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**UNIVERSITÄT
BERN**

Clinical Investigators I: basic GCP and clinical research training

2-day course organized by CTU Bern

Contact

Universität Bern
CTU Bern
Mittelstrasse 43
3012 Bern

Tel. +41 31 684 34 04
training@ctu.unibe.ch
www.ctu.unibe.ch

Clinical Investigators I:

basic GCP and clinical research training

Teaching language
English

Discussions
German or English

Course objectives

This course is aimed at providing prospective clinical investigators with the essential knowledge of Good Clinical Practice (GCP) and of other regulatory and ethical requirements, and the skills for contributing to clinical trials.

Course content

This is a two-day course split in two parts. The first part consists of self-learning and home-based exercises. Participants have two weeks to complete the tasks. The second part consists of a series of interactive lectures supplemented with workshops taught in one day.

The topics covered will include:

- Ethical and legal principles
- Swiss regulations for research involving humans (HRA, ClinO, HRO and OrgO)
- GCP guidelines
- Basics of clinical research and study designs
- Basics of data management in clinical research
- Patient information and consent
- Study conduct & quality assurance
- Safety

Target audience

The course is designed to approach a broad audience from those who have little experience in clinical trials to those who wish to widen their knowledge of the conduct of such trials.

Attendance would be primarily appropriate for: Principal Investigators (mandatory), physicians, investigators, study nurses/coordinators recruiting patients into clinical trials, informing or treating

patients, conducting follow-ups (as required by ethics committees and regulatory authorities)

Others such as members of ethics committees, biostatisticians interested in clinical research are also welcome.

Registration & course fee

Please register online at www.ctu.unibe.ch
CHF 400 internal participants (staff of Bern University Hospital and University of Bern)
CHF 700 external participants

Online registration:
www.ctu.unibe.ch

For additional information:
training@ctu.unibe.ch

Legal requirements

Swissethics has recognized that this training course fulfills the published requirements for Investigator Level courses. Participants finishing this training program fulfill the requirements of Art. 10 HRA and Art.6 ClinO.

Certificate & credit points

Certificate will be issued at the end of the course.

The attendance is acknowledged with

- 8 credits of the SIWF/ISFM, Schweizerisches Institut für ärztliche Weiter- und Fortbildung, «SIWF-approved»
- 8 credits of the SGKPT, Schweizerische Gesellschaft für Klinische Pharmakologie und Toxikologie
- 8 credits of the SGPM, Schweizerische Gesellschaft für Pharmazeutische Medizin

In addition 1 European Credits Transfer System (ECTS) credit will be granted to participants successfully completing a written examination at the end of the training course.