

# SAKK Investigators' Education 2023

## GCP training – Investigator level

**Day 1: Thursday, March 23, 2023** (SAKK, Effingerstrasse 33, Bern)

8:45 *Coffee / Registration*

**9.00 Welcome & introduction to 2-day GCP training course** (Céline Hummel, SAKK CC)

**9.15 Introduction on research and GCP** (Geraldine Dal Pra, Smart GCP)

History of research and GCP  
Research, ethics and clinical trials – Definitions  
Fundamental principles and normative framework  
Conflicts of interest

**10.15 International regulations and national laws, Investigator's responsibilities**

(Geraldine Dal Pra, Smart GCP)  
International regulation on research involving human participants  
Regulatory framework in Switzerland  
Categorisation of research in Switzerland  
Investigator's Responsibilities

10.45 *Break*

**11.00 International regulations and national laws, Investigator's responsibilities** (continuing)

**11.30 Subject information and consent – Practical workshop**  
(Geraldine Dal Pra, Smart GCP; Céline Hummel, SAKK CC)

12.15 *Lunch*

**13.15 Subject information and consent** (Geraldine Dal Pra, Smart GCP)

Subject information and informed consent form: Definitions, content, rights of participants, responsibilities, document change management, re-consenting, additional issues; special populations / situations

**14.00 Quality of research data** (Geraldine Dal Pra, Smart GCP)  
Source data and CRFs: Good documentation practice and SDV  
Anonymisation, audit trail, queries and management  
Data protection and archiving  
Principles of monitoring: Visits, reports, risk-based approach  
Data Integrity

15.00 *Break*

**15.15 Ensure transparency and reproducibility of study procedures and documentation**  
(Geraldine Dal Pra, Smart GCP)

Principles of quality assurance and quality control, SOPs, audits and inspections  
Risk based Quality Management System  
Essential documents and filing  
Common audit/inspection's findings

**15.45 Wrap-up of day 1 training**

**16.00 End of day 1 training**

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## GCP training – Investigator level

**Day 2: Thursday, March 30, 2023** (SAKK, Effingerstrasse 33, Bern)

9.00 *Coffee / Registration*

**9.15 Welcome & introduction to SAKK** (Céline Hummel, SAKK CC)

**9.30 Development and structure of clinical study protocol** (Katrin Eckhardt, SAKK CC)  
Structure and content of trial protocol according to ICH-GCP E6  
Protocol adherence and management of amendments

**10.00 Overview on study regulatory processes in Switzerland** (Barbara Daubner, SAKK CC)  
Study categorization, submission and registration to Swiss law  
Change management and reporting requirements after study notification  
Role of sponsor, coordinating investigator and lead EC for multicentre trials

10.30 *Coffee break*

**10.45 IMP / Medical device handling, storage and documentation** (Céline Hummel, SAKK CC)  
Definition of IMP / Investigational medical device  
Drug / Device labelling, storage, accountability and destruction

**11.00 Study monitoring** (Julia Decoudre, SAKK CC)  
Aim of monitoring as part of quality control  
Risk-based monitoring strategies  
Different monitoring visits, source data verification, monitoring plans and reports

**11.30 Safety reporting** (Amelie Stüger, SAKK CC)  
Definitions  
Requirements for documenting and reporting of adverse events and liability  
Handling of safety signals by the investigator and sponsor  
Practical examples

12.00 *Lunch*

**13.15 Basic statistical concepts and principles** (Stefanie Hayoz, SAKK CC)  
Different designs and objectives in research  
Hypothesis testing, parameters and distributions,  
sample size calculations; power; confidence intervals  
Measures to avoid bias and confounding; blinding and randomization

**14.15 Workshop on study conduct at the local site** (Céline Hummel, SAKK CC)  
Workshop to consolidate and practice two day investigator training

15.00 *Coffee break*

**15.15 Workshop on study conduct at the local site: Discussion of results** (Céline Hummel, SAKK CC)

**16.00 End of day 2 training**