Clinrex Munich
Dr. Dagmar Chase

EU Clinical Trial Regulation 536/2014 (CTR)
Clinical Trial Information System (CTIS)
4. AMG Änderungsgesetz

Referent: Dr. Dagmar Chase

CTR and CTIS

- Actual Status
- Transition of Trials started under the CT Directive 2001/20/EC: New Rules to Facilitate the Process
- New Concepts
  - Co-sponsoring
  - Low-intervention clinical trials
- Submission and Authorization Procedures
  - Responsibilities
  - Timelines
- CTIS
  - Overview and Interface to other EMA Data Sources (OMS, xEVMPD)
  - Sponsor Functionality (Workspace)
  - User and Access Management (Roles and Permissions)
  - Organization Centric vs Trial Centric Approach
- Application Dossier (Part I, Part II)
  - Language Requirements
  - Differences between Member States
  - Patient Facing Documents
- Substantial Modification / Non-substantial Modifications / Subsequent Addition of a MS concerned
- Safety Reporting: What is new?
- New EU Transparency Rules
  - How to protect Personal Data and Commercially Confidential Information when using CTIS?
  - New Publication Rules incl. Removal of Deferrals

4. AMG Änderungsgesetz:

- Verfahren zur Genehmigung einer klinischen Prüfung
- Registrierungsverfahren für Ethik-Kommissionen
- Verfahrensordnung und Geschäftsverteilungsplan
- Ausblick auf das Medizinforschungsgesetz (Kabinettsentwurf)