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Dr. Dagmar Chase

GCP Refresher:

ICH Guideline E6(R3) (ICH-GCP)
CTR / CTIS
4. AMG Änderungsgesetz und Medizinforschungsgesetz (MFG)
Aktuelle Fragen zu GCP

Referentin:
Dr. Dagmar Chase

ICH Guideline E6(R3) (ICH-GCP Principles and Annex I)

- New Structure
- Principles
- Independent Review Board /Independent Ethics Committees (IRBs/IECs)
- Investigators, in particular
  - Responsibilities
  - Informed Consent of Trial Participants
  - Records (Source and Case Report Forms)
- Sponsors, in particular
  - Agreements
  - Communication with IRBs/IECs
  - Sponsor Oversight
  - Risk-based Quality Management / Risk-based Monitoring
  - Investigational Product
  - Data and Records
- Data Governance
- Essential Records (TMF / eTMF)

EU Clinical Trials Regulation 536/2014 and CTIS

- Actual Status
- New Concepts
- Submissions and Authorisation Procedure
- CTIS Roles and Permissions
- Safety Reporting
- Revised Transparency Rules

4. AMG Änderungsgesetz und Medizinforschungsgesetz (MFG)

Aktuelle Fragen zu GCP

- Protocol Waivers
- Unblinding