# CT12 How to Conduct Clinical Research Under the EU Clinical Trials Regulation

**Approximate study time:** 1 hour

**Level:** Introductory/intermediate

**Audience:** Regulatory affairs professionals, clinical development staff, healthcare professionals

**Category:** Clinical, Regulatory affairs

**Region:** Europe

**CPD Points:** 1

**Module outline**
- Substantial modifications
- Adding an MSC
- Notifications
- Notices, alerts, and RFIs
- Ad hoc assessments
- Corrective measures
- Reporting adverse events
- Reporting SUSARs
- Annual safety report
- Submitting trial results
- Assessment

The European Union (EU) Clinical Trials Regulation ensures that the rules for assessing clinical trial applications and for conducting clinical trials are identical throughout the European Economic Area (EEA). It establishes a harmonised procedure for gaining and maintaining authorisation for trials on the basis of a single electronic application per trial, and subsequent interactions, via a single EU online information system. Member states concerned in a trial (MSCs) collaborate on, and coordinate, its evaluation and supervision. The Regulation also mandates greater transparency of information on trials. The Regulation applies from 31 January 2022 and, after a grace period of one year, sponsors of all new clinical trials in the EEA must comply with it.

This course describes the requirements that must be met by, and options available to, the sponsor during the conduct of an authorised clinical trial. It identifies the various interactions with MSCs that occur via the Clinical Trials Information System (CTIS), and it summarises and links to the extensive guidance available from the European Commission and the European Medicines Agency. Its companion course CT11 sets out the European legal and regulatory context for clinical trials and describes how to apply via the CTIS for authorisation to conduct trials. The two courses therefore provide an ideal foundation for understanding and complying with the new law.

## Who will benefit from this module?

Regulatory affairs professionals, clinical development staff, and healthcare professionals who sponsor or participate in clinical trials will benefit from this module.

## Learning objectives

- Access the relevant information on the Clinical Trials Regulation's requirements for good clinical practice, product manufacture and importation, and product labelling
- Identify the types of change that can be made to a clinical trial under the Regulation
- Describe how to apply for authorisation of a substantial modification to a trial
- Outline how to extend a trial to an additional member state of the EEA
- Identify the types of interactions between sponsor and MSCs that are possible via the Clinical Trials Information System in the management of a trial, and describe circumstances in which the sponsor must respond to requests for information
- Specify requirements for safety reporting
- Specify requirements for reporting of trial results