CT03 ICH Good Clinical Practice

Approximate study time: 3 hours

Level: Foundation

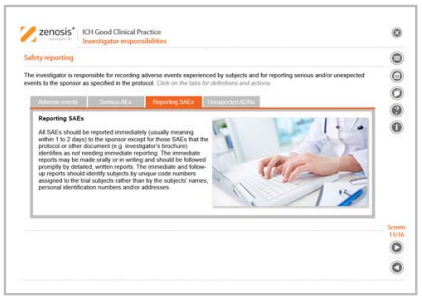
Audience: Research, Regulatory, Compliance

Category: Clinical, Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 3

Module outline
- Module overview
- ICH, harmonisation, and principles of GCP
- Clinical research teamwork
- Documentation
- Investigator responsibilities
- Informed consent
- Monitor responsibilities
- Assessment



Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements for designing, conducting, recording and reporting clinical trials. Compliance with GCP principles is required by regulatory authorities in many countries for the authorisation of clinical trials and the acceptance of their data. The International Council for Harmonisation's guideline E6, often referred to as ICH GCP, is the international standard specification for Good Clinical Practice.

This module introduces GCP and sets it in the context of typical collaborative work in clinical research. We discuss the role and goals of the International Council for Harmonisation and the principles of GCP. We describe the roles of members of a team working on a clinical trial. We set out the documentation that must be created and maintained. We specify the responsibilities of trial sponsors, clinical investigators and monitors. We explain the rationale and execution of the informed consent process, and discuss issues that arise in practice.

The module is fully up to date with Revision 2 of ICH GCP.

Who will benefit from this module?

This module will benefit all those who participate in clinical research, whether they work in the pharmaceutical or biotechnology industry or as healthcare professionals. A sound knowledge of GCP is essential for clinical research associates / monitors, project managers, clinical investigators, clinical research coordinators / study nurses, data managers, pharmacists, and others contributing to clinical trials.

Learning objectives

- Explain why and how the ICH influences clinical research practice through its guideline on GCP, and summarise the principles of GCP.
- Identify the major roles in a clinical trial team, outline the responsibilities of each, and discuss how they work together.
- Describe the responsibilities of a trial sponsor.
- Describe the responsibilities of a clinical investigator.
- Explain the rationale and execution of the informed consent process, and discuss issues that arise in practice.
- Describe the responsibilities of a trial monitor.

Module outline

Module overview
Sets out the module's scope, objectives and notes on terminology.

ICH, harmonisation, and principles of GCP
Describes the ICH's role in the harmonisation of regulations, introduces its guideline E6, and sets out the principles of GCP.

Clinical research teamwork
Introduces the major roles in a typical clinical research project and outlines their duties and relationships.

Documentation
Identifies the documents designated by ICH GCP as essential to the conduct of a clinical trial, describes important examples, and outlines how they should be maintained.

Sponsor responsibilities
Duties and functions discussed in this session include risk-based quality management, selection of investigators, trial management, data handling and record keeping, finance and compensation, regulatory submissions, management of investigational product(s), safety reporting, monitoring, audit, dealing with noncompliance, and clinical trial reports.

Investigator responsibilities
Duties and functions discussed in this session include: provision of adequate resources and oversight of delegatees; liaison with institutional review boards / independent ethics committees; compliance with protocol; management of investigational product(s), informed consent and data records; and safety reporting.

Informed consent
Sets out the principles and requirements of informed consent, describes the process, and provides examples of practical issues confronting healthcare professionals and subjects.

Monitor responsibilities
Explores the responsibilities of the monitor and provides insight into key challenges. Describes assessment of investigators and investigational sites, education and trial initiation, risk-based monitoring of clinical conduct, including CRF review and source document verification, and trial close-out. Discusses noncompliance and how to deal with it

Assessment
Multiple-choice mastery assessment.

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