swiss
clinical
trial
organisation

SCTO REPORT: THE FRUITS OF OUR WORK

2017–2020

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Value

High-impact, patient-relevant clinical research

Promoting the next generation of clinical researchers

We foster high-quality results in clinical research by offering training, which in turn leads to higher impact and enhances Switzerland's international reputation.

As mandated by the Federal Office of Public Health (FOPH), the SCTO coordinates activities that implement the ideas in the national roadmap for developing the future generation of clinical researchers.

Via its Education Platform, the SCTO's Executive Office is currently leading and coordinating two work packages that are crucial to harmonising and standardising the development of a globally competitive clinical research workforce:

- Define clinical research core competences (CRCC) for sub-investigators, investigators, and sponsor-investigators. Since clinical research is a team effort, CRCC for other clinical research specialists will follow.
- Develop a web portal facilitating the path to clinical research careers in Switzerland, which will be called Clinical Research Careers (CR-Careers.ch). This platform is a collaboration between the SCTO, the Swiss Academy of Medical Sciences, and unimedsuisse. It will combine information on training, career support instruments, funding, mentoring, and core competencies, thereby assisting and orienting young clinicians interested in pursuing a clinical research career. The platform's launch is anticipated for autumn 2021. In the next step, other clinical research specialists will be considered as well.

Clinical Trial Unit Network

We coordinate an interconnected infrastructure network to facilitate high-quality and cost-effective clinical research in Switzerland.

The SCTO's Clinical Trial Unit (CTU) Network plays a key role in **facilitating academic clinical research in Switzerland at the local, operational level**. Acting as partner in academic clinical research, the CTU Network offers comprehensive support and represents the country's largest provider of training and services throughout all phases of a clinical study. Because it has been active since 2007, the CTU Network has developed a well-established and nationally coordinated clinical research infrastructure. As of 2017, each CTU also coordinates one of our SCTO Platforms focused on a key area of clinical research. More than 150 people work in the CTU Network.

CTU Network's added value: CTU performance indicators

CTU performance indicators are collected annually to demonstrate the added value and multiplying effect of the support the CTU Network provides researchers. These performance indicators feed into the diverse reporting mechanisms of the SCTO. In future, these indicators will be used in the impact monitoring and evaluation of the SCTO.

More information:

- CTU performance indicators in our previous annual reports
- CTU Network
- SCTO Platforms

ECRIN: A distributed research infrastructure

We are competent partners for implementing investigator-initiated trials (IITs) in multicentre and multinational settings.

Switzerland currently participates in about 20 – out of a European portfolio of 60 – clinical trials that are supported by ECRIN, the European Clinical Research Infrastructure Network (ECRIN). Through its CTU Network, the SCTO supports these trials as a scientific and service partner. All fee-based services are coordinated by the ECRIN European Correspondent (EuCo) for Switzerland, who is based at the SCTO.

ECRIN helps sponsors and investigators conducting multicentre, multinational trials to overcome the challenges of diverse and country-specific regulatory and administrative frameworks. ECRIN is a distributed research infrastructure – a network of networks that connects research facilities at multiple sites in countries across Europe – and it provides services for top-level clinical research. The SCTO has been given a mandate by the State Secretariat for Education, Research and Innovation (SERI) to represent Switzerland in the ECRIN consortium.

ECRIN's COVID-19 task force: Anticipating and reacting early to a changing environment

In response to the initially uncoordinated research activities related to COVID-19, the SCTO and its CTU Network contributed to the special COVID-19 task force established by ECRIN. This included contributions to the regulatory environment, literature, and study scanning, among others.

EOSC-Life
EOSC-Life aims to provide an open, collaborative space for digital biology in Europe by developing a comprehensive model for providing data and access tools via the cloud. This will empower life scientists and put largescale computation within the reach of all laboratories, with the aim of making Europe an international leader in data-driven research. The SCTO is a linked third party of ECRIN, which is a beneficiary in the project, and coordinates the contribution of CTU Network experts to distinct work packages.

EU-RESPONSE: Engaging with sustainable funding opportunities for academic clinical research projects
The EU-RESPONSE consortium, led by France's Institut national de la santé et de la recherche médicale (INSERM), brings together 21 partners with world-class research capabilities from 13 EU countries, Norway, Switzerland, and Turkey to build a European network for adaptive platform trials (APTs) for COVID-19 and emerging infectious diseases. APTs have an innovative randomised controlled trial design, which enables various therapies for a disease to be studied simultaneously. The project started in 2021 and will last for five years.

The SCTO is the EU-RESPONSE's project partner for Switzerland through its observer status in ECRIN, which will play a role in realising the project's key objectives.

SwissPedNet

We facilitate and promote clinical research in paediatrics.

The Swiss Research Network of Clinical Pediatric Hubs (SwissPedNet) facilitates national research in paediatrics on a countrywide scale and thus meets an unmet and urgent need for paediatric translational and clinical studies. Currently, about 300 clinical research projects are being run at the SwissPedNet's member institutions.

SwissPedNet consists of nine clinical paediatric hubs throughout Switzerland: within the five university children's hospitals in Basel, Bern, Geneva, Lausanne, and Zurich as well as in the cantonal children's hospitals in Aarau, Lucerne, St. Gallen, and the Ente Ospedaliero Cantonale (EOC) in Ticino. These paediatric hubs are complemented by two platforms: SwissPedPha and SwissPedRegistry. SwissPedPha provides services in paediatric pharmacology for all hubs; SwissPedRegistry works together with relevant organ and disease specialists to coordinate several national paediatric registries and cohort studies. SwissPedNet has become a reliable partner for researching paediatricians in their institutions; the SwissPedNet Coordinator is located at the SCTO.

To support young paediatric researchers, SwissPedNet organises regular get-togethers – for example the Translational and Clinical Research Session, which has become a yearly fixed point in young researchers' agendas since 2013, and the annual NextGen Research Day, which offers young paediatricians training and opportunities for exchange and interaction.

Exchange and contributions at the European level
Via the SCTO, SwissPedNet is a beneficiary of three European project consortia granted by the EU's Horizon 2020 programme (PedCRIN and Id-EPTRI projects) and the Innovative Medicines Initiative (IMI2 project conect4children (c4c)). SwissPedNet is a member of these consortia and acts as the Swiss hub. This European connection increases the visibility of SwissPedNet in Europe and brings interesting study projects to Switzerland.

PedCRIN is the paediatric branch of ECRIN, and it aims to develop capacity for managing multinational paediatric non-commercial clinical trials. PedCRIN was launched on 1 January 2017, and during its four-year term, PedCRIN effectively connected paediatricians with other partners across Europe to combine resources and expertise and to develop useful tools for conducting and managing robust studies while minimising risk and protecting child participants.

CONECT4CHILDREN (c4c) is a large collaborative European network that aims to facilitate the development of new drugs and other therapies for the entire paediatric population. It is a collaborative effort between industry and academia and is funded by the EU's Horizon 2020 programme and IMI2 Research and Innovation Actions (RIA). It was launched in May 2018 and will last for six years (until April 2024). c4c is a pioneering initiative that builds capacity to implement multinational paediatric clinical trials whilst ensuring that the needs of babies, children, youth, and their families are met.

c4c is currently conducting three investigator-initiated proof-of-viability studies. Two of the studies (cASPerCF and TREOCAPA) have sites in Switzerland, and four of the nine clinical paediatric hubs of SwissPedNet are involved. Switzerland was the first country after France (the sponsor country) to recruit patients for TREOCAPA, a neonatology study. cASPerCF opens in 2021.

Patient and public involvement (PPI)

We prioritise patient and public involvement and empowerment.

The success of clinical research in Switzerland depends not only on the goodwill of patients as participants in clinical trials but also increasingly on their **active involvement**. Patients can offer a unique perspective on research. Through their experience with a disease or condition, patients know best what matters most to them. By sharing this specific knowledge, they can contribute to the quality, appropriateness, relevance, and credibility of clinical research. From an ethical point of view, one can argue that patients should have an influence on research that affects them, along the lines of the motto "nothing about us without us". For in the end, today's clinical research is tomorrow's medicine.

The SCTO is committed to implementing and fostering patient and public involvement in clinical research. As a first step, we have established a **multi-stakeholder working group** with the aim to identify and characterise all PPI projects/initiatives that already exist in Switzerland. The results of this mapping exercise will lay a solid basis for advancing and implementing a holistic PPI approach.

More information:

- SCTO's PPI Fact Sheet
- "Enabling truly meaningful cooperation with patients", an interview with the SCTO's Communications and Stakeholder Engagement Director Cordula Landgraf

Patient empowerment through EUPATI CH

The European Patients' Academy on Therapeutic Innovation (EUPATI) provides education and training tools for representatives of patient organisations, including a one-year expert training course for patients, a patient advocate toolkit, and an online resource library. The national platform EUPATI Switzerland helps to distribute these tools and adapt them to national needs and peculiarities. It also serves as a point of contact for enquiries. The national platform EUPATI CH has existed as an association since 2016 and is led by patient representatives.

The SCTO facilitated the foundation of this national platform and hosts its secretariat. The SCTO regularly supports EUPATI CH with administrative tasks, fundraising, and project application processes. In addition, the SCTO brings together relevant Swiss stakeholders in R&D to join efforts in empowering patient representatives to actively engage in medicinal R&D processes.

Under the patronage of the SCTO and other stakeholders (defined by topic), EUPATI CH organises the annual **Swiss Patient Forum**. The last forum was held virtually early in 2021 on the topic of **patients in a pandemic**.

Guidelines for Good Operational Practice

We develop lean, harmonised processes.

The SCTO's Guidelines for Good Operational Practice (GGOP) represent a **framework of common standards for professional and operational practice in clinical research**. These guidelines are regularly updated and adapted to reflect the latest parameters in clinical research. The last revision (version 3.0) was completed by the SCTO and experts from the CTU Network in early 2018. The guidelines' next thorough review is planned during the 2021–2024 funding period and will be conducted by the SCTO's Auditing Platform.

The SCTO is proud to have our GGOP publication included in the International Compilation of Human Research Standards (2020 Edition), collated by the U.S. Department of Health & Human Services (HHS).

More guidelines:

- Guidelines for Risk-Based Monitoring and Risk-Based Monitoring (RBM) Score Calculator
- Data Management Guidelines and Guidelines for Risk-Adapted Monitoring

Innovation

Clinical research that provides reliable answers to current questions

SCTO Platforms

We ensure harmonisation and innovation with our interconnected network.

Increasing the quality of research is crucial to enhancing its impact, while simultaneously eliminating unnecessary waste, redundancy, and duplication. In line with our goals of supporting the successful development of new therapies and improving existing treatments, we established eight topic-based platforms in 2017.

SCTO Platforms serve as pools of expertise: each platform consists of a team with expertise, skills, and knowledge related to one key field of clinical research. Because SCTO Platforms are **interconnected**, they facilitate networking within the SCTO's CTU Network and act as **incubators of innovation**. Their members aim to not only provide leadership and share resources but also inspire one another, revitalise their fields, and keep apace with the latest trends and best practices.

Support for national and international stakeholders

Our platforms strive to assist the following national and international stakeholders in a variety of ways:

- competent authorities and ethics committees by promoting (inter)national harmonisation and the simplification of processes
- clinical researchers, sponsors, and their teams (from industry and academia) by setting national standards, making recommendations (e.g. facilitating multicentre studies), ensuring international compatibility, and promoting skills training and maintenance
- other partners by serving as an information hub
- patients by supporting patient empowerment and fostering the active involvement of patients and the public in academic clinical research (PPI).

SCTO Platforms provide a variety of benefits to clinical research, including:

- increased and accelerated **harmonisation** and **cooperation nationwide** through the exchange and dissemination of know-how
- useful recommendations and relevant resources, including **practical tools**
- clear **national points of contact** for specific topics
- greater exchange and alignment with the **European and the international research communities**.

During the 2017–2020 funding period, SCTO Platforms **developed a variety of ready-to-use tools**:

- free online safety training for clinical study staff to consolidate or refresh their knowledge about patient safety and reporting considerations in clinical research, developed by the Education and Safety platforms;
- a framework of clinical research core competencies (CRCC) that investigators and sponsor-investigators should acquire throughout their career, developed by the Education Platform;
- a web portal named Clinical Research Careers that provides the following: centralised information on the various career paths physicians can follow, overviews or filtrable databases on career support and funding instruments, postgraduate training opportunities, mentoring programmes, and a clinical research core competencies (CRCC) framework, developed by the Education Platform and co-funded by the Swiss Academy of Medical Sciences, unimedsuisse, and the SCTO;
- an online resource tool for clinical research management named Easy Guide to Clinical Studies (Easy GCS) that provides short and straightforward information on all aspects of managing clinical studies, from set-up to completion, developed by the Project Management Platform;
- *Regulatory Affairs Watch*, an online journal that regularly shares news of a scientific and regulatory nature from Switzerland and abroad and aims to reach a wide, national audience of human research professionals, issued by the Regulatory Affairs Platform;
- diverse risk assessment tools and risk-based resources to facilitate improved and more informed decision-making and to better plan available resources, developed by the Auditing and the Monitoring platforms;
- pilot audits at two CTUs with specifically established tools and auditing training opportunities to boost the CTU Network's auditor pool, conducted by the Auditing Platform;
- templates for monitoring plans and monitoring visit reporting, Guidelines for Risk-Based Monitoring (Risk-Based Monitoring (RBM) Score Calculator and User Instructions), and the fact sheet Central Data Management in Clinical Trials, all developed by the Monitoring Platform;
- unified data processing solutions throughout the CTU Network with the secuTrial® R package published on CRAN, GitHub, and the Anaconda Cloud, developed by the Data Management Platform;
- open-access statistical tools developed by statisticians from the CTU Network as part of an annual competition for a grant to develop statistical

codes or programmes, initiated by the Statistics & Methodology Platform;
– guidelines for sharing clinical research data, with particular reference to the national context and applicable laws, developed by the Statistics & Methodology Platform in collaboration with the Data Management Platform;
– an annual safety reporting template and a serious adverse event (SAE) reporting template, developed by the Safety Platform.

More information:
Visit the SCTO Platforms' Tools & Resources website to browse through all of their resources: www.sctoplatforms.ch

Coordination and networking
The **SCTO Liaison Officers** provide a link between the SCTO Executive Office and the platforms while also supporting them in the implementation of their projects and the release and publication of their tools.

In order to facilitate networking between themselves and present their activities and tools to each other, the platforms hold a **joint biannual event**.

More information:
SCTO Platforms Event in 2020

Swiss clinical Trials Empirical Assessment & Methods (STEAM)

We make clinical research leaner and meaner.

The SCTO supports the Swiss clinical Trials Empirical Assessment & Methods (STEAM) working group, which aims to increase the overall value of clinical research in Switzerland. The working group collects challenges encountered in clinical studies and incorporates the findings of **research on research (RoR)**, e.g. tools and guidelines, into:
– teaching and training for Swiss clinical researchers
– CTU services (e.g. consulting, monitoring, data management, and statistics) for clinical researchers.

In addition, the STEAM working group links Swiss RoR efforts with international initiatives. STEAM members helped organise the **SCTO Forum** on the topic of "Research on research: From starting blocks to finishing line" in January 2020.

More information:
– Swiss clinical Trials Empirical Assessment & Methods (STEAM) working group
– SCTO Forum "Research on research: From starting blocks to finishing line"

Visibility

Clinical research news that is objective and shared with all parties involved

SCTO events

We organise events that allow direct interactions and promote discussions of controversial issues.

SCTO Forum

For ten years, the SCTO has been anticipating and unravelling compelling topics in clinical research by bringing together **key Swiss stakeholders** at its annual forum to network, learn, debate, and ask questions. Each year, the SCTO invites representatives from academic clinical research, the pharmaceutical industry, institutions for research development, and Swiss ethics committees to its forum to present and discuss their perspectives on hot and controversial topics in the field of clinical research.

The 2021 SCTO Forum asked highly relevant questions: How can **clinical research results** be **communicated in the most effective way to diverse audiences**? How can we do better than we have so far in the COVID-19 pandemic? How can we ensure a circular flow of information rather than one-way communication?

More information:
- Podcasts SCTO Forum 2021 on Vimeo
- Programme for the SCTO Forum 2021
- Reports and presentations from our previous forums

SCTO Symposium

At our SCTO Symposium, we spend the day exploring the challenges and solutions that lie ahead in clinical research. This annual SCTO event, which we have been jointly organising with our member institutions since 2010, is open to all those interested in the latest developments in dynamic research areas. Each year, **international experts** take a deeper look at current trends in translational and clinical research on both the scientific and political levels. In addition, the event offers the opportunity to **network beyond Swiss borders**.

The 2021 SCTO Symposium was initially planned for June 2020 but had to be postponed to June 2021 due to COVID-19 restrictions and the postponement of the European Medical Devices Regulation. Yet its topic **Medical Devices: Lost in Translation?** remains highly relevant in 2021.

More information:
- Programme SCTO Symposium 2021
- Reports and presentations from our previous symposiums

Seminar for scientific journalists

From 2014 to 2019, the Swiss Academy of Medical Sciences (SAMS), Interpharma, and the SCTO organised a health seminar aimed primarily at science journalists and stakeholders from the science environment. The seminars offered an overview of where we stand at present with regard to current topics such as:
- New Opportunities in the Health Field, Thanks to Improved Coordination and Quantification (2019)
- Better Medicine, Thanks to Data? The Uses and Challenges of Personalised Health and Big Data (2018)
- Fighting Cancer Cells with the Immune System: Benefits and Challenges of Immune and Combination Therapies (2017).

More information:
Seminar for science journalists

Trinational congress on clinical trials in Germany, Austria, and Switzerland (D|A|CH)

Every other year, the SCTO organises the trinational DACH Symposium together with the coordination centres for clinical studies in Germany and Austria. The DACH Symposium is aimed at all those involved in clinical trials: study nurses, study coordinators, medical experts, monitors, data managers, project managers, pharmaceutical industry representatives, and patients.

The second congress in 2018 was held in Zurich and attracted about **600 participants**. The 2020 congress was postponed to 2021 and will take place as a virtual seminar series. Participants may register for individual modules, so they can target which specific areas of clinical trials they want to delve into.

More information:
Trinational congress on clinical trials in Germany, Austria, and Switzerland (D|A|CH)

Social media

We are continuously and systematically expanding our social media presence.

In 2019, the SCTO joined the social media sphere, starting with **Twitter** as @SwissClinTrial. We reach out regularly, fostering open dialogue with followers in Switzerland and beyond on #humanresearch, #clinicalresearch, and #patientengagement.

Look out for news about our 8 SCTO Platforms, each with its unique hashtag: #SCTOauditing, #SCTOdatamanagement, #SCTOeducation, #SCTOmonitoring, #SCTOprojectmanagement,

#SCTOregulatoryaffairs, #SCTOsafety, and #SCTOstatsmethodology.
Follow us on @SwissClinTrial for tweets on the latest news, events, and initiatives.

In 2020, we joined the professional networking service **LinkedIn** as part of our strategic priority to strengthen ties with all parties involved in clinical research. We are looking forward to fostering our ongoing dialogue with longstanding partners and establishing new contacts on this digital platform.
Join our professional community on LinkedIn.

In addition, we use the **Vimeo** channel to showcase video interviews, such as two interviews from 2020 with our Communications and Stakeholder Engagement Director Cordula Landgraf and with Prof. Peter Villiger, principle investigator of the CORON-ACT study, a Swiss multicentre randomised controlled trial (RCT) aimed at combatting COVID-19.

Watch our videos on Vimeo:
- The CORON-ACT study: An example of a Swiss multicentre trial to combat COVID-19
- Interview with Cordula Landgraf: "Enabling truly meaningful cooperation with patients"

Positioning and media presence

We support optimal framework conditions for Swiss clinical research.

In line with our overall goal to ensure that Switzerland remains an attractive location to conduct clinical trials in the future, we **implemented a horizon scanning** and **issues management process** to address issues as early as possible and thus help to prevent them from turning into a crisis.

We regularly publish statements on topics and issues we have identified – for example, in 2020 the SCTO commented on two highly controversial Swiss popular initiatives:

- "No" to the Limitation Initiative – Preserve favourable conditions for research and innovation in Switzerland
- A statement on the Swiss popular initiative for a testing ban on humans and animals (in French and German)

More information:
SCTO statements

Media coverage

General interest in clinical research in Switzerland has increased considerably during the last four years. The global trend towards **more open and participative clinical research** is reflected in a greater media interest in topics such as ethical standards, overall transparency in science, and the insufficient publication of clinical research results.
As the central cooperation platform for patient-oriented clinical research in Switzerland and as part of our mandate to facilitate the integration of national clinical research with international networks, the SCTO regularly answers questions from the media on topics about clinical research in Switzerland.

More information:
Media articles

SCTO newsletter

We provide high-quality and independent information.

Our regular newsletter keeps readers up to date on relevant **national and international news related to clinical research**. In addition, our newsletter keeps them informed about current projects in our networks and platforms. We also give reading recommendations for interesting articles or relevant videos. Our newsletter community includes 3,000 readers from Switzerland and other countries, for example Germany, France, Italy, the UK, and the USA.

Register for the SCTO newsletter to stay up to date on national and international news related to clinical research.

To stay informed about **local news from Swiss clinical research departments and CTUs within our network**, register for the individual newsletters from our network.

Sharing one spirit and speaking with one voice: Internal communication

To align communication activities within and between members of the CTU Network, we established a **communications hub** in 2020. In addition to our regular meetings, an internal newsletter keeps members of the SCTO and its CTU Network up to date, including members of our boards, our observers, and platform coordinators.

More information:
CTU Network

Exchange with partners

We ensure that communication flows effectively.

To promote information exchange between partner organisations, and to improve overall future collaboration, the managing directors of the Swiss Personalized Health Network (SPHN), the Swiss Biobanking Platform (SBP), and the SCTO invite each other to their respective board meetings.

Experts from the **Swiss Group for Clinical Cancer Research** (SAKK) actively collaborate with the SCTO's topic-based platforms. Furthermore, the SAKK and SCTO collaborate in specific fields of common interest in clinical research. One of the areas where they have joined forces is summarising clinical trial results in lay language. Two joint events on this topic have come out of this collaboration.

More information:
Contributions to good lay summary practice

Framework

Consistent, practice-oriented implementation of the Human Research Act

Legal basis: Human research legislation

In Switzerland, how research involving humans is conducted is governed by the Human Research Act (HRA) and its implementing ordinances. This legislation is designed to safeguard the dignity, privacy, and health of people involved in research.

The Coordination Office for Human Research (kofam), operated by the Federal Office of Public Health (FOPH), undertakes a coordinating role in the area of human research in Switzerland and provides information to the general public and to researchers.

Collaboration with authorities

The SCTO's Regulatory Affairs Platform organises a roundtable for the Swiss research community and authorities each year. This roundtable provides an important exchange platform to discuss with Swissmedic and swissethics issues and challenges related to the implementation of the Human Research Act (HRA). Topics mainly cover the changing regulatory landscape at the European level, such as the EU's General Data Protection Regulation (GDPR), Clinical Trial Regulation, or new medical devices regulations. Many different kinds of national challenges are addressed at the roundtable as well.

Public consultations

Evaluation of the Human Research Act

The SCTO contributed to the evaluation and revision of the Human Research Act (HRA) by participating in working groups and projects, including:

- a working group initiated by the Federal Office of Public Health (FOPH) comprised of representatives from groups of relevant stakeholders;
- a survey project on descriptive statistics in the HRA (using BASEC data), executed jointly by the SCTO's CTU Network, Cochrane Switzerland, and the Basel Institute for Clinical Epidemiology and Biostatistics.

Complete revision of the Medical Devices Ordinance and the Ordinance on Clinical Trials with Medical Devices

Through its CTU Network and Regulatory Affairs Platform, the SCTO coordinated contributions to the public consultation of the total revision of the Medical Devices Ordinance (MedDO) and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). Furthermore, the SCTO network provides training for research teams on how to comply with these regulations.

Contributions to good lay summary practice

The EU Clinical Trial Regulation requires a lay summary of trial results to be disseminated in accessible language within 12 months after the end of the study and even earlier, within 6 months, for paediatric trials. In response to this, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Forum for Good Clinical Practice (EFGCP) put in motion the Roadmap Initiative to Good Lay Summary Practices. The SCTO and EUPATI CH, the Swiss national platform of the European Patients' Academy on Therapeutic Innovation, both contributed to this initiative.

In addition, the SCTO, its Regulatory Affairs Platform, and SwissPedNet contributed to the EU Commission's public consultation on recommendations for good lay summary practice. Together with its partner organisation the Swiss Group for Clinical Cancer Research (SAKK), the SCTO submitted comments to the Good Lay Summary Practice document.

Moreover, the SCTO and the SAKK developed a concept for **two joint events in 2021**: the SCTO Forum and the SAKK Symposium, both of which address good lay summary practice with the goals to raise awareness of the topic within Switzerland and provide information on how to best prepare for this new requirement.

GDPR and its impact on Swiss clinical research

The first issue of our Regulatory Affairs Platform's online journal *Regulatory Affairs Watch (RA Watch)* featured a deep dive article on the EU's General Data Protection Regulation (GDPR) and its implications for Switzerland.

General consent

Under the Swiss Human Research Act (HRA), patients who agree to the further use of their data and samples for potential research projects need to give their written informed consent (referred to as *general consent*, or GC).

In order to establish a harmonised, nationwide basis for this type of informed consent, the Swiss Academy of Medical Sciences (SAMS) and the Swiss Association of Research Ethics Committees (swissethics) established a task force (supported by the SCTO) and published a general consent template for Switzerland in 2017. Based on experience with this template and in consultation with the SAMS, unimedsuisse (a Swiss association of university medicine) published a revised version in autumn 2018, which was prepared by a university hospital working group.

The third issue of our RA Platform's online journal *RA Watch* featured a deep dive article on general consent.

What's next?

Clear guidance and best practices for clinical research projects falling under the Human Research Ordinance

From 2021 to 2024, SCTO Platforms will place an emphasis on supporting clinical research projects falling under the Human Research Ordinance (HRO). Increasingly more projects are being run in this field; however, **clear guidance and best practices are still missing**. The SCTO's topic-based platforms will work on closing this gap in order to support the clinical research community and help improve the quality of such projects.

Impact monitoring for better clinical research infrastructures

Does the SCTO provide a return on investment? In order to get clearer answer to this question, the SCTO is planning to build up a **monitoring system for its impact and performance as a research infrastructure**. Furthermore, at the European level, we are leading a task force to establish an impact monitoring system for ECRIN. This will allow us to collect valuable information on how a research infrastructure can be evaluated by adapting it to a national context.

Implementing patient and public Involvement (PPI) in academic clinical research

The SCTO is committed to implementing and fostering patient and public involvement in clinical research. Therefore, one of our key strategic goals for the current 2021–2024 performance period is to work together with all relevant stakeholders to establish a **central coordination and contact point** that is pathology-independent and works across organisations (working title: Swiss PPI Hub). The conceptional framework will build upon the results of a mapping exercise that has already started.

Regional clinical research infrastructure clusters (CRICs)

The SCTO plans to collaborate more closely with other institutions and infrastructures involved in clinical research in Switzerland. Regional CRICs bring together cantonal and private hospitals and other clinical research organisations from one region to **exchange ideas, learn from each other, and harmonise processes**. The local CTU is in the lead for all CRIC activities in its region. The SCTO's Executive Office supports CTUs in administrative matters and promotes the national importance of this initiative.

Virtual inter-university faculty for clinical research

Clinical research is a complex enterprise, and experience has shown that high-quality clinical research leading to patient-relevant results is best performed by **multidisciplinary teams with complementary sets of skills**. Extending the Clinical Research Careers web portal to all clinical research professionals would improve the coordination of clear and defined pathways for various clinical research careers, and it would enhance the overall quality of clinical research in Switzerland, thus increasing its visibility.

Swiss early development network

In order to **close the translational gap and best utilise the existing expensive infrastructure for early development**, the SCTO suggests building up a Swiss network to improve the collaboration of existing facilities. The aim is not to create a new infrastructure, but to build a national network that coordinates existing local expertise and facilities, focusing on the common denominator of early development.

Organisation

The Swiss Clinical Trial Organisation (SCTO) is an independent organisation and is based on a joint initiative of the Swiss National Science Foundation and the Swiss Academy of Medical Sciences. As of 2017, the SCTO is **a research infrastructure of national importance** funded by the State Secretariat for Education, Research and Innovation and the Swiss National Science Foundation.

The SCTO is a Swiss not-for-profit association based in **Bern**. Our ordinary members are the five Swiss university hospitals, the cantonal hospital in St. Gallen, the Ente Ospedaliero Cantonale (EOC) in Ticino, the Swiss Academy of Medical Sciences (SAMS), and the Collège des Doyens (Deans of the medical faculties of the Swiss universities). As a not-for-profit institution involved in clinical research, the Swiss Paraplegic Centre (SPC) in Nottwil is the SCTO's first associated member.

The **Steering Board** runs the SCTO from a strategic point of view and consist of representatives from the member institutions. The **Executive Office** in Bern manages the day-to-day business of the organisation. The **Advisory Board** is an independent committee that supports the Steering Board in strategic decision-making.

The SCTO's primary objective is to catalyse valuable, innovative, and visible clinical research in Switzerland so as to deliver better therapies to society.

More information about us
– Members and boards
– Executive Office
– Vision and mission

Contact

Do you have any questions or want to give us feedback?
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