

Quality Policy

The Swiss Clinical Trial Organisation (SCTO) is the umbrella organization of the Clinical Trial Units (CTUs) in Switzerland.

This document should provide guidance and define the Quality Policy of the SCTO, which is in accordance with the requirements of Good Clinical Practice Guidelines of the International Conference of Harmonisation (ICH-GCP) and regulatory authorities.

The SCTO supports the SNSF-funded CTUs to implement a process-oriented standard in Quality Management as well as in the SCTO itself. The quality management systems create a strategic framework in which every organization can meet the requirements. The Quality Management System (QMS) has the aim to guarantee the highest customer satisfaction in the most effective manner, especially by following functions:

- a) *Top priority is to adhere to the ethical principles of the Declaration of Helsinki protecting the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects and assuring the highest service quality for them.*
- b) Creating environment oriented to continuous improvement of processes.
- c) For all study-related activities, the Quality Management System must comply with the applicable guidelines, e.g. ICH-GCP for drug trials, the statutory and regulatory requirements, as it is **mandatory** for all parties involved in clinical research.

Quality is an essential part of our corporate strategy; therefore:

- We plan, develop and document processes needed for the realization of our services in order to guarantee the traceability of the service throughout the realization. For the planning, conduct, management and reporting of clinical studies, the cornerstones of the procedures are based on the applicable guidelines, e.g. ICH-GCP for drug trials. They provide guidance for an ethical and appropriate conduct of a study and ensure the accuracy of the data recorded.
- We apply methods for monitoring and measurement of the QMS processes and we keep under surveillance the suitability and correctness of our QMS processes on a regular basis, e.g. by performing internal audits.
- We continuously improve the effectiveness of the QMS by taking corrective and preventive measures to eliminate non-conformities and determine means to identify and eliminate potential non-conformities.
- We ensure that all individuals contributing to a clinical study in our organizations will be qualified by education, training and experience to perform his or her respective task(s) and adhere to the protocol, the applicable regulatory requirement(s) and guidelines, and the relevant written SOPs.

By complying with this Quality Policy, we make our contribution that studies are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, the applicable regulatory requirement(s) and guidelines.