Clinrex Munich
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Project Management in Clinical Trials
Working with CROs
Sponsor Oversight

Referent: Dr. Dagmar Chase

Project Management – Overview

- **Definitions**
- **Hard Factors – Soft Factors**
- **Quality**
- **Time Management**
  - **Work break down structure**
  - **Critical path**
- **Budget / Resource Planning**
- **Project Controlling (The PDCA Cycle)**

Risk-based Quality Management in Clinical Trials including Project Plan and Risk Mitigation Plan

Sponsor Oversight

Working with CROs **(see next page)**

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(Fortsetzung)

Working with CROs

General Aspects

- Regulatory Framework
- Typical CRO and Clinical Trial Team Structure
- CRO Selection Process and Contracts: What Inspectors Expect

Trial Start-up

- Kick-off Meeting
- Preparation of Trial Documents
- Site Selection and Site Approval Process
- Training of the Trial Team (Sponsor / CRO)
- Setting up Trial Files (TMF, ISF)

Trial Conduct

- CRO Oversight and Key Performance Indicators
- How to Handle Out of Scope Costs?
- Sponsor-CRO Relationship
    - What can go wrong?
    - How to manage a crisis?
    - Developing a good relationship

Trial Completion

- Report Writing
- Returning Trial Material
- Archiving Duties
- How to Measure CRO Performance at Trial End?
- Lessons Learned