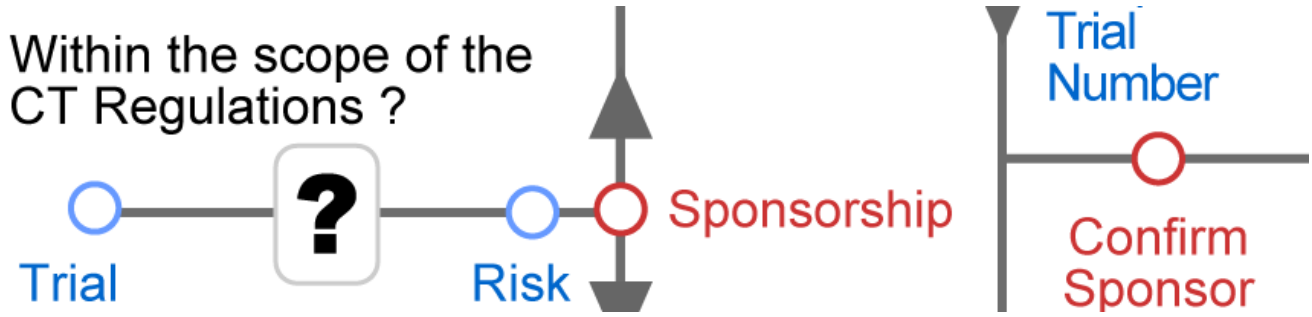
Routemap

Within the scope of the Clinical Trial Regulations?



Trial Planning Phase

Confirming whether a trial falls **within the scope of the Clinical Trial Regulations** sits between the Trial Planning and Design station and the Risk Assessment station. This is a standard process and this station is part of the 'trial planning phase' group of stations.

The Medicines and Healthcare Regulatory Agency (MHRA) is the competent authority that regulates CTIMPs in the UK. Before a trial can begin, it is important to confirm whether it falls within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004, which together with its amendments, are referred to as the **Clinical Trial Regulations** within this Toolkit. The MHRA has produced an algorithm (PDF) (.PDF) to help researchers determine whether their trial is a CTIMP.

Researchers planning a CTIMP should be familiar with the MHRA Clinical Trials Pages to help ensure all legal requirements are considered.

Brexit Transition

The European Directive (2001/20/EC) (PDF, 152 KB) no longer applies in the UK. The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 to enable

the MHRA to operate as a regulator outside the EU.

The MHRA has published new guidance for clinical trials for organisations to follow.