

Implementing Good Clinical Practice E6(R3) Annex 2

£49

Course Overview

This online training course provides a practical introduction to the final ICH E6(R3) Annex 2 Guideline, adopted on 03 June 2026. It is designed for clinical research professionals who have already completed Good Clinical Practice (GCP) training and need to understand the additional considerations introduced for modern clinical trial designs.

Annex 2 expands upon the core GCP principles by providing guidance for trials that incorporate decentralised elements, pragmatic approaches, digital health technologies (DHTs), real-world data (RWD), remote visits, home healthcare services, and external service providers. As these approaches become increasingly common, organisations must ensure that participant safety, data integrity, informed consent, investigational product management, oversight, and regulatory compliance are maintained across a wider range of trial settings.

Through interactive learning, practical examples, knowledge checks and scenario-based exercises, participants will explore the responsibilities of investigators, sponsors and ethics committees when implementing these modern trial approaches. The course focuses on applying Annex 2 requirements in real-world situations and understanding how the guideline supports reliable trial results while protecting participants.

Learning Objectives

- Explain the purpose and scope of ICH E6(R3) Annex 2 and its application to decentralised clinical trials, pragmatic trial designs and the use of real-world data.
- Describe the responsibilities of investigators, sponsors and IRBs/IECs when implementing modern clinical trial approaches while maintaining participant safety, data integrity and regulatory compliance.
- Apply Annex 2 principles to real-world clinical trial scenarios involving remote activities, digital health technologies, investigational product management, oversight and data governance.

Module One:

1. Introduction to ICH E6(R3) Annex 2 and Key Concepts

2. Quality by Design (QbD) in Annex 2

3. The Role of the IRB/IEC in Modern Clinical Trials

4. Investigator Responsibilities in Decentralised and Pragmatic Trials

5. Sponsor Responsibilities: Trial Design, Service Providers and Investigational Product Management

6. Sponsor Responsibilities: Data Sources, Real-World Data, Monitoring and Safety Oversight

7. Applying Annex 2 Guidance: Practical Scenarios and Case Studies



Duration: Approx. 2 hours