



## ICH Guideline E6(R3) (ICH-GCP)

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### 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
- Institutional Review Board / Independent Ethics Committee (IRB/IEC)
- Investigators, in particular
  - Responsibilities
  - Protocol Compliance and 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
  - Non-Compliance
  - Safety Assessment and Reporting
  - Investigational Product
  - Data and Records
  - Reports
- Data Governance - Investigator and Sponsor
- Essential Records (TMF / eTMF)
- Challenges of the new Guideline