Clinrex Munich
Dr. Dagmar Chase

ICH Guideline E6(R3) (ICH-GCP)

Referentin: Dr. Dagmar Chase

Introduction

- History of GCP
- International Council for Harmonisation – The ICH Process
- New Declaration of Helsinki (October 2024)

ICH Guideline E6(R3) (ICH-GCP)

- Principles of ICH-GCP
- Independent Review Board /Independent Ethics Committees (IRBs/IECs)
- Investigators, in particular
  - Responsibilities
  - Protocol Deviations
  - Participant Medical Care and Safety Reporting
  - Informed Consent of Trial Participants
  - Investigational Product Management
  - Records (Source and Case Report Forms)
- Sponsors, in particular
  - Trial Design
  - Agreements
  - Sponsor Oversight
  - Risk-based Quality Management / Risk-based Monitoring
  - Safety Assessment and Reporting
  - Investigational Product
  - Data and Records
  - Reports
- Data Governance - Investigator and Sponsor
- Essential Records (TMF / eTMF)