SAKK Investigators' Education 2021

GCP training – Investigator level

Day 1: Thursday, October 21, 2021 (Krebsliga, Effingerstrasse 40, 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, CLINIPACE)
Research, ethics and clinical trials – Definitions
History of research and GCP
Fundamental principles and normative framework
Conflicts of interest

10.15 International regulations and national laws (Geraldine Dal Pra, CLINIPACE)
Overview of applicable laws and regulation of research involving human participants in Switzerland and at international level
Ethics review by the competent REC and further requirements after approval

10.45 *Coffee break*

11.00 International regulations and national laws (continuing)

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

12.15 *Lunch*

13.15 Subject information and consent (Geraldine Dal Pra, CLINIPACE)
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, CLINIPACE)
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

15.00 *Coffee break*

15.15 Ensure transparency and reproducibility of study procedures and documentation
(Geraldine Dal Pra, CLINIPACE)
Principles of quality assurance and quality control, SOPs, audits and inspections
Essential documents and filing

15.45 Wrap-up of day 1 training

16.00 End of day 1 training

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Day 2: Thursday, October 28, 2021 (Krebsliga, Effingerstrasse 40, 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 (Miriam Paulisch, 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 (Angela Ros, 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 (Raoul Kammerlander, 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