

swiss
clinical
trial
organisation



2021 ANNUAL REPORT

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Editorial

Dear reader,

As a reference institution for patient-oriented clinical research in Switzerland, the Swiss Clinical Trial Organisation (SCTO) has been liaising ever since 2009 between stakeholders and continues to offer the necessary access to national and international networks and platforms. Our driving principle is to catalyse **valuable, innovative, and visible clinical research in Switzerland so as to deliver better therapies to society**.

What were our highlights in 2021? Did we walk the talk?

This annual report offers you an overview of our main achievements. We cordially invite you to dive deeper into the following highlights of the SCTO's Clinical Trial Unit (CTU) Network, topic-based platforms, and Executive Office:


- We took a major step forward in fostering **patient and public involvement (PPI)** in clinical research in Switzerland by working closely together with PPI representatives from different organisations and by providing practical information, overviews, and an online course for different stakeholders concerned.
- We continued to invest in providing **tools and resources for the academic clinical research community** and improving their accessibility (resulting in over 1,000 visitors within six months to our SCTO Platforms' new website [Tools & Resources](#)).
- We contributed to **European clinical research and projects** via [ECRIN](#), [EU-RESPONSE](#), [SwissPedNet](#), and [conect4children \(c4c\)](#).
- We continued to foster the **dialogue with national authorities**, for example by jointly organising a roundtable with Swissmedic and swissethics and by initiating other interactions.
- We heavily invested in the **education and training of the next generation of clinical researchers** by providing a new portal for young researchers ([Clinical Research Careers](#)), by (co-)organising numerous national and international events, and by training over 8,000 participants in close to 200 courses at the local CTU level.
- We contributed to several media publications against the initiative “Yes to the ban on animal and human research” and issued **statements and publications** on other relevant topics for clinical research.

Many of these achievements were possible thanks to **trusting and fruitful partnerships with stakeholders and partner organisations**. We thank our network, its collaborators, and our partners, whose work and commitment contributed to the collaborative spirit and promising developments of the past year!

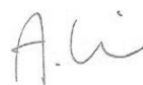
The results we achieved in 2021 profoundly and sustainably support our primary objective to deliver **better therapies to society**. We will continue to base our new and ongoing activities on past achievements and experiences while regularly adapting them to reflect the latest developments in the dynamic field of clinical research.

We thank you for your interest in our activities.

Yours sincerely,



Prof. Christiane Pauli-Magnus
President



Annette Magnin
Managing Director

Strategy 2021–2024

2021 marked the start of a new four-year funding period for the SCTO and its CTU Network. Based on the two mandates we received from the State Secretariat for Education, Research and Innovation and the Swiss National Science Foundation, we revised our strategy and adapted it to new developments and technological advances in clinical research.

Our strategic and operational priorities for 2021–2024 are based on the **three main pillars supporting our vision and mission statements**:

- value and innovation
- education and the next generation
- visibility and transparency.

Over these next four years, we are focusing on **clinical research governed by Switzerland's Human Research Ordinance**. This includes observational clinical research as well as research with data and biological samples. Our [topic-based platforms](#) complement our partners' activities in this area by offering methodological and technical support, training opportunities, and regulatory guidance.

In addition, our strategy focuses on promoting and **implementing [patient and public involvement \(PPI\)](#) in academic clinical research**.

Because we aim to achieve results that are sustainable and broadly supported, our implementation strategy includes long-term goals that extend beyond the current four-year funding period. We base our future activities on past achievements and experiences while regularly adapting them to reflect the latest developments and requirements of the research community, regulatory authorities, and international stakeholders.

Visit our main website to learn more about our strategic priorities for 2021–2024: [Strategic priorities for 2021–2024](#).

Highlights

Patient and public involvement (PPI)

A partnership based on both mutual trust and transparent communication is what forms the foundation of a dialogue between researchers and those affected by research. One of our most important strategic objectives for the funding period 2021--2024 is to promote patient and public involvement (PPI) in academic clinical research in Switzerland and to implement it in a sustainable manner. To this end, we are currently focusing on coordinating and streamlining existing PPI initiatives with the aim to reduce parallel efforts and use synergies. Together with other national stakeholders and patient initiatives, we are bundling forces to develop and implement a national PPI strategy that makes patients an integral part of the clinical research process.

Identifying the status quo and preparing the ground for a national PPI strategy

As a first step, we established a multistakeholder working group. Together with this group and SCTO partner organisations, we conducted an online survey to identify and characterise **all PPI initiatives and projects that already exist in Switzerland**. The results of this survey are presented on the dedicated [PPI mapping](#) section of our website, which shows all PPI initiatives and projects identified in Switzerland. This first step provided a solid basis for determining the status quo of PPI in academic clinical research in Switzerland.

In addition, we compiled a **fact sheet explaining the overall concept of PPI**, its benefits and challenges, and how it can be incorporated into clinical trials. Furthermore, we published a **practical guide for researchers on how they can address PPI in clinical trials**. This guide aims to help researchers who are planning a clinical research project and seeking potential funding find appropriate ways to ensure effective and meaningful PPI in their clinical trials. Both documents were prepared in close collaboration with the Swiss National Science Foundation

(SNSF) and are available on our main website under the section [Patient and public involvement](#).

The topic of PPI was also explored from the perspectives of various important stakeholders in the October 2021 issue of our **Regulatory Affairs Platform's professional magazine** [Regulatory Affairs Watch](#). The authors illustrated where active Swiss stakeholders, such as the Swiss National Science Foundation and the Swiss Agency for Therapeutic Products (Swissmedic), stand on this subject and how they are promoting PPI in clinical research.

Outlook: All stakeholders on board!

As a second step, we envision establishing a centralised coordination hub and point of contact for all PPI stakeholders in academic clinical research. This PPI hub's activities will span organisations and diseases. The conceptional framework for this Swiss PPI hub will be built upon the results of the mapping exercise performed in the first step. This PPI hub will be inclusive and open to all interested stakeholders within the field of academic clinical research.

Supporting best practices: Tools and resources for the academic clinical research community

The SCTO Platforms form an interconnected, nationwide network that provides practical resources and innovative tools for clinical research professionals. By combining their efforts and Swiss clinical research expertise, the SCTO Platforms develop best practices, standards, and tools that are freely available to the clinical research community.

Promoting networking throughout the country

Each platform consists of a team with expertise and skills related to a key area of clinical research. Each Clinical Trial Unit (CTU) in our CTU Network runs a platform, and each platform includes staff from all CTUs. Collaboration within and between the platforms as well as with partner organisations and external experts promotes networking throughout the country and enables the platforms to be incubators of innovation. In June 2021, we launched the new Tools & Resources website to increase the visibility of the platforms and their products and to facilitate measuring their performance.

5 new tools in 2021

The SCTO Platforms are continually developing new practical tools. The following tools were developed in 2021:

- [Monitoring Site Initiation Visit Report Template](#) (Monitoring Platform)
- [presize: Precision-based sample size calculation](#) (Statistics & Methodology Platform)
- [Set of comprehensive forms for safety reporting](#) (Safety Platform)
- [Clinical Research Core Competencies Framework](#) (Education Platform)
- [Clinical Research Careers website](#) (Education Platform)

5 new publications and guidelines in 2021

Our SCTO Platforms' publications provide guidance and keep the clinical research community up to date. Publications in 2021 include:

- [a guidance document on sharing data from clinical research projects](#) (Statistics & Methodology Platform)
- [a guidance document on the requirements for electronic health record \(EHR\) systems](#) when using them for clinical research purposes in Switzerland (Regulatory Affairs Platform)
- [an evaluation report of clinical data management systems](#) (Data Management Platform)
- Two new issues of [Regulatory Affairs Watch \(RA Watch\)](#) were published, highlighting COVID-19 and patient and public involvement in clinical research. In addition, an entire section of the Tools & Resources website is dedicated to RA Watch. Readers can write comments and download a PDF of individual articles, thus making it easier to exchange ideas and cite articles.

All tools and publications from the SCTO Platforms are available on the [Tools & Resources website](#).

2021 key figures for the Tools & Resources website

In 2021, **more than 1,000 new users visited the website in after its launch in June**. Users downloaded tools **247 times** and voluntarily provided their personal data to help us interact with them and continually improve the website.

Swiss contribution to European clinical research and projects

In 2021, Switzerland participated as an active partner in large European projects funded through the European Union. The SCTO's CTU Network provides services to these trials.

Several large European projects aim to prepare Europe for an increased threat of coronavirus variants. For example, as part of the European bio-defence preparedness plan called HERA Incubator, these projects aim to build a European network for adaptive platform trials (APTs) for COVID-19 and emerging infectious diseases.

The SCTO's CTU Network provides consulting, regulatory support, monitoring, and project management services to these trials. Since 2021, Swiss researchers have been excluded as coordinators of EU grant applications due to the non-associated status of Switzerland; therefore, none of the projects are being led by Swiss researchers.

- [HERA Incubator – a European bio-defence preparedness plan](#)
- [Adaptive platform trials \(APTs\): definition, design, conduct and reporting considerations](#)
- [Clinical Trial Unit \(CTU\) Network performance indicators](#)

SCTO acts as project partner for Switzerland in the EU-RESPONSE project

The EU-RESPONSE project (EUropean RESearch and Preparedness netwOrk for pandemics and emerging iNfectious diseaSEs) launched several clinical trials to test treatments for COVID-19 and other emerging infectious diseases. One of these trials is the EU-SolidAct, an adaptive platform trial currently investigating baricitinib in patients with severe COVID. The trial is recruiting patients in 14 countries, and Switzerland has initiated the process to join Eu-SolidACT. APTs have an

innovative randomised controlled trial design, which allows various therapies for a disease to be studied simultaneously. The SCTO is the project partner for Switzerland through its observer status in ECRIN (European Clinical Research Infrastructure Network), which will play a role in the realisation of the project's key objectives.

- [EU-RESPONSE](#)
- [EU-SolidAct – a pan-European platform for pandemic research and preparedness](#)
- [ECRIN](#)

Three Swiss paediatric centres contribute to European study

SwissPedNet (Swiss Research Network of Clinical Pediatric Hubs) and the CTU Network continue to contribute to the TReOCAPA study (Prophylactic TReatment Of the duCtus Arteriosus in Preterm infants by Acetaminophen) on preterm babies. The study aims to assess the effectiveness of paracetamol on the closure of the ductus arteriosus in very preterm infants. The study is part of the pan-European paediatric clinical trial network c4c (conect4children), which is funded by the European Union's Horizon 2020 programme and IMI2-RIA (Innovative Medicines Initiative 2 – Research and Innovation Action). The study is being performed in Zurich, Geneva, and Lausanne, with Zurich being the first centre in Europe that recruited patients and the centre with the highest recruitment rate.

- [SwissPedNet](#)
- [conect4children \(c4c\)](#)
- [TReOCAPA – a c4c study](#)

Fostering dialogue with national authorities

Over the years, the SCTO has initiated various regular and ad hoc exchanges with national authorities involved in clinical research. One example is the annual roundtable with representatives of Swissmedic, swissethics, and the SCTO's CTU Network. In 2021, this roundtable served as a valued platform to exchange ideas and information on the current hot topics listed below and to reflect on potential new projects or initiatives for cooperation.

Innovative technologies in clinical trials

Thanks to the use of innovative technologies in clinical trials, study visits no longer necessarily have to be carried out in a hospital; they can also take place at home and are therefore decentralised. With their patient-centred approach, these **decentralised clinical trials (DCTs)** bring new opportunities but also pose new challenges for all those involved. At the roundtable, **swissethics and Swissmedic presented their shared position on DCTs.**

In a joint position paper published in September, Swissmedic and swissethics summarised the main, current challenges of DCTs with medicinal products and showed under which conditions such clinical trials could be conducted in Switzerland. The paper is addressed to researchers and sponsors as well as all those interested in clinical research.

– [Position paper by Swissmedic and swissethics on decentralised clinical trials \(DCTs\) with medicinal products](#)

New requirements and new authorisation procedures for medical devices

At the 2021 roundtable – which took place 100 days after the introduction of the EU's Medical

Device Regulation (MDR) and its Swiss ordinances (e.g. ClinO-MD) – swissethics and Swissmedic shared their initial **experiences and recommendations on the new requirements and authorisation processes.**

– [Swissmedic: Clinical trials with medical devices](#)

Greater emphasis on clinical research projects falling under the Human Research Ordinance

The SCTO Platforms informed the authorities at the 2021 roundtable about their overarching topic for the current funding period (see also our strategic outline in this report): from 2021 to 2024, the 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, there is currently a lack of clear guidance and best practices. 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.

Education and the next generation

Continually enhancing the quality and the outcomes of translational and clinical research is of high priority in order to allow Switzerland to remain internationally attractive and competitive in the field. In this regard, promoting young clinical researchers, setting up appropriate programmes, and improving working conditions and career opportunities are all essential for maintaining and enhancing the sustainability of the academic working environment.

Roadmap for developing the next generation of clinical researchers in Switzerland

The Roadmap 2016–2021 for Developing the Next Generation of Clinical Researchers, published in 2016 by the Federal Office of Public Health (FOPH), defined five specific measures which have mostly been successfully implemented by various stakeholders in the field.

The SCTO was mandated by the FOPH to coordinate the implementation of this roadmap and has contributed substantially to two of its work packages (WPs): defining core competencies (WP2) needed to run clinical trials and developing a clinical research careers website (WP3, see both projects below).

The projects defined within this roadmap will continue to develop in accordance with the goals, recommendations, and measures formulated in the White Paper: Clinical Research, which was published in July 2021 by the Swiss Academy of Medical Sciences (SAMS). Indeed, the White Paper: Clinical Research suggests how to use resources more efficiently and how to align efforts along common priorities; it also includes the development of the next generation of professionals in clinical research. The SCTO will continue supporting related activities.

- [Roadmap 2016–2021 for Developing the Next Generation of Clinical Researchers](#)
- [White Paper: Clinical Research](#)

Centralised source of relevant information for the academic community

Two of the five work packages defined within the FOPH's Roadmap 2016–2021 for Developing the Next Generation of Clinical Researchers (see above) were allocated to the SCTO and its Education Platform: defining core competencies needed to run clinical trials (WP2) and developing a clinical research careers website (WP3).

Interactive core competencies framework

To facilitate the acquisition of uniform professional qualifications in clinical research, the core competencies needed to run clinical trials were defined and put into a Clinical Research Core Competencies Framework. This framework is based on the internationally recognised Core Competency Framework developed by the Joint Task Force (JTF) and includes regulations and guidelines applicable in Switzerland. It is available online and contains links to the various training opportunities provided by the **CTU Network**. It aims to guide the academic community in the development of training options and the support of researchers throughout their careers.

Dedicated website that guides young physicians throughout their careers

The Clinical Research Careers website was developed through a collaboration between the SAMS, the SCTO, and unimeduisse. The website was launched online in September 2021 and has already been visited more than 2,000 times. It provides all relevant information in one place and aims to help medical students and young physicians make their way in the complex and exciting field of clinical research. The website contains searchable databases of career support, funding and mentoring programmes, and postgraduate training options in Switzerland. It also includes the Clinical Research Core Competencies Framework (see above) as well as inspiring success stories of physicians who combine clinical research and clinical duties.

- [Education Platform](#)
- [Core Competency Framework](#)
- [Clinical Research Careers website](#)
- [Joint Task Force for Clinical Trial Competency \(JTF\) framework](#)
- [CTU Network](#)

Training and further education opportunities provided by the SCTO's Clinical Trial Unit Network

One of the major drivers of high-quality clinical research is knowledge and expertise. Indeed, well-educated and well-trained project leaders and research collaborators is of paramount importance to keep Switzerland at the forefront of biomedical research. Since its establishment, one of the priorities of the SCTO and its CTU Network has been to continually develop and harmonise up-to-date and innovative training opportunities that are adapted to a constantly changing environment. For example, many training options needed to be adapted to the Ordinance on Clinical Trials with Medical Devices (ClinO-MD), which entered into force in May 2021.

An overview of all the training opportunities in the entire CTU Network is available on the Clinical Research Careers website. The website allows all clinical research professionals to find the best training option for their own career advancement.

– [Training opportunities in the entire CTU Network](#)

Training for more than 8,000 individuals in 2021

In 2021, the CTU Network provided 190 training courses and trained more than 8,000 individuals who are active in clinical research. These numbers reflect both online and on-site courses.

While training opportunities included postgraduate training (CAS, DAS, MAS), research ethics and good clinical practice (GCP) courses, and other shorter training options and seminars, the various research ethics and GCP courses had the largest attendance (80%). This high attendance comes from the fact that this training is mandatory for investigators and sponsor-investigators running clinical trials.

Moreover, in a relatively short amount of time (two- or three-day courses), this training provides research teams with a good overview of the most important elements to keep in mind when running clinical research projects.

Partnering with stakeholders and relevant organisations

In 2021, the SCTO and its CTU Network continued to foster their cooperation with key stakeholders and partner organisations with the objective of avoiding the duplication of efforts, using synergies where possible and speaking with one voice for the benefit of academic clinical research in Switzerland.

Regular exchange with the Swiss Biobanking Platform and Swiss Personalized Health Network

In order to align activities with complementary clinical research infrastructures, a regular meeting with the Swiss Biobanking Platform (SBP) and the Swiss Personalized Health Network (SPHN) was put in place. The aim of these meetings is to address topics of mutual interest and share expertise.

- [Swiss Biobanking Platform \(SBP\)](#)
- [Swiss Personalized Health Network \(SPHN\)](#)

Swiss Group for Clinical Cancer Research and SCTO join forces on lay summaries of clinical trial results

Based on the new EU requirement to provide the results of clinical trials in lay language (Art. 37 of the EU's Clinical Trials Regulation (CTR)) of the European Parliament and of the Council on clinical trials (CTR), the Swiss Group for Clinical Cancer Research (SAKK) and the SCTO joined forces and elaborated a concept to introduce the topic of lay summaries to their stakeholders, in particular to their academic clinical research network, and to ensure that lay summary preparation is compliant with the new requirement and is started on time. Two events were organised to raise awareness of the topic:

- At the SCTO Forum 2021 in January, the issues of general requirements for a lay summary of clinical trial results and what needs to be considered from an academic point of view were addressed.
- During the Swiss Oncology and Hematology Congress in November, the SAKK Patient

Advisory Board held a discussion around bringing patient organisation representatives, researchers, Swiss authorities, and sponsors of clinical trials together to discuss lay summaries and exchange experiences.

- [Swiss Group for Clinical Cancer Research \(SAKK\)](#)
- [SCTO Forum 2021](#)
- [Swiss Oncology and Hematology Congress](#)

Polish Medical Research Agency meets the SCTO

The SCTO and its CTU Network were happy to welcome representatives from the Polish Medical Research Agency (Agencja Badań Medycznych) during their visit to Switzerland at the beginning of December.

Among other things, we discussed and exchanged ideas on:

- how to best establish a national clinical research infrastructure
- what needs to be considered from a governance point of view
- how to overcome potential challenges.

During their visit, our Polish colleagues also met staff from the Clinical Trials Unit Bern and Clinical Trials Center Zürich. The visit marked the beginning of cooperation on potential future projects or initiatives.

- [Polish Medical Research Agency \(Agencja Badań Medycznych\)](#)
- [Clinical Trials Unit Bern](#)
- [Clinical Trials Center Zürich](#)

Statements and publications

In 2021, two topics in particular occupied us, and we devoted separate publications and articles to them: patient and public involvement (PPI) in clinical research and the Swiss popular initiative to ban animal and human research. In addition, members of our Clinical Trial Unit (CTU) Network contributed to over 230 scientific publications.

Patient and public involvement in clinical research

In close collaboration with the Swiss National Science Foundation (SNSF), our Executive Office published a fact sheet on patient and public involvement (PPI) in clinical research and a guidance document to support researchers with their PPI activities early on.

In addition, we contributed to a scientific publication by the European Patients' Academy on Therapeutic Innovation (EUPATI) named *The Role of EUPATI CH in Promoting Patient Involvement in Clinical Research: A Multi-Stakeholder Project*. With these publications, we aim to increase the visibility of one of our main strategic goals of the current funding period.

All documents are available on our regular website:

- [Patient and public involvement in clinical research \(PPI\)](#)
- [Scientific papers](#)

Swiss popular initiative to ban animal and human research

In addition to our position paper against the popular initiative “Yes to the ban on animal and

human research”, which was published in June 2020, we also contributed to several media publications, press releases, and press conferences. The SCTO actively stood up against this initiative by informing media and the public about its devastating consequences for clinical research and for patients in Switzerland.

The media articles are available in German and French:

- [Medienberichte](#)
- [Rapports des médias](#)

Contribution to over 230 scientific publications

At the local, operational level, our Clinical Trial Unit (CTU) Network plays a key role in facilitating academic clinical research. Acting as an academic partner, the network offers comprehensive support and represents the country's largest provider of training and services through all phases of a clinical study. In this role, members of the network co-authored 238 scientific publications in 2021.

SCTO events in 2021: Digital, virtual, hybrid

We (co-)organised our first digital events in 2021!

SCTO Forum 2021 on communicating clinical research results

The SCTO Forum in January 2021 was held as a fully digital event via Zoom – with external help and a large amount of effort from our Executive Office. The nearly 70 participants were treated to interesting presentations on the topic of "Communicating clinical research results: Moving from vicious to virtuous circles". Thanks to practical, new features like digital breakout rooms and chats for discussions, we were able to offer plenty of opportunities for exchange among the participants.

About our annual SCTO Forum

For over ten years, we have been anticipating and unravelling compelling topics in clinical research by bringing together key Swiss stakeholders at our annual SCTO Forum, which is an opportunity to network, learn, debate, and ask questions. Each year, we invite representatives from academic clinical research, the pharmaceutical industry, institutions for research development, and Swiss ethics committees to our forum to present and discuss their perspectives on current and controversial topics in the field of clinical research.

Forum 2021 "Communicating clinical research results: Moving from vicious to virtuous circles"

– [SCTO Forum 2021](#)

SCTO Symposium 2021 on medical devices

Later, in June, the SCTO Symposium faced an even more sophisticated challenge: a hybrid event on the topic of "Medical devices: Lost in translation?". Thanks to external support, we were able to allow the speakers and moderators to give their presentations in-person at site in Bern, while participants followed the event on their screens at their homes or offices. There was a lively exchange, especially among those present at site. The approximately 180 online participants were able to ask the speakers questions; however, they could only exchange ideas with each other during the short breakout sessions at noon.

About our annual SCTO Symposium

At our SCTO Symposium, we spend the day exploring 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 at both the scientific and political levels. In addition, the event offers the opportunity to network beyond Switzerland's borders.

– [SCTO Symposium 2021](#)

In addition to our annual SCTO events, we also helped organise the following events in 2021:

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. In 2021, the congress took place as a virtual seminar series. Participants could register for individual modules, so they could target which specific areas of clinical trials they wanted to delve into. 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.

Third NextGen Research Day: An innovative teaching and networking event for young researchers in the field of paediatrics

This annual teaching and networking event is tailored to young researchers who are keen to get the right tools for successful paediatric research. Besides interactive workshops on topics such as project development and project leadership, the event 2021 included a "Scientific Speed Dating" session and a novel "Scientific Escape Room" session. These sessions were followed by a round-table discussion on the topic "I want it all & I want it now: Career paths in the 21st century", which was held in a town hall format with interactive questions from the audience. The event was held live in Bern in November 2021.

International Clinical Trials Day: ECRIN event on platform trials

On 20 May, which is International Clinical Trials Day (ICTD), the European Clinical Research

Infrastructure Network (ECRIN) held a virtual event on platform trials. The event brought together international stakeholders to share examples and learnings, best practices, methods, and regulatory challenges.

ECRIN CTU Day 2021

Later in November, ECRIN hosted its first Clinical Trial Unit (CTU) Day, bringing together members of its CTU community from all 12 of its national networks. As part of this community, we shared with the other networks how we collaborate with ECRIN. With over 225 participants, this was the

first in a series of meetings for the ECRIN CTU community. The objective of these meetings is to encourage staff in organisations affiliated with ECRIN's national networks to get to know one another, exchange information and best practices, and discuss training opportunities and potential synergies.

- [DACH Symposium](#)
- [NextGen Research Day](#)
- [ECRIN's ICTD event](#)
- [About International Clinical Trials Day](#)

Facts and figures:

Clinical Trial Unit Network performance indicators

The SCTO's Clinical Trial Unit (CTU) Network offers comprehensive support for conducting high-quality academic clinical research in Swiss and foreign centres. In addition, it represents the country's largest provider of training and services through all phases of a clinical study. In 2021, the CTU Network was involved in a wide range of projects and provided numerous services, including consulting: overall, 2,131 projects were supported by the CTU Network with 3,576 services. In addition, the network trained more than 8,000 clinical research staff.

Main services provided to projects in an academic setting

Services were mainly provided in the areas of data management (29%), consulting (19%), advice on methodology and/or statistics (16%), monitoring (11%), regulatory support (10%), onsite/project management (7%), and auditing (2%). Several different services may have been provided for one project.

One-third of the projects supported were **multicentre projects**, nearly half of which were international projects. The two most supported project types were research involving human beings according to the Human Research Ordinance (HRA) (44%) and clinical trials according to the Clinical Trials Ordinance (ClinO) (40%).

Most of the funding for the projects came from **academic sources** (38%), from industry (8%), and from external competitive funding sources (12%) such as the Swiss National Science

Foundation (SNSF) or the EU's Horizon Europe programme.

More than 8,000 clinical research staff trained in 2021

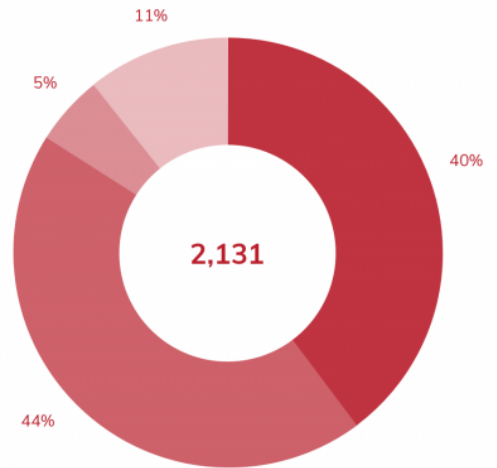
In Switzerland, the CTU Network is the main provider of education and continuing training in clinical research. More than 8,000 clinical research staff were trained in 2021, mainly in ethics and good clinical practice (GCP) courses (80%) or in undergraduate or postgraduate training programmes (MD, MSc, CAS, DAS, PhD) (17%). GCP training courses have increased significantly in recent years (6,443 in 2021 compared to 4,800 in 2017) due to the new GCP refresher courses as well as the increasing availability of online training opportunities.

Visit our main website to learn more about our CTU Network:

– [CTU Network](#).

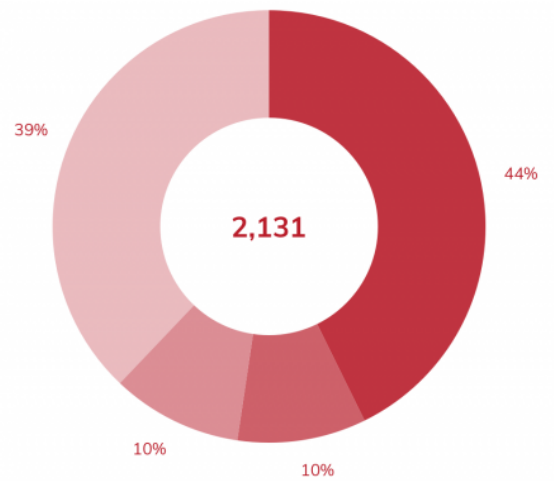
HRA type of project

- Clinical trials (ClinO)
- Research involving persons (HRO)
- Non-HRA regulated projects
- Unknown / N/A



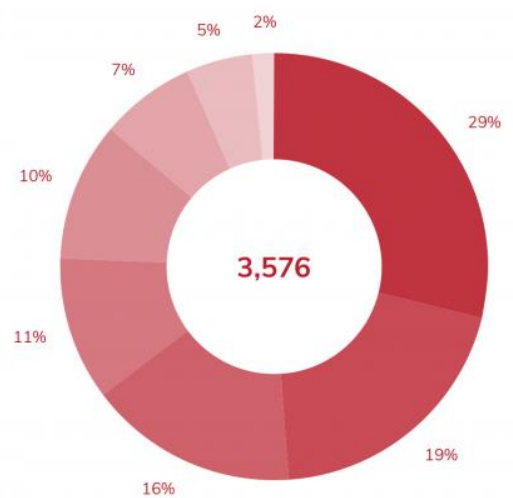
Risk categories of supported projects

- Risk category A
- Risk category B
- Risk category C
- Unknown / N/A



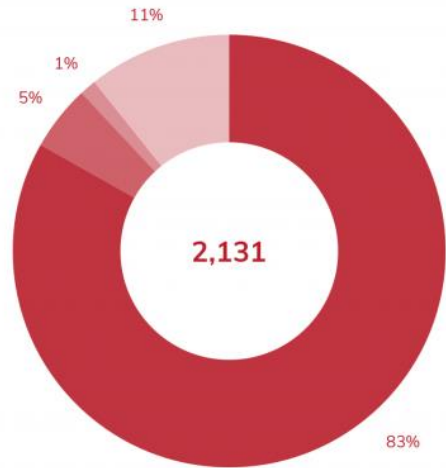
CTU network services to projects

- Data Management
- Consulting
- Statistics / Methodology
- Monitoring
- Regulatory Affairs
- Project Management / Study Coordination
- Coordinator / Study nurse / Physician
- Audits / Pharmacovigilance / Safety



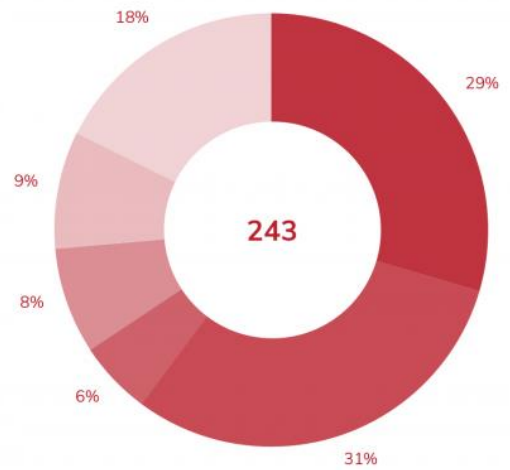
Sponsor

- Academy
- Industry
- Other
- Unknown / N/A



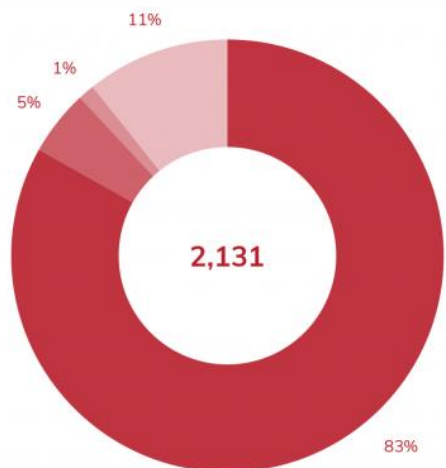
Training courses delivered

- GCP refresher courses
- Research Ethics and GCP (Investigator Level)
- Research Ethics and GCP (Sponsor-Investigator Level)
- Undergraduate e.g. MD, MSc
- Postgraduate (CAS, DAS, MSc/MAS, PhD)
- Other teaching and training



Sponsor

- Academy
- Industry
- Other
- Unknown / N/A



Facts and figures: Tools & Resources website

The SCTO Platforms form an interconnected, nationwide network that provides practical resources and innovative tools for clinical research professionals. In June 2021, we launched the new Tools & Resources website to increase the visibility of the

platforms and their products and to facilitate measuring their performance. Visit the SCTO Platforms' website Tools & Resources to learn more about the platforms' members: [Tools & Resources website](#)

>1,000

new users visited Tools & Resources from June to December 2021

247

items were downloaded from June to December 2021

8

topic-based platforms developed new tools and resources for the clinical research community in 2021

27

tools have been developed for the clinical research community since the SCTO Platforms were launched in 2017

5

new tools were developed in 2021

5

publications were released in 2021

Facts and figures: Executive Office

The Executive Office (EO) is the SCTO's national coordination office, and it oversees the execution of the SCTO's strategy. The EO carries out various coordinating, liaising, networking, and overarching functions for the SCTO, its members, and the SCTO's CTU Network. In total, ten people work at the EO (which corresponds to 7.7 FTE). Find out below what kept us on our toes in 2021 and meet our Executive Office team.

Digital, virtual, hybrid: We (co-)organised five digital events in 2021!

Holding events digitally presents practical advantages. For example, anyone can participate from anywhere, and new virtual opportunities open up for exchange among participants. Even though we are grateful to have learned how to use new digital tools – which we will continue to use in the future as the situation demands – for holding events during 2021, in our specific case, having informal exchanges at the coffee machine or at a post-event reception is also very important and significant for event success.

Find out which events we (co-)organised in 2021 in the [Events section](#) of our online Annual Report 2021.

We keep nearly 3,000 readers updated on national and international topics relating to clinical research

In 2021, the Executive Office published 12 newsletters sharing national and international news in three languages with nearly 3,000 readers. Our newsletters covered current topics such as COVID-19, regulatory requirements, education, and the next generation of clinical researchers as well as news on our networks and partners.

Our complete newsletter archive is available on our main website: [SCTO newsletters 2021](#).

Spotlight on SCTO Platforms

We launched a new newsletter series in 2021 featuring the experts in our SCTO Platforms. Our platform members are located in the Clinical Trial Units (CTUs) at university and cantonal hospitals across Switzerland. The collaboration within and between our topic-based platforms promotes networking throughout the country and enables them to share resources, inspire one another, revitalise their fields, and keep pace with trends and best practices. In our regular newsletter, we

highlighted the tools and resources resulting from their projects.

Our complete newsletter archive is available on our regular website: [SCTO newsletters 2021](#).

Promoting patient and public involvement (PPI) in clinical research

One of our most important objectives is to promote patient and public involvement (PPI) in academic clinical research. In 2021, we published a PPI fact sheet and we collaborated with the Swiss National Science Foundation (SNSF) to develop a PPI guide for researchers who are planning a clinical research project and seeking potential funding. In addition, the October issue of our Regulatory Affairs Platform's Regulatory Affairs Watch explored regulatory aspects of PPI from the perspectives of various important stakeholders. The issue also contains concrete examples of how PPI can be integrated into clinical research. Moreover, our Executive Office worked together with partner organisations to conduct an online survey to identify which PPI initiatives and projects currently exist in academic clinical research in Switzerland.

The results of this survey as well as all relevant PPI documents are available on our main website: [Patient and public involvement in clinical research](#).

More accessible tools and resources for academic clinical research professionals

We developed a new, user-friendly website for our SCTO Platforms' project results: Tools & Resources. The website allows academic clinical research professionals to conveniently access resources for their day-to-day work and fosters interaction between them and the tools' developers. The Tools & Resources website will be continually updated and expanded with additional tools, so it's worth visiting regularly!

Start exploring our [Tools & Resources website](#).

Interactive 4-Year Report 2017–2020

In 2021, we published our first interactive report. Our online 4-year report shows our achievements between 2017–2020 and how we have worked together as a decentralised network to shape the future of clinical research in Switzerland.

Click through our tree of achievements:

[SCTO 4-Year Report: The fruits of our work.](#)

White paper: Seven goals for clinical research

The Swiss Academy of Medical Sciences (SAMS) presented a roadmap with seven goals to

strengthen the impact of clinical research in Switzerland in its White Paper: Clinical Research. This white paper suggests how to use resources more efficiently and how to align efforts around common priorities. The Executive Office actively participated in developing the white paper and will continue to participate in implementing the measures outlined in it. The SCTO's engagement in this project reflects its commitment to a shared vision and approach to strengthening patient-centred clinical research in Switzerland.

Find out more about this paper on the SAMS's website: [White Paper: Clinical Research.](#)

Financial statement

The SCTO will remain on a firm financial footing provided the government does not reduce its funding. Its balanced financial result for 2021 is due to responsible management as well as accurate financial planning and effective financial controls.

The SCTO closed out its 2021 financial year with a minimal loss of CHF 837. This loss resulted from higher expenditures for the Executive Office's IT infrastructure and for the creation of a separate SCTO Platforms website; the loss is covered by the association's capital. All other expenditures correspond to the SCTO's 2021 budget.

BDO AG audited the SCTO's 2021 financial statement and did not find any violations of laws or statutes.

In order to carry out any new mandates, the SCTO will require additional funding or will need to reduce the scale of its existing activities.

Expenses	CHF
Personnel expenses	
Salaries	912K
Social charges	192K
remaining personnel expenses	40K
Total	1,144K
Clinical Operations	
Platforms management and liaison costs	40K
Funding Network (CTU Network and SwissPedNet hubs)	3,652K
other	194K
Total	3,886K
Business Operations	
Administration charges	98K
Fiduciary charges	21K
IT	22K
Total	141K

Communication	
Website	29K
Translation service	8K
Miscellaneous	21K
Total	58K

Patient and Public Involvement	
organisational costs	8K
Total	8K

Events	
Symposium / Forum / other	32K
Total	32K

Total expenses	5,269K
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Income	CHF
Swiss National Science Foundation	1,000K
State Secretariat for Education, Research and Innovation	3,900K
SCTO Association	140K
Other (Events, SecuTrial, Advisor)	229K
Total income	5,269K
Status of association assets 31.12.2021	208K

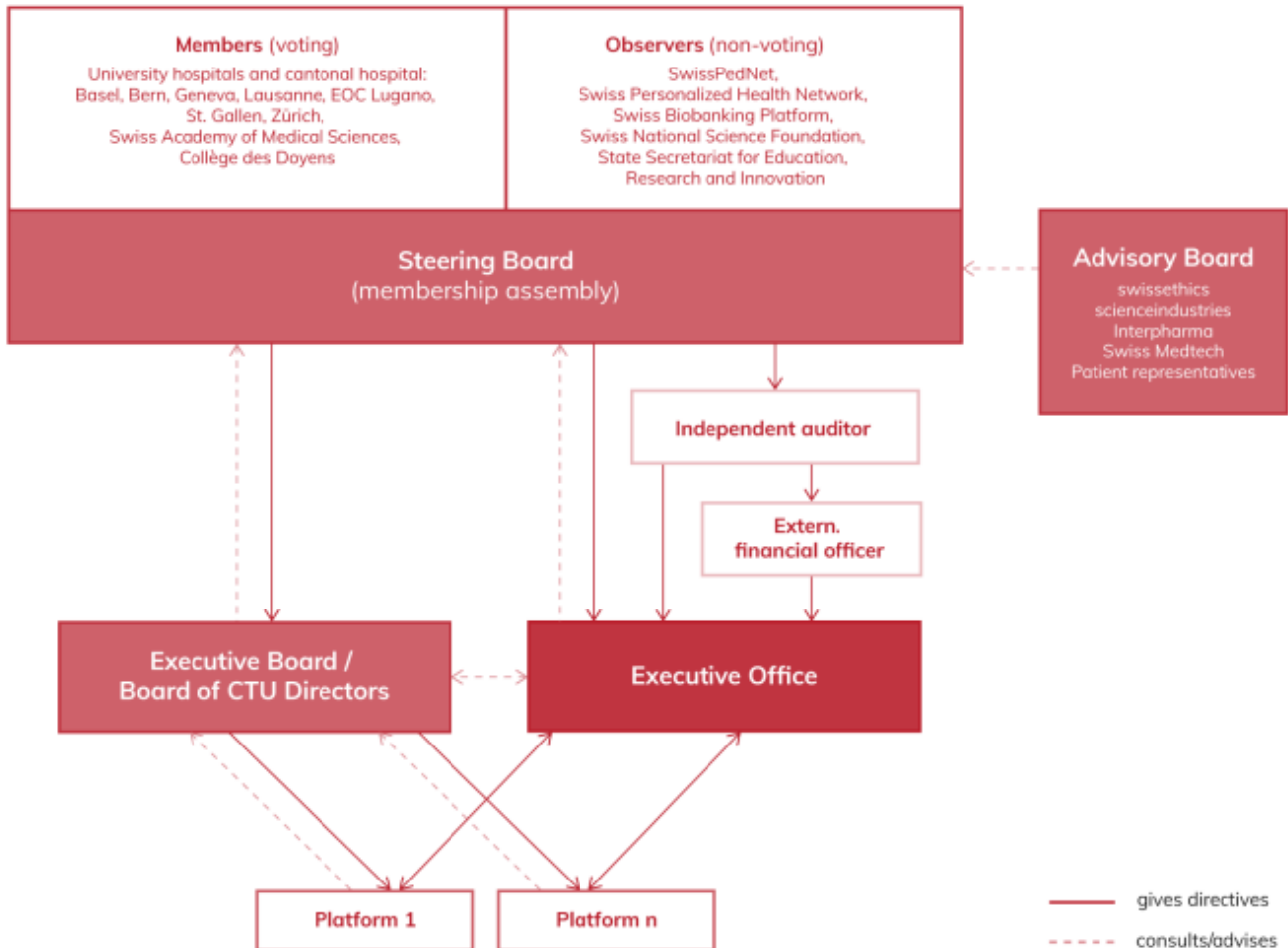
Governance

In line with our strategic focus, which is set out in our Strategy Paper 2021–2024, and our commitment to critically review our governance structure on a regular basis, our Steering Board decided to add new members to our Advisory Board.

New members on the SCTO’s Advisory Board

With **Dr Nicole Gusset**, the president of the patient organisation [SMA Schweiz](#) and a graduate of the European Patients’ Academy on Therapeutic Innovation’s ([EUPATI](#)’s) Patient Expert Training Programme, we can bring in more knowledge and experience from the field of patient and public involvement (PPI) in clinical research, one of our key priorities for the coming years.

Dr Daniel Delfosse, Head of Regulation & Innovation at the Swiss Medical Technology Association ([Swiss Medtech](#)), will explore with us ways in which we can jointly advance clinical research with medical devices in Switzerland. From the point of view of the current political situation and the regulatory framework in Switzerland, this is of great importance both for the patients, for potential users of medical devices, and for the manufacturers concerned.



About us

We promote valuable, innovative, and visible clinical research in Switzerland.

The Swiss Clinical Trial Organisation (SCTO) is the **central cooperation platform for patient-oriented clinical research in Switzerland.**

The 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'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?
Contact us at info@scto.ch.

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