Learning Objectives

“Good Clinical Practice (GCP) Training for Investigators and Study Teams” (1½ days training)

(Swissethics accredited)

Goals and competences

- To understand the historical development, the principles and content of international guidelines for clinical research (Declaration of Helsinki, ICH-GCP) and their influence on the Swiss legislation (HMG, VKlin)
- To describe the different phases of drug development
- To gain an understanding of the role of ethics committees, in particular their mandate to protect the patient’s well-being, integrity and autonomy
- To define the investigator’s role and responsibilities in a clinical study, particularly with regard to informed consent and safety reporting
- To learn about the submission process to ethics committees and regulatory authorities
- To understand the principles of quality assurance and quality control and their implementation in clinical studies, including the importance of Standard Operation Procedures, study monitoring and audits
- To become acquainted with the essential study documents and to understand structure and content of the study protocol and investigator’s brochure
- To understand the different study designs of clinical trials, the prevention of bias and the basic principles of statistics as well as protocol optimization
- To describe Good Documentation Practices
- To understand the principles of data capture (e.g. CRF), data quality and data management
- To learn about the definition and consequences of research misconduct