

## Course Overview

Clinical trials regulation affects everyone involved in designing, conducting, and overseeing clinical studies in the EU. This practical course helps learners understand the European Clinical Trials Regulation (CTR) and how to ensure compliance throughout a trial's lifecycle, without assuming prior regulatory expertise.

The course covers core topics such as trial authorisation, safety reporting, transparency obligations, ethics and participant protection, regulatory oversight, TMF management, and end-of-trial responsibilities. Realistic examples are used to show how trials are conducted in practice and how adherence to the CTR supports participant safety and regulatory compliance. Suitable for sponsors, investigators, and service providers, this course builds the knowledge and skills needed to run clinical trials confidently and responsibly under the CTR framework.

### Module One:

- Background, Purpose & Scope
- Overview of the Main Changes Introduced by the CTR
- Key Definitions and Classification of Clinical Trials
- Good Clinical Practice E6(R3) and its Relationship with the CTR
- Clinical Trial Authorisation and the CTIS
- Management of Substantial Modifications
- Pharmacovigilance and Safety Reporting
- Transparency, Disclosure, and Public Access to Clinical Trial Information
- Transitioning Legacy Trials to CTR Before April 28th 2026
- Old Rules vs New Rules After 28 April 2026

### Module Two:

- Ethics, Consent, and Participant Protection Requirements
- Investigational, Auxiliary and Other Products in Clinical Trials
- Regulatory Oversight, Inspections, and Compliance Expectations
- Data Protection and GDPR Considerations in Clinical Trials
- Roles and Responsibilities Under the CTR
- Trial Master File (TMF) and Record Retention
- Risk-Based Quality Management and Monitoring
- Service Provider Oversight and Delegated Activities
- Protocol
- End of Trial, Early Termination, and Results Reporting Obligations

**Duration:** Approx. 2 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.

