Routemap

Download Print document

Routemap

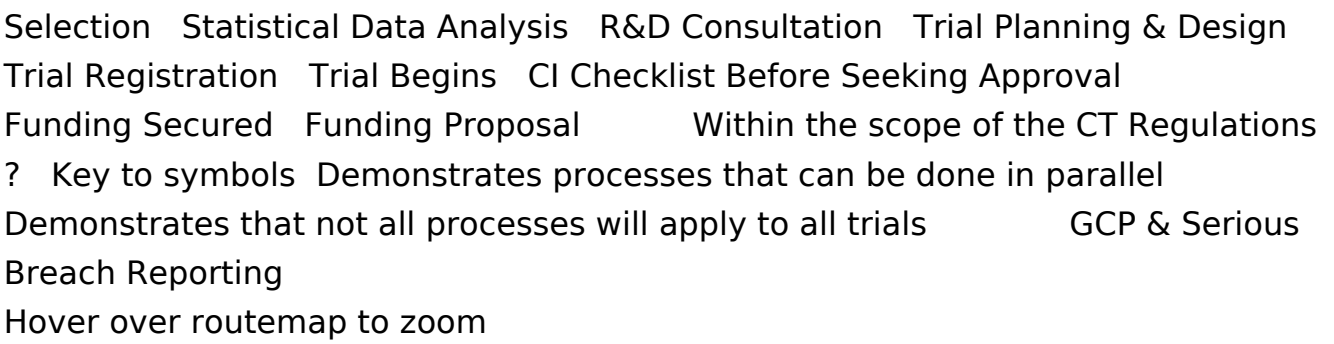
The Clinical Trials Toolkit is an interactive colour-coded routemap* to help navigate through the legal and good practice arrangements surrounding setting up and managing a Clinical Trial of an Investigational Medicinal Product (CTIMP). The routemap distinguishes between legal and good practice requirements, and indicates which aspects of these are relevant to wider clinical research in general. It includes an overview of trial practices, along with more detailed information available at 'stations' along the route.

**Mobile users will be able to access the stations from the list shown*

Download a copy of the Clinical Trials Toolkit routemap (pdf, 221.33 KB) (.PDF).

Skip the Routemap image and continue reading

Randomised Controlled Trials Qualitative and mixed methods studies Technology Assessment Reports Pilot and Feasibility Studies Economic Evaluations References Reporting guidelines PGfAR Dual publication Forms Permissions Copyright Abstract Scientific summary Plain English summary Report submission Evidence Synthesis/ Systematic Reviews Editorial review process Step by step guide to obtaining permissions Editorial policies Editorial review timescales Production process Dissemination Open access Production timescale Publication ethics End of Trial Declaration Safety Reporting MHRA Inspection Substantial Amendments Final Trial Management Documentation Archiving Ongoing Management & Monitoring Urgent Safety Measures Temporary Halt Early Termination CTA Submission Ethics Submission Informed Consent Permissions & Approvals Obtained R&D Submission Trial Master File Confirm Sponsor Sponsorship Protocol Development Trial Management & Monitoring Trial Supplies Pharmacovigilance Trial Documentation Final Protocol
Addition of New Sites & Investigators Risk Assessment Peer Review Audit Trial is abandoned Dissemination of Results Clinical Trial Summary Report Progress Reporting IRAS Contracts & Agreements Feasibility & Investigator



Getting started with the Routemap

The Clinical Trials Toolkit is designed to help understand the requirements of the UK Medicines for Human Use (Clinical Trials) Regulations, which together with its amendments, are referred to as the **Clinical Trial Regulations** within this Toolkit.

Users should note the following features;

- The positioning of the stations (from left to right on the routemap or from top to bottom on the station list) gives an indication of the critical path and process flow.
- Activities that may be undertaken in parallel are indicated on the routemap and explained within each station.
- By clicking on a station, you will be taken to a description of the process and a list of relevant resources and/or related stations.
- Station symbols can either apply to trials covered by the CT Regulations, or apply to all trials (please see the key to symbols).
- Where a station includes statutory requirements for CTIMPs, (even if the requirement is not a general legal requirement for non-CTIMPs) the station, by default, will be identified as a legal requirement.
- In many cases, good practice requirements may be considered mandatory even if the requirement does not have statutory force (e.g. by Funders or the NHS).
- Stations are grouped into four categories: Planning, Approval, Recruitment, and Close Out.

Before using the routemap, take time to think about your trial and its setting. Consider the following:

- **The research question**
  The nature of the intervention will determine whether the trial is subject to the regulations. The routemap contains advice on management

arrangements for different kinds of trial.

- **Where you are in the trial process**
  The key stages of the trial process are identified as 'stations'. By selecting a station you will find one or more 'resources'. The resources provide advice and links to other useful websites and resources.
- **The expertise of your trials team and organisation**
  Some resources within the Toolkit address the needs of trialists, whilst others are of particular interest to those involved with R&D management. Using the resources may reveal gaps in the capacity of your trials team or organisation to support trials to the required standards. Organisations vary considerably in how they approach their responsibilities to support high quality clinical trials.
- **The importance of Patient and Public Involvement**
  Consider how best to involve members of the public in your work. See NIHR's briefing notes for researchers.

PPI guidance for Chief Investigators of UK surgical trials has been developed from the 'Patient and public involvement Intervention to enhance Recruitment and Retention in Surgical Trials' (PIRRIST) project.

Trials that began before 1 May 2004

The Medicines for Human Use (Clinical Trials) Regulations came into force on 1 May 2004. Any trials initiated before this date (i.e. trials which had a Clinical Trial Certificate (CTC) or Clinical Trial Exemption (CTX) or which had been notified under the Doctors and Dentists Exemption (DDX) scheme) and that were ongoing after 1 May 2004 were required to ensure that systems were put in place to comply with these regulations.

The MRC/DH Joint Project produced a Checklist for Ongoing Trials in 2004 which helped sponsors identify any immediate actions to be taken in relation to their trials. The MHRA also published advice on amendments or end of trial declarations for clinical trials that were originally CTX/DDX/CTC applications.