swiss
clinical
trial
organisation

Appendix 4

TRAINING AND EDUCATION IN CLINICAL RESEARCH IN SWITZERLAND

→ under revision

Version

1.0

INTRODUCTION

All Swiss academic clinical research centres (Clinical Trial Units, CTUs, located in Basel, Bern, Geneva, Lausanne, St. Gallen, Zurich) are affiliated in a network coordinated by its umbrella organisation Swiss Clinical Trial Organisation (SCTO). Together with the partner organisation Swiss Group of Clinical Cancer Research (SAKK), the overall goal of this network is to promote a high-quality and nationally harmonised environment for clinical research.

One of the major drivers for the quality of a clinical study is the knowledge and expertise of both medical and non-medical members of the clinical study team. Therefore, standardised trainings of clinical investigators and clinical research staff as well as structured and up-to-date continuing education programmes are key requirements for the high-level of education needed.

OBJECTIVES

The CTU network is the largest provider of training and continuing education in Good Clinical Practice and related topics in the field of clinical research in Switzerland. This consensus paper defines the common mission and goals in training and (continuing) education of the CTU network.

Furthermore, the common strategies, the quality standards and future perspectives are specified for internal (the CTU network) and external readers.

MISSION STATEMENT

The CTU network aims to be the leading training provider in clinical research for high-quality, up-to-date and innovative training and education programmes specifically designed for the different target audiences in clinical research.

GOALS

- To ensure a high level of competence for study centre staff (medical and non-medical) in planning and conducting clinical research.
- To encourage professional careers in clinical research management by providing in-depth and practice-oriented postgraduate education programmes.
- To advocate the development of relevant curricula as part of the graduate education of medical and nursing students by advising authorities and universities.

STRATEGIES

To fulfil its mission the CTU network implements different strategic principles that are aimed to achieve the above mentioned goals:

- Training and education offers are designed for the specific roles and needs of the target audiences in clinical research (see Chapter 1 Target Audience (Roles and Needs)).
- GCP trainings are designed to train investigators (on three levels) and provide them with the certification needed to prove adequate training for clinical research (see Chapter 2.1 Investigator Trainings / GCP Trainings).
- Special training events are implemented to keep investigators and site staff updated on new developments and topics under discussion (see Chapters 2.2 Specific and Hands-on Trainings for Study Personnel and 2.3 Symposia/Forums).
- New technologies in training and education are explored and made available for a broad audience where useful and applicable (e.g. online courses and blended learning, see Chapter 2.4 Online Trainings).
- Postgraduate education programmes are especially designed as professional trainings conveying a high level of practical and hands-on expertise (see Chapter 2.5 Postgraduate Educational Programmes).
- The quality of the CTU network's training and education is harmonised with the Swissuni recommendations (see Chapter 3 Quality Management). Quality Management is driven by voluntary self- and external evaluation.
- In collaboration with the SCTO the CTU network provides input on clinical research topics to the development of curricula of graduate and postgraduate medical, life science and nursing students (see Chapter 4 Graduate and Postgraduate Trainings of Medical, Life Science and Nursing Students).

1 TARGET AUDIENCE (ROLES AND NEEDS)

Clinical research is a multi-disciplinary field that requires a high degree of collaboration and coordination between professionals with different specialisations. The CTU network focuses mostly on the training of study centre staff and the staff of the superordinate institution (e.g. the university hospital) which primarily includes (sponsor-) investigators and study nurses/study coordinators. However, trainings are generally open to a broader public. In some cases training programmes are designed to also serve the needs of clinical research staff from industry and regulatory agencies or train people without practical experience in clinical research. These training programmes contribute to the purpose of building bridges between academia, industry and authorities.

1.1 CTU Personnel /Specialists in Pharmaceutical Medicine

Roles

CTU personnel and pharmaceutical medicine specialists are of diverse professional groups and are assigned to a large variety of tasks. Thus, the CTU personnel and pharmaceutical medicine specialists are responsible for the provision of services for clinical research internally (CTU) as well as externally (customer).

Needs

The CTUs have the obligation to train their study personnel and should therefore provide structured training programmes for their own personnel to ensure high quality knowledge within the CTU. The personnel should be trained in appropriate manner to their working tasks and their professional education.

1.2 Clinical Investigator

Roles

The clinical investigator is the person responsible for the conduct of the clinical study at the site. Clinical investigators are in most cases medical doctors and show a highly variable degree of experience in conducting clinical studies. In industry-driven trials they closely collaborate with the sponsor who takes many responsibilities like initiation, management and financing of a trial.

Academic clinical research, characterised by so-called investigator-initiated trials (IITs), is partially lacking external sponsoring (many projects receive some support by an external source e.g. foundation, career grant, etc.). Consequently, in this type of trials the principal investigator has to take all responsibilities attributed to the sponsor of a clinical study in addition to the investigator-specific responsibilities. Sponsor-investigators usually have many years of clinical study experience. However, in some cases also young physicians are in the situation of setting up their own research project.

Needs

Training certificates for investigators at the respective level of competence are considered mandatory and are enforced by Swiss competent authorities since 2010. Training requirements as developed conjointly by Swissmedic, swissethics and leading professional organisations are defined as a catalogue of topics for three role-specific levels. These levels are called “sub-investigator”, “investigator” and “sponsor-investigator”.

Clinical investigators need course offers at the three defined levels on a regular basis to be able to obtain the GCP certificate that is requested to run a clinical study. The substantially different levels of knowledge and experience among investigators and the extensive catalogue of requirements and topics defined for the three levels are the main challenges for training providers of clinical investigator courses (often referred to as “GCP courses”).

1.3 Study Nurse / Clinical Study Coordinator

Roles

A majority of tasks and responsibilities in planning and running a clinical study can be delegated to non-MD clinical study staff by the investigator. Clinical study staff mostly exhibits a nursing background (e.g. study nurse) or education in one of the life sciences (e.g. study coordinators).

Needs

Traditionally most study nurses/coordinators are still being trained “on the job” only. Since investigator trainings (“GCP courses”) have become mandatory for clinical investigators, more and more study nurses/coordinators attend these courses, too. However, their level of competence and responsibility varies and is different from the main tasks of investigators. Nevertheless, considering the importance of their role for the success of a clinical study, it becomes clear that structured training in practical aspects of clinical study planning and conduct is crucial.

1.4 Clinical Research Assistants / Associates, Clinical Monitors, Clinical Trial Managers

Roles

Staff in commercial clinical operations carries a number of different job titles like clinical research assistants/associates, clinical monitors or clinical trial managers. Their tasks and level of competence as well as level of responsibilities vary between companies and are dependent on the job hierarchy.

Needs

Similarly to study nurses/coordinators, the clinical operations staff from industry, CROs and other institutions is mostly trained "on the job". Structured training could help shape their profile and develop different levels of competence in clinical trial operations. Moreover, given that the needs for clinical operations staff from the sponsor site and clinical site staff from the investigator site are quite similar, a joint training programme for these two groups can be considered an opportunity to create a mutual understanding for the respective tasks.

1.5 Newcomers

Roles

Clinical research offers entry-level jobs both at clinical study sites as well as at sponsor organisations. While study nurses need a nursing background to fulfil the typical job requirements, people with a life science background at the Bachelor's level or higher bring the perfect basis for continuing education in clinical research.

Needs

Structured basic and advanced training programmes for these newcomers to clinical research could greatly enhance both job performance of these young collaborators as well as their career development.

2 TYPES OF TRAININGS

The CTU network aims to develop training offers for each target audience. To this end the individual training providers carefully consider the appropriate combination of content and format. Currently the main types of trainings that have been established over the past years are listed below. The current course offer of the CTU network is published on the SCTO webpage, where a regularly updated list can be downloaded. New offers are under discussion or in planning.

2.1 Investigator Trainings / GCP Trainings

The content of the three different levels of investigator trainings (often referred to as "GCP courses") is standardised to a great extent (see Chapter 1.2). The level of detail, however, at which each topic is covered, varies among training providers. As a result, the courses also vary in length from one-day courses to courses that last a few days.

2.2 Specific and Hands-on Trainings for Study Personnel

The CTU network offers diverse hands-on and clinical research-specific trainings for study personnel with the aim to further train and educate on selected topics/issues in clinical research. Examples of such trainings include for example: statistics in clinical research, research lunch, seminars, CTU theme days, clinical research days, safety training.

2.3 Symposia/Forums

Symposia and forums offered by the SCTO and the CTU network are usually dedicated to a specific topic with the purpose to offer continuing education for investigators and other clinical research staff. The goal is to regularly update the clinical research community on new developments in all relevant areas of clinical research. The usual frequency of symposia/forums is once or twice per year.

2.4 Online Trainings

Due to the growing number of people who need and want to be trained, new training tools based on the online techniques have been established recently. Online courses can be developed both for topics related to basic knowledge and for teaching recent developments e.g. in regulations. The obvious advantages of online courses are the independence in location and time to participate. The CTU network deems that there is a growing potential for online trainings, however, has to oppose a strong competition in this field.

2.5 Postgraduate Educational Programmes

The purpose of postgraduate educational programmes covering different levels and aspects of clinical research is to provide structured in-depth education for those who seek comprehensive training in this field. It serves mostly as true professional training for newcomers to the field of clinical research but also for medical doctors or non-medical staff with or without work experience in clinical research.

According to the Bologna system three levels of postgraduate educational programmes are available:

- Certificate of Advanced Studies (CAS, minimum 10 European Credit Transfer System (ECTS) credit points)
- Diploma of Advanced Studies (DAS, minimum 30 ECTS credit points)
- Master of Advanced Studies (MAS, minimum 60 ECTS credit points)

The focus of currently existing postgraduate programmes offered by the CTU network is on clinical trial management, clinical monitoring and clinical research methodology. Additional programmes focusing on other topics (e.g. data management, drug development, biobanking, translational medicine) could be realised as a joint venture within the CTU network (see also Chapter 4 Graduate and Postgraduate Trainings of Medical, Life Science and Nursing Students).

2.6 Continuous Professional Specialist Training in Collaboration with Other Recognised Providers

On a national level and in collaboration with selected CTUs, several societies and associations provide and/or issue accreditations for continuous professional specialist trainings in clinical research and pharmaceutical medicine (see also Chapter 4 Graduate and Postgraduate Trainings of Medical, Life Science and Nursing Students).

The SwAPP (Swiss Association of Pharmaceutical Professionals) promotes a Life Long Learning (LLL) Program for non-medical specialists on pharmaceutical medicine with SwAPP diplomas and continuous professional training and issues accreditations for training providers.

The SGPM (Swiss Society for Pharmaceutical Medicine) was founded for physicians in Switzerland with (or in training for) specialisation in pharmaceutical medicine to promote the scientific discipline of pharmaceutical medicine in medical faculties and regular continuous education. It supports the professional training needed for FMH board certification in pharmaceutical medicine.

3 QUALITY MANAGEMENT

3.1 Recommendations for Quality Development by Swissuni

Most training programmes offered through the CTU network are registered at and promoted through one of the Swiss universities. They are labelled as official Swiss university continuing education programmes and, as a consequence, are obliged to adopt the recommendations for quality development prepared by the Swiss University Continuing Education programme (Swissuni), in partnership with the Swiss Center of Accreditation and Quality Assurance in Higher Education (OAQ). These recommendations reflect the shared view of Swissuni's member institutions of quality in continuing education and offer a set of benchmarks to training providers [1].

The recommendations for quality management include four key principles, which are also pertinent to other quality systems in the area of education and training and which are therefore widely recognised:

Impact: The aim of a university continuing education programme is to build and develop knowledge and competences in both objective and subjective terms. The knowledge and competences acquired by students have an impact on their professional and social lives.

Target group: The programme is "made to measure" for the target group in terms of aims, organisation, methods and learning culture.

Flexibility: The programme is dynamic; its ability to adapt to the constantly changing needs of students and new conditions that arise on an ongoing basis is persuasive.

Relevance and partnership: The programme reflects the current state of research and the opinions of specialists in the field, primarily as a result of involving relevant stakeholders and specialist organisations.

3.2 Evaluation of Training Programmes and/or Training Units

The evaluation of continuing education programmes in Switzerland is a voluntary procedure whose primary aim is to stimulate an internal reflection on the programme's inputs, processes and outcomes (self-evaluation) and to benefit from a constructive peer review (external evaluation). The suggested process contributes to the quality improvement of the programme as well as to the development of an institutional quality culture. On behalf of Swissuni, OAQ has developed both quality standards specific for continuing education programmes [2] and a guide for evaluation of continuing education programmes [3]:

Quality Standards [2]: The OAQ developed a set of 20 quality standards, grouped under 6 examination areas: positioning, implementation and training objectives; internal structure and quality management; studies; teaching; student body; resources.

Guide 3: This guide has been created as a supportive tool for both the self-evaluation conducted internally by the institution and the external evaluation carried out by the selected group of independent experts. It provides detailed contextual and procedural information as well as two sections dedicated respectively for the self-evaluation phase and for the external evaluation phase.

All training units within the CTU network have access to the above mentioned quality standards and the guide for self- and external evaluation. It is up to the individual training unit to decide of how they want to implement the provided tools. The external evaluation should preferably be guided by the SCTO.

1 Swissuni, Recommendations for quality development in university continuing education programmes, 2010

2 OAQ, Evaluation of continuing education programmes at universities of applied sciences in Switzerland, Quality Standards, January 2013

3 OAQ, Evaluation of continuing education programmes in the university of applied sciences sector in Switzerland, Guide dated 15 April 2013

4 GRADUATE AND POSTGRADUATE TRAININGS OF MEDICAL, LIFE SCIENCE AND NURSING STUDENTS

The formats of the university continuing education courses in Switzerland are standardised and match those in various European countries. They are oriented to people with an initial university degree or equivalent education and professional experience.

Master of Advanced Studies (MAS) and Diploma of Advanced Studies (DAS) programmes span several semesters and are completed with a thesis and exams. In addition to study programmes, numerous shorter continuing education courses are offered.

Similar to other academic disciplines (e.g. public health) the continuous training offer in clinical research should encompass all degrees (or formats) of continuing education (Weiterbildung) to Master of Advanced Studies (MAS; for an example see illustration in German below) and beyond (e.g. PhD programme).

Figure 1: Example of structure, requirements and degrees of advanced studies

UNIVERSITÄT BASEL | ADVANCED STUDIES

Weiterbildungsformate

	WEITERBILDUNGSKURS	CAS CERTIFICATE OF ADVANCED STUDIES	DAS DIPLOMA OF ADVANCED STUDIES	MAS/MBA MASTER OF ADVANCED STUDIES MASTER OF BUSINESS ADMINISTRATION
AUFBAU	Präsenzunterricht	Lehrveranstaltungen, selbstständige Arbeitsleistungen, Prüfungen	Lehrveranstaltungen, selbstständige Arbeitsleistungen, Prüfungen, Abschlussarbeit	Lehrveranstaltungen, selbstständige Arbeitsleistungen, Prüfungen, Abschlussarbeit
ARBEITSAUFWAND	Halbe bis mehrere Tage	mindestens 300 Arbeitsstunden, davon ca. 150 Stunden Präsenzlehrveranstaltungen	mindestens 900 Arbeitsstunden, davon ca. 300 Stunden Präsenzlehrveranstaltungen	mindestens 1800 Arbeitsstunden, davon ca. 600 Stunden Präsenzlehrveranstaltungen
ECTS*	In der Regel werden keine Credits vergeben	mindestens 10 Credits	mindestens 30 Credits	mindestens 60 Credits
ABSCHLUSS	Kursbestätigung	Certificate of Advanced Studies der Universität Basel	Diploma of Advanced Studies der Universität Basel	Master of Advanced Studies der Universität Basel
ZULASSUNGSBEDINGUNGEN	Programmabhängige Bedingungen	Tertiärer Bildungsabschluss oder gleichwertige Bildung und programmabhängige Bedingungen	Tertiärer Bildungsabschluss oder gleichwertige Bildung und programmabhängige Bedingungen	Tertiärer Bildungsabschluss oder gleichwertige Bildung und programmabhängige Bedingungen

*ECTS – European Credit Transfer and Accumulation System: ECTS ist das Kreditsystem für Lernleistungen im Europäischen Hochschulraum. Die Credits sind ein Mass für den Arbeitsaufwand, der Studierende für das Erreichen des erforderlichen Lernergebnisses erbringen.

4.1 Applicable Laws

Basic ethical principles for medical research recognised worldwide as binding standards are the Declaration of Helsinki (DoH)[4] and the Guideline for Good Clinical Practice from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GCP)[5].

Research involving human beings in Switzerland is regulated in the Federal Act on Medicinal Products and Medical Devices[6] and the Federal Act on Research involving Human Beings[7] with its applicable Ordinances (Ordinance on Clinical Trials in Human Research[8] and the Ordinance on Human Research with the Exception of Clinical Trials[9]).

Medical university professions are regulated in the Federal Act on Medical University Professions (Medizinalberufegesetz (MedBG)[10] with its applicable Ordinance (Medizinalberufeverordnung (MedBV)[11]. The MedBG provides general job-specific training targets that are applicable for all medical university professions (Articles 4, 6–10) and requires the expansion and consolidation of knowledge, skills, abilities, behaviours, and social skills acquired during the initial training (Article 17, paragraph 1).

The legal basis for the professional qualification of clinical research study personnel is the Ordinance on Clinical Trials in Human Research (ClinO).

4 World Medical Association (WMA), Declaration of Helsinki (DoH), Ethical Principles for Medical Research Involving Human Subjects, 2013

5 ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice ICH GCP E6 (R1), 1996

6 Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), 2000, SR 812.21

7 Federal Act on Research involving Human Beings (Human Research Act, HRA) 2011, SR 810.30

8 Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance; ClinO) 2014, SR 810.305

9 Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) 2014, SR 810.301

10 Federal Act on Medical University Professions (Medizinalberufegesetz, MedBG) 2006, SR 811.11

11 Verordnung über Diplome, Ausbildung, Weiterbildung und Berufsausübung in den universitären Medizinalberufen (Medizinalberufeverordnung, MedBV) 2007, SR 811.112.0

4.2 Situation Analysis

During the last years, the SNSF has been involved in the efforts to advance clinical research in Switzerland to an internationally competitive level, e.g. through project and cohort studies support, the creation of Clinical Trial Units (CTUs) and the special programme "University Medicine" (SPUM). However, for a sustainable promotion of clinical research not only suitable research infrastructures and funds are needed but also well-trained and continuously educated medical doctors and health professionals. In addition, work conditions must allow clinical research during the activities of daily routine as well as during the obligations for continuing education.

In 2013 the Federal Council issued a masterplan with specific measures to strengthen the biomedical research and technology in Switzerland[12]. One of its key measures is the education and training of the next generation of clinical researchers. A thematic working group "Nachwuchs für die klinische Forschung in der Schweiz" of the platform "Zukunft ärztliche Bildung" of the Federal Office of Public Health (FOPH)[13] has addressed the issue of training and continuing education of medical doctors in clinical research.

The working group has analysed the current situation (2013/2014) with regard to qualitative or quantitative deficiencies in clinical researchers and evaluated whether

- the recognised weaknesses in clinical research in Switzerland within the existing structures of education and training can be resolved and
- what suitable measures for improvement could be proposed.

Factors such as working conditions of researchers in education and training and general conditions in clinical research that also influence the attractiveness of biomedical research should be taken into account as well.

The report[14] and its recommendations will be released once it has received the approval from the "Plattform Zukunft ärztliche Bildung" and the "Dialog Nationale Gesundheitspolitik" (Berset/Perrenoud and cantonal health directors, expected autumn 2014).

12 Federal Council Switzerland, Masterplan des Bundes zur Stärkung der biomedizinischen Forschung und Technologie, 2013

13 Federal Office of Public Health, «Plattform Zukunft ärztliche Bildung», 2010

14 Bericht der Themengruppe «Nachwuchs für die Klinische Forschung in der Schweiz»

4.3 Advanced Training in Clinical Research

Future training offers should consider and meet the needs of a broad field of disciplines (professions) involved in clinical research. A possible recommendation of the above mentioned working group could lead to a jointly developed and established advanced training module in clinical research, a unique opportunity for the CTU network towards a coordinated country-wide training offer.