

## Requirements for GCP Refresher course

### Learning objectives (LO) and list of content (LC): Investigator and Sponsor-Investigator Level

#### Part 1: Basic principles

##### LO:

- At the end of the course, the participants are able to describe the different types of human research including the applicable law and regulations in Switzerland.

##### LC:

- What is research involving human beings (different types of research as per HRA, ICH and ISO14155)
- Applicable laws, regulations and standards of research involving human participants in Switzerland (e.g. Declaration of Helsinki, ICH-GCP, HRA, ...)

#### Part 2: Planning and preparation

##### LO:

- At the end of the course, the participants are able to determine the study feasibility in terms of patient recruitment, resources and logistics needed, time and budget and regulatory obligations. They are able to list the roles and responsibilities of all those involved in the study and their working relations. They know the essential study documents and their "raison d'être".

##### LC:

- Roles and responsibilities of all those involved in research (investigators, sponsors, the combined role of a sponsor-investigator, CRO, monitor, competent authorities: Swissmedic, Ethics Committee, FOPH)
- Feasibility and resource planning (e.g. Targeted patient population vs number of potential patients / test persons, investigational sites selection and recruitment potentials, competing studies, personnel and material equipment at the investigational site, risk mitigation plan)
- Costs and funding; budgeting
- Ensure transparency and reproducibility of study procedures and documentation (e.g. Quality management system and SOPs)
- Tasks assignments in study team (e.g. Training of site staff, delegation log, risk management, quality assurance)
- Key study documents (Protocol, patient information, data source, contracts, ...)

### Part 3: Execution

#### LO:

- At the end of the course, the participants know how to conduct a clinical trial. They know the roles and responsibilities of the investigator and site staff, the tools and documents needed and how to track and keep records during the course of the study. They know the informed consent process and the management of subjects' safety and safety reporting, as well as how to handle, store and document the study medication and medical devices.

#### LC:

- Submission to obtain the study approval from the competent authorities and reporting requirements during the course of the study
- Information and consent process (e.g. vulnerable groups, ...)
- Protocol adherence (e.g. inclusion and exclusion criteria, randomisation and treatment, changes to the protocol: significant, non-significant amendments, ...)
- Handle, store and document study medication and medical devices
- Documentation (e.g. Case Report Form (CRF) and data source, version control, archiving, ...)
- Patient safety (definitions: SUSAR, medical devices deficiencies, ..., reporting requirements, unblinding, ...)
- Sponsor/Investigator Oversight (monitoring, audit, inspections)
- Study end (reporting obligations, study report, publication)

### Part 4: Update on legal and ethical norms (if relevant changes have been made to the norms), advanced topics

#### LO:

- The participants are up to date with some of the new developments in clinical research and some current burning themes (new regulations and standards, new modes of operation and tools, ...).

#### LC:

- Relevant changes to current laws, national / international regulations and processes, including new and updates to ethical guidelines
- Advanced topics (e.g. dynamic consent, vulnerable populations, adaptive study designs, data protection laws, BASEC, Swissmedic submission portal)

Note: The content of Part 4 may be subjected to changes, at discretion of the course provider