Requirements for Courses on Research Ethics and GCP

Sponsor-Investigator Level

In addition to requirements for Investigator Level

Learning Objectives (•) and List of content (□)

- Describe the combined role of a sponsor-investigator in a clinical study
  - Short repetition of responsibilities of an investigator and a sponsor according to ICH-GCP E6 and Swiss law, incl. ordinances

- Develop a scientific question into a research hypothesis
  - Focused question
  - Clinical relevance
  - Use of prior evidence
  - Definition of study objectives and primary and secondary endpoints
  - Definition of efficacy and safety parameters

- Explain essential methodological and statistical considerations
  - Study design
  - Statistical methods
  - Sample size
  - Interim analysis
  - Level of scientific evidence
  - Measures to avoid bias and confounding

- Conduct feasibility assessments for a planned project
  - Resource management (patients, personnel, space, materials, competing studies)
  - Time management
  - Costs and funding; budgeting
  - Partners and collaborations; contracts
  - Liability/insurance statements

- Ensure quality of investigational medicinal products and medical devices
  - Requirements for pharmaceutical quality data
  - GMP/ISO requirements
  - Labelling requirements
  - Shipping requirements
  - Accountability, traceability, destruction, distribution and storage of drug/medical device

- Describe submission and reporting requirements towards competent authorities
  - Definition of studies that need approval by Swissmedic/BAG
  - Submission process and dossier structure
  - Reporting requirements, incl. Pharmaco- and Materiovigilance

- Ensure transparency and reproducibility of study procedures and documentation
  - QMS and SOP systems
  - Adequate training of staff
  - Documentation, trial master file and change management
  - Study reports
  - Obligation to publish/disclose research results