

# Routemap

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## 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  
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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

Selection   Statistical Data Analysis   R&D Consultation   Trial Planning & Design  
Trial Registration   Trial Begins   CI Checklist Before Seeking Approval  
Funding Secured   Funding Proposal   Within the scope of the CT Regulations  
?   Key to symbols   Demonstrates processes that can be done in parallel  
Demonstrates that not all processes will apply to all trials   GCP & Serious  
Breach Reporting  
Hover over routemap to zoom

## 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](#).