Clinrex Munich
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Project Management in Clinical Trials / Working with CROs

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

Project Manager / Leadership / Project Team

Risk-based Quality Management in Clinical Trials

Writing a Project Plan

Sponsor Oversight

Tracking and Controlling

Communication Plan and Good Communication Practice

- Writing a Communication Plan
- Telephone skills / business letters / e-mails
- Making meetings work
- Why is communication so difficult?

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(Fortsetzung)

Working with CROs

- 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 / Site Approval Process
    - Training of the Trial Team (Sponsor / CRO)
    - Writing a Safety Plan
    - Setting up Trial Files

- Trial Conduct
    - CRO Oversight: What Inspectors Expect when Using a Risk-based Approach
    - How to Handle Out of Scope Costs?
    - Sponsor-CRO Communication
        - 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 / Key Performance Indicators (KPIs)
    - Lessons Learned

Interface to Investigators (Investigator Meetings, Newsletters)

What makes a project successful?