMJE), require registration as a pre-condition of publication.

Since 1 January 2022, 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 ISRCTN Registry. Further information, including information on registration of other types of clinical trial and also deferral of registration, can be found on the HRA website and the MHRA website.

* Unless the HRA are informed that the trial has/will be registered on ClinicalTrials.gov or other registry.

CTIMPs that have sites in the European Union (EU), the European Economic Area (EEA) or Northern Ireland (and outside these areas if they are part of a Paediatric Investigation Plan) should also apply for a EudraCT number.

Further reading:

- Ethics Submission station
- Clinical Trial Authorisation Submission station
- Step by step guide to using IRAS for combined review
- EudraCT & EU CTR frequently asked questions (.PDF)