

## Clinical Trials Toolkit

### What is it?

The Clinical Trials Toolkit is an innovative website designed to help navigate through the complex landscape of setting up and managing clinical trials. This interactive online resource describes current regulatory and good practice requirements and processes in clinical trials including:

- Trial planning and documentation
- Regulatory advice
- Pharmacovigilance
- Safety reporting
- Inspection and audit
- Protocol amendment
- Analysis, reporting and dissemination.

This resource was developed by the NIHR, with support and assistance from the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA).

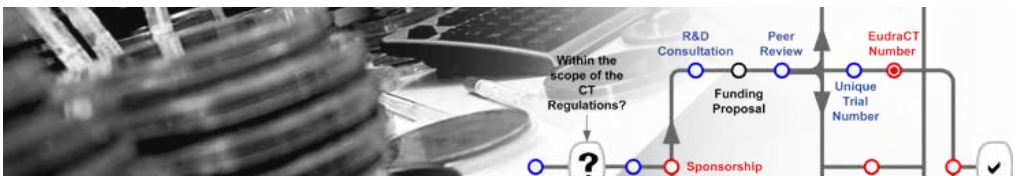
### How does it work?

Based on the design of a tube map, the Clinical Trials Toolkit uses an interactive colour-coded routemap to differentiate between legal and good practice requirements. It provides essential information at the 'stations' along the route and gives the users an idea of the critical path for trial set-up and delivery.

The design and format of the website allows users to quickly access their areas of interest and to dip in and out. It also provides easy access to templates, key documents and a glossary.

### Who is it for?

This resource is primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs). However, the Clinical Trials Toolkit may also benefit researchers and R&D staff working on trials in other areas, as useful information and guidance relevant to the wider trials environment is also available.



To find out more visit  
[www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk)