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Quality Policy of the SCTO's CTU Network

1. Executive Summary

The Swiss Clinical Trial Organisation's (SCTO) vision is to turn patient-relevant research questions into excellent clinical research: Through the support of the SCTO's Clinical Trial Unit (CTU) Network, Swiss academic clinical research gains relevance, impact, and quality.

Quality in clinical research is of utmost importance to gain significance and impact with research results. The CTU Network aims to be a guarantor for high-quality research projects carried out in collaboration with a CTU. This Quality Policy of the CTU Network describes the framework and scope of the CTUs' contribution to increase the quality in clinical research projects. It is binding for all staff of the SCTO's CTU Network.

2. Introduction

As a reference institution for patient-oriented clinical research in Switzerland, the SCTO liaises between stakeholders and offers the necessary access to national and international networks and platforms.

A priority of the SCTO mandates[1] is the coordination, collaboration, and harmonisation of the SCTO's CTU Network, which represents the point of contact for academic clinical research. The CTUs of the SCTO's CTU Network play a key role in facilitating academic clinical research and collaborations between different stakeholders. Additionally, they contribute to the generation and harmonisation of processes, structures, and quality standards across Switzerland. With a central office (the Executive Office) and interlinked nodes (CTU Network), the SCTO forms a distributed clinical research infrastructure (RI) as defined by the European Strategy Forum for Research Infrastructures (ESFRI)[2].

This policy

- applies to the CTU Network, the thematic platforms and the Executive Office (EO) of the SCTO;
- describes the CTU Network's understanding of and commitment to quality in clinical research in terms of its mandate and activities;
- does not describe the whole content of a quality management system (QMS) nor does it give a universal definition of quality in clinical research.

To be noted: Individual CTUs first and foremost operate their own quality systems for local activities.

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1 Mandates as stipulated in the service level agreements with the State Secretariat for Research, Education and Innovation (SERI) and the Swiss National Science Foundation (SNSF) and as reflected in the SCTO strategy paper https://www.scto.ch/en/about-us/strategy.html

2 See the European Strategy Forum on Research Infrastructures' glossary https://www.esfri.eu/glossary

3. Background

The CTUs of the SCTO support the Swiss-wide collaboration and harmonisation. They stand out due to their joint and continuous efforts in co-shaping the national landscape by agreeing on and providing national standards for an adequate quality in clinical research.

Within the SCTO association, the CTUs and their directors advise the SCTO Steering Board (SB) and support the implementation of the SCTO strategy.

The CTUs belonging to the SCTO's CTU Network are all mandated by their home institutions to ensure adequate quality in clinical research. This mainly implies to support clinical research projects and facilitate their conducting.

4. Definition of quality in clinical research

According to the standard DIN EN ISO 9000:2015-11[3] (the valid standard for quality management), quality is defined as the "degree to which a set of inherent characteristics of an object fulfils requirements". Quality thus indicates the degree to which a product (good or service) meets existing requirements.

Derived from the most important framework conditions for clinical research as defined in the Human Research Act (HRA)[4], the International Council for Harmonisation (ICH) guidelines E6 (Good Clinical Practice; R3 – principles)[5] and E8 (General Considerations on Clinical Studies; R1)[6], the CTU Network agrees on the following definition of quality in relation to its mandates:

- The quality and amount of information generated by clinical research should be sufficient to support good decision-making (**aim of quality**).
- Quality should be built into the scientific and operational design and conduct of clinical research early on. Clinical research projects must be feasible and should be reproducible (**quality by design**).
- Quality of clinical research is considered as fit for purpose (adapted to the respective situation). Factors critical to the quality of the research project should be identified (**risk-adapted quality**).

The graph below illustrates the **process of (clinical) research**, namely providing an answer to a scientific question with the help of reliable and credible information. Each step requires a specific expertise and procedure to finally result in quality.

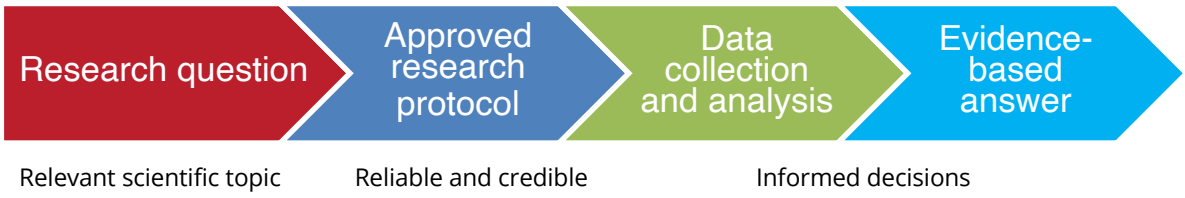

Figure 1: clinical research process

Although of utmost importance, the assessment of the relevance of the scientific topic itself ("question") is usually not part of the CTU Network's mandate, but mostly falls under the responsibility of other stakeholders. The CTU Network's support to reach adequate quality is mainly directed to the generation of reliable and credible information in order to provide valid answers to such relevant scientific questions with the best attainable level of evidence. Taking informed decisions based on this reliable and credible information is again usually not part of the CTU Network's mandate.

[3] https://www.iso.org/iso-9001-quality-management.html
4 https://www.fedlex.admin.ch/eli/cc/2013/617/en, in particular articles 1, 5, and 10
5 https://database.ich.org/sites/default/files/ICH_E6-R3_GCP-Principles_Draft_2021_0419.pdf, in particular chapter 7
6 https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2022_0204%20%281%29.pdf, in particular chapter 3

5. Scope of application

All CTUs of the SCTO's CTU Network continue to adhere to local processes on how to deal with suspected non-compliance. The present high-level Quality Policy aims at complementing local guidance, harmonising a CTU's general approach in this matter. Project-specific guidance for eligibility is and must be established and followed locally.

The CTU Network commits to adhere to the present Quality Policy, the SCTO's Guidance on Good Operational Practice (GGOP)7 as well as the laws and guidance mentioned therein. Their compliance is audited against these standards.

The CTU Network takes the present Quality Policy into consideration to decide on the eligibility of a research project in general. Eligibility depends for the CTU Network on the compliance with basic quality requirements (e.g., regulatory, ethical, feasibility, etc.) for a clinical research project, ensuring the generation of reliable and credible information. The CTU Network will in all cases offer consultancy and advise on how this can be best achieved.

6. Processes, responsibilities, and stakeholders

As mentioned above, quality along **all** steps in clinical research depends on the engagement of different stakeholders and their close interaction. The (non-exhaustive) list below depicts responsibilities and concerned stakeholders along the different steps in clinical research. The table illustrates the area of influence of the CTUs on quality in clinical research on which the present CTU Network's Quality Policy focuses on.

Local CTUs support all steps listed below			
Identify relevant scientific topic **"Research question"**	**Formalise scientific approach** **"Research protocol"**	**Generate reliable and credible information** **"Data collection and analysis"**	**Enable informed decisions** **"Evidence-based answer"**
Sponsor	Sponsor	Sponsor	Sponsor
Clinical researcher (individual and groups)	Clinical research teams (research question development)	Clinical research teams (study execution)	Clinical researcher (individual and groups) / public health
Patients and public	**CTUs and other RIs** (methodology, regulatory, feasibility, budgeting, etc.)	**CTUs and other RIs** (clinical operations, quality control, data management, analyses)	Patients and public
Scientific advisory boards	Ethics committees / other authorities (approval)	Ethics committees / other authorities (follow-up incl. safety)	Health care community and guidelines groups (integration / implementation)
Funders	Funders	Funders	Funders
Hospitals / universities	Hospitals / universities	Hospitals / universities	Hospitals / universities

7 https://www.scto.ch/en/publications/guidelines.html (current version)

7. Continuous quality improvement and aspects of quality governance

Quality is a moving target. The CTU Network therefore needs to ensure that quality (as described in section 4) is continuously monitored, evaluated, improved, and audited. To do so, the **CTU Network** has put different measures and activities in place:

- **Guidance**: The directors of the CTU Network guide and supervise the network and platforms. They do so by following the *SCTO Rules of internal procedure for the Board of CTU Directors (BCD)*.
- **SCTO Platforms**: The platforms serve as pools of expertise and develop high-quality tools for facilitating the smooth conduct of clinical research projects. The SCTO Platforms follow the overarching *SCTO Rules of Procedure for Thematic Platforms*.
- **Surveillance**: The CTU Network agree on an auditing procedure, controlling compliance and ensuring continuous learning, since audit findings feed back the system through training.
- **Continuous training**: The CTU Network commit to the implementation of continuous training programmes for their internal staff, updating knowledge in line with clinical research environment evolution and integrating return on experience.
- **Providing training**: The CTU Network is the major provider for training offers in academic clinical research and thus helps to professionalise the current and future clinical research workforce.
- **Performance monitoring**: The CTU Network is subject to the overall performance monitoring of the SCTO as a publicly funded RI. Furthermore, external evaluations are initiated by authorities and funders.
- **Exchange**: The SCTO's CTU Network is part of the European Clinical Research Infrastructure Network and as such in continuous exchange with similar RIs in Europe.

The **BCD** applies the following further measures to govern quality:

- **Risk management:** Quality (as described in section 4) is discussed on a regular basis during BCD meetings to identify potential new issues. In addition, potential and new quality issues are on the agenda of the annual BCD retreat.
- **Escalation:** If the BCD identifies new risks for quality or compliance issues, these issues are escalated to the SB (and other relevant persons or bodies as appropriate).

8. Signatures

By complying with this Quality Policy, we make our contribution to quality in clinical research.

	Signature and date
SCTO EO	v.sarraf@scto.ch 11/01/2023 AES **Advanced electronic signature** Signed on Skribble.com
DKF Basel	Jörg Willers 05.01.2023 FES **Fortgeschrittene elektronische Signatur** Signiert auf Skribble.com
CTU Bern	Sven Trelle 09/01/2023 AES **Advanced electronic signature** Signed on Skribble.com
CRC Geneva	Isabelle Semac 04.01.2023 SEA **Signature électronique avancée** Signé sur Skribble.com
CRC Lausanne	Marc Froissart 04/01/2023 AES **Advanced electronic signature** Signed on Skribble.com
CTU-EOC Lugano	Alessandro Ceschi 09/01/2023 AES **Advanced electronic signature** Signed on Skribble.com
CTU St. Gallen	reinhard.maier@kssg.ch 05/01/2023 AES **Advanced electronic signature** Signed on Skribble.com
CTC Zurich	Regina Grossmann 05/01/2023 AES **Advanced electronic signature** Signed on Skribble.com