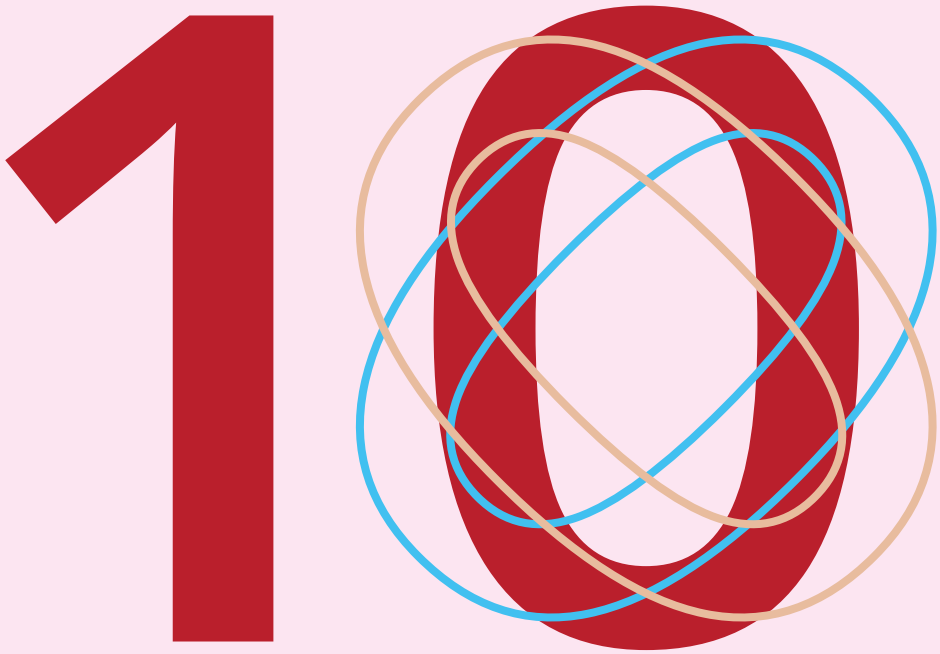
swiss
clinical
trial
organisation

SCTO



10 YEARS

OF THE CTU NETWORK

An SCTO Anniversary
Publication

CELEBRATING **10 YEARS** OF THE CTU NETWORK

An SCTO Anniversary Publication

CONTENTS

INTRODUCTION

Putting Switzerland back on the map

Across the globe, a drive is underway to improve the framework for academic clinical research, to enhance its quality and outcomes, and to optimise the performance of its multicentre trials. In Switzerland, the Swiss Federation is engaged in several ways. These include: establishing and implementing a master plan to promote biomedical research and technology; identifying the most urgent issues and potential measures; revising the Federal Act on the Promotion of Research and Innovation (RIPA); and this, in the context of Swiss voters having accepted the Swiss Human Research Act. Overall, this revised framework promises a bright future for clinical research in the country. The Clinical Trial Unit (CTU) network is part of this forward-looking solution and plays a **key role in facilitating academic clinical research – locally, nationally, and internationally.**

Clinical Trial Units – a powerful organisation for over a decade

Ten years ago, the Swiss National Science Foundation (SNSF) laid the groundwork to establish Clinical Trial Units at Swiss university hospitals and the St.Gallen cantonal hospital. Since then, the CTU network has developed into an important national infrastructure, supporting academic clinical researchers during the **planning, implementation, analysis, and publication of patient-oriented clinical research projects.**

Largest provider of services and education

With a countrywide influence, the network is made up of six local CTUs, situated in Basel, Bern, Geneva, Lausanne, St.Gallen and Zurich. Each of these six centres for clinical research is closely linked to the medical faculties of a Swiss university, either as part of a local university hospital or linked to the university.

Combining forces, the CTU network not only forms a well established and nationally coordinated structure. Most notably, it also serves as the **largest provider of services and education in academic clinical research in Switzerland**. Altogether, more than 140 people work within this network.

The 10th anniversary of the CTU network

This landmark of a decade provides an opportunity to present the local CTUs and their local, national, and international roles and to reflect on their impact. We are very proud of what has been achieved so far and we are striving to continue adding value in clinical research, while ensuring a reasonable cost–benefit ratio.

Since 2017, the CTU network has been recognised and funded as a research infrastructure of national and international importance. As such, we are engaged to use funds as efficiently, effectively, and sustainably as possible for the sake of new and better future therapies.

How can you become involved?

You are invited to contact the SCTO or one of the CTUs to explore how you can collaborate with the CTU network.[1] Let's work together, to make scientific clinical research in Switzerland ever stronger.

Enjoy reading and don't hesitate to use scissors[2] while browsing through our publication!

Yours sincerely

Prof. Gregor Zünd
President

Annette Magnin
Managing Director

[1] The contact pages in the centre spread of this publication can easily be removed.
[2] Assemble the puzzle and learn interesting facts about the history of clinical research.

"The CTUs have contributed considerably to the key issues of increasing scientific value and reducing scientific waste."

swissethics

Read more on what our partners say about the CTU network on pages 20 and 25.

CTU PORTRAIT
BASEL

A highlight of the work conducted by the CTU Basel

The highlight of our work to date was conducting a study on adjunct prednisone therapy for patients with community-acquired pneumonia – a randomised, double-blind, placebo-controlled multicentre trial, for which the results were then published in *The Lancet*:

Blum, Claudine, et al. 2015. 'Adjunct Prednisone Therapy for Patients with Community-Acquired Pneumonia: A Multicentre, Double-Blind, Randomised, Placebo-Controlled Trial.' *The Lancet*, Vol. 385, No. 9977. January, pp. 1511–18.

In the past, clinical trials have yielded conflicting data about the benefit of adding systemic corticosteroids for the treatment of community-acquired pneumonia. Therefore, this multi-centre, double-blind, placebo-controlled trial evaluated whether short-term corticosteroid treatment reduces the time to reach clinical stability in patients hospitalised for community-acquired pneumonia.

Overall, 802 patients were randomised in seven Swiss hospitals, from December 2009 to May 2014. The results showed that the primary endpoint (time to clinical stability) was one day shorter in the prednisone group compared to the placebo group. Furthermore, secondary end-points were observed as follows: As compared to the placebo group, the prednisone group reached hospital discharge one day sooner and received an intravenous antibiotic treatment for one day less. The rates of all-cause mortality, intensive care unit stay, recurrent pneumonia, and rehospitalisation were similar in both groups (for all, one day less in the prednisone group). The incidence of pneumonia-associated complications through to day 30 tended to be lower in the prednisone group, too.

The conclusion of this trial is that prednisone treatment for 7 days in hospitalised patients with community-acquired pneumonia reduces their time to clinical stability, hospital discharge, and their duration of intravenous antibiotic treatment, without an increase in complications.

At the CTU Basel, we were involved in all phases of this research project and we covered a variety of different activities. These included statistical planning and analysis, data management support, quality assurance and monitoring, as well as study conduct, thanks to our experienced study nurses.

Learning gained from this collaboration

We believe that close interaction with clinical research groups and rapid response to centre-specific needs form the cornerstone to success. As is often the case, the recruitment took much longer than anticipated, but was ultimately completed. We now regard the close monitoring of recruitment and easy definition of measures to take (in the event of recruitment failure) as top priorities when we are consulting with researchers and supporting them.

Testimonial

"The close interaction with the CTU Basel was one of the key factors for the successful realisation of this study. The CTU staff helped us through all phases of the study: in the complicated regulatory process in the beginning, with data management, on-site management, and monitoring. The input from the CTU thereby guaranteed a high-quality standard, which was crucial for publication in a journal such as *The Lancet*."

Prof. Mirjam Christ-Crain, Deputy Chief Physician, Department of Endocrinology, Diabetology and Metabolism, University Hospital Basel

What makes the CTU Basel unique

The CTU Basel has an outpatient study centre for children and adults, which is a highly specialised infrastructure for conducting all types of clinical research projects in paediatric and adult populations. Relating to research, we operate a web-based Quality Management System. It is easy to manage and available to all clinical research groups, to ensure that they comply with good clinical practice and are ready for inspections or audits. We also offer a comprehensive training and education portfolio, to serve all professionals working in clinical research.

Benefits the CTU offers

At the CTU Basel, we provide a comprehensive list of services in support of all types and phases of clinical research projects and studies, including study methodology and statistics, regulatory affairs and project coordination, data management, monitoring, on-site management, and quality management.

We actively support different services and offer free-of-charge consulting to more than 100 registered clinical research groups in the Basel area. We work in close collaboration with the local ethics committee on regulatory and training matters.

Synergies gained from being a member of the CTU network

Our CTU has gained from improved harmonisation relating to quality and to data management, thanks to the working groups initiated by the SCTO. We benefit from the rich exchange and coordination of training and education opportunities.

The decade ahead for clinical research in Switzerland

We look forward to exploring ways to exploit the opportunities of digitalisation, to carry out more efficient and patient-centred research and we expect that innovation will generate alternative teaching approaches and blended-learning concepts in training and education. Through the increasing "research about research" and "research within research" approaches, we look forward to seeing both research methodology and best scientific practices advancing and improving.

By fighting for her right to education and the acceptance to practise her profession, Marie Heim-Vögtlin helped younger generations of women to gain access to studies and employment.

CTU BASEL

Director
Prof. Christiane Pauli-Magnus
Secretary
Manisha Boxler,
Regina Mattmüller-Maier

Consulting and Services Unit

Head of consulting and services
Dr Thomas Fabbro
Quality manager
Astrid Mattes
Computer system validator
Lisa Collins

Consulting, Coordination, and Regulatory Affairs Unit

Team leader of consulting, coordination and regulatory
Dr Jörg Willers
Consultants of regulatory affairs
Claudia Becherer,
Renate Huber-Wunderle
Consulting clinical scientists
Dr Anya Hammann-Hänni,
Dr Martina Sonderegger

Statistics and Data Management Unit

Team leader of statistics and data management
Dr Thomas Zumbrunn
Data managers
Dr Pascal Benkert, Dr Nicole Bruni,
Marielle Rutquist, Dr Michael Scharfe,
Patrick Simon, Dr Constantin Sluka
Statisticians
Dr Michael Coslovsky, Dr Gilles Dutilh,
Dr Tobias Erlanger, Sabine Schädelin,
Dr Deborah Vogt, Dr Stefanie von Felten

On-Site Management and Monitoring Unit

Team leader of on-site management and monitoring
Klaus Ehrlich
Senior study nurse
Karin Wild
Study nurses
Vanessa Grassedonio,
Joyce Santos de Jesus
Managing study nurse
Silke Purschke
Monitors
Dr Marie Mi Bonde Hansen, Petra Forst,
Emilie Müller, Astrid Roesler

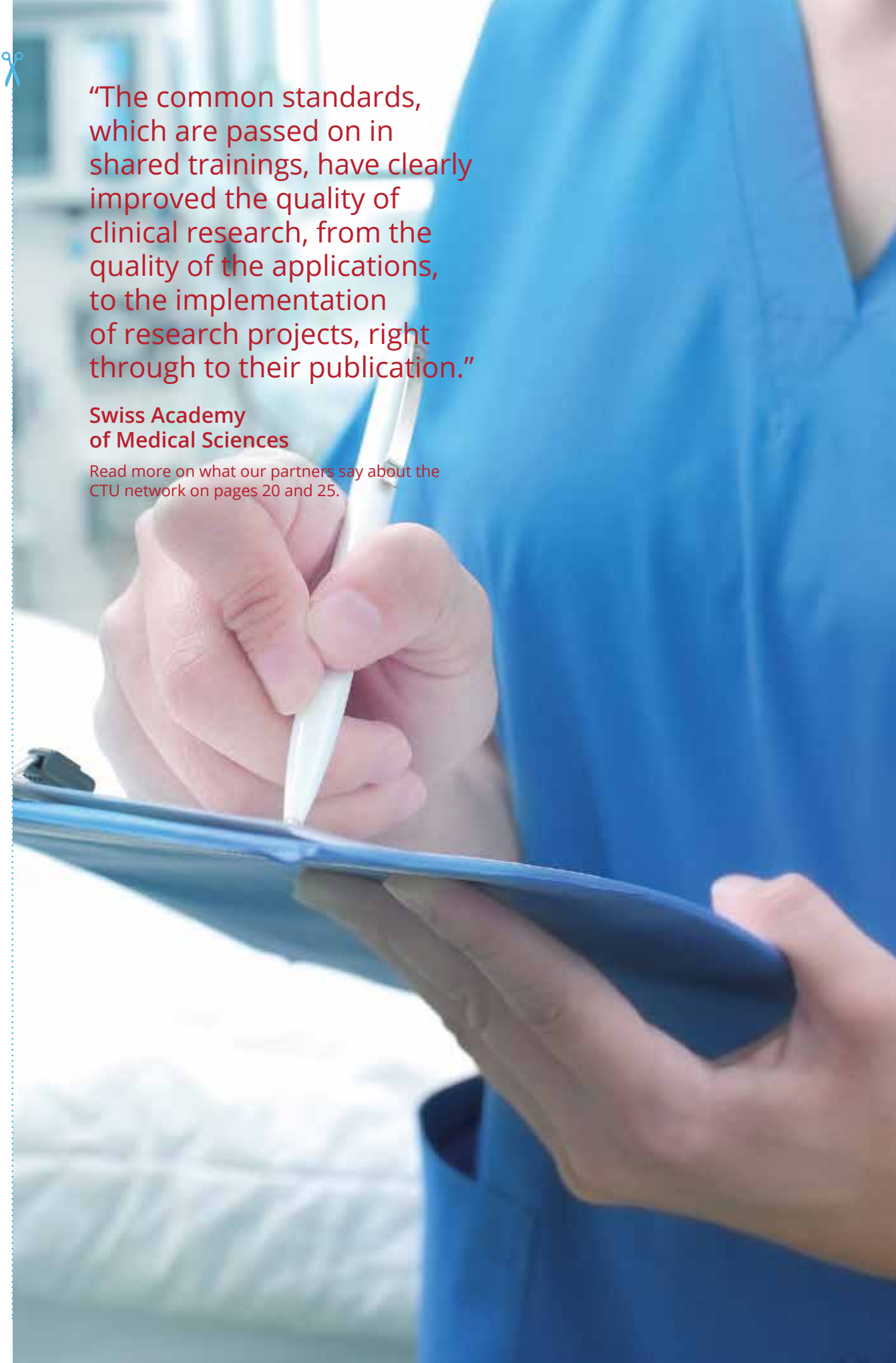
Training and Education Unit

Head of training and education
Dr Barbara Peters
Course administrator
Annett Fröhlich
Scientific officer of GCP training
Dr Sandra Kohlmaier
Scientific officer of postgraduate programmes
Dr Marie Mi Bonde Hansen

SCTO MEMBER OF THE CTU NETWORK

University Hospital Basel

University of Basel
Department of Clinical Research



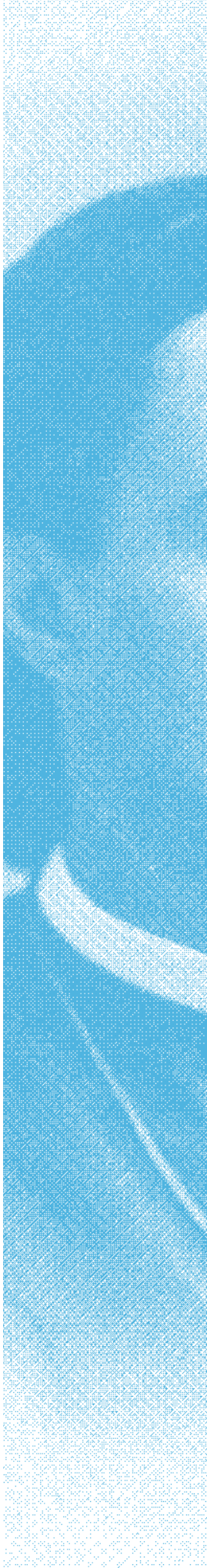
“The common standards, which are passed on in shared trainings, have clearly improved the quality of clinical research, from the quality of the applications, to the implementation of research projects, right through to their publication.”

Swiss Academy of Medical Sciences

Read more on what our partners say about the CTU network on pages 20 and 25.

Since no support could be expected from her husband, Marie Heim-Vögtlin was probably one of the first Swiss women to struggle to reconcile work and family life.

CTU PORTRAIT
BERN



A highlight of the work conducted by the CTU Bern

West Africa experienced the largest outbreak of Ebola virus disease in recorded history, between March 2014 and June 2016. One year after the start of the outbreak, a large trial was launched to test the efficacy of the vaccine candidate rVSV-ZEBOV to prevent the disease. “Ebola ça suffit!” (meaning “Enough of Ebola!”) was a phase III, cluster-randomised, ring vaccination trial conducted in Guinea, West Africa. The CTU Bern was responsible for the data management and contributed to the study design. Overall, more than 3,500 participants were included over the 7 month recruitment period. This was the first such large-scale trial to show that rVSV-ZEBOV offers substantial protection against this disease.

Learning gained from this collaboration

The CTU Bern was first approached at the beginning of November 2014. Initially, our contribution to study design aspects took priority. It was soon clear that data management is also a crucial aspect of supporting trial conduct. Our work started in mid-December and within 11 weeks, a productive, GCP-compliant, electronic data-capturing system was set up and a local data management centre, initially with 4 staff members, started its work. This challenging trial start required a lot of flexibility, teamwork, and arranging of priorities. Processes had to be developed and improved swiftly. In time, the centre staff grew to 23 data entry clerks, 3 local data managers, and one statistical data manager from the CTU Bern, who received regular visits from other CTU Bern staff.

Testimonial

“Despite the huge challenges faced and very short timelines, the CTU team’s expertise and unconditional commitment made it possible to successfully set up and implement the data management system for the trial and to do so in compliance with international standards. This was critical for the success of the ‘Ebola ça suffit!’ trial.”

Dr Ana Maria Henao Restrepo, Medical Officer, Department of Immunization Vaccines and Biologicals, World Health Organization

What makes the CTU Bern unique

The CTU Bern supports clinical researchers in the planning and conduct of their patient-oriented clinical study projects. Our overarching aim is to strengthen and expand the evidence base for health care. We try to achieve this by striving for the most robust design for a given question while considering feasibility, participants' safety, respect for their rights, and regulatory compliance. The services offered by the unit enable clinical researchers to comply with scientific standards, and legal and regulatory requirements.

Our team is dedicated to improving communication with our partners in patient-oriented clinical research projects. We recognised, right from the start, that only an open communication policy and a commitment to listening to each other and learning from each other's experiences, education, training and know-how can improve the quality of such projects. A pragmatic approach is often needed, because many projects are initiated by academic investigators with only a small budget. We also support clinical researchers beyond their individual projects by providing training and other support. For example, we help to implement quality management or data management infrastructure on an institutional level.

Benefits the CTU offers

At the CTU Bern, we offer services that will help clinical researchers comply with scientific and regulatory standards. Collaborations can be set up in a modular fashion i.e. researchers can choose areas of collaboration with the CTU Bern, according to their needs. We aim to provide our services in a low-threshold fashion meaning that it should be easy for investigators to get fast access to services with a favourable cost–benefit ratio. For each project, consulting is offered free of charge to clarify the research question, study design, or specific needs. Although we also provide "simple" services when requested, we aim for true collaborations with clinical partners, as we believe such partnerships result in higher quality projects.

Synergies gained from being a member of the CTU network

Networking and collaborating with other CTUs and the SCTO are an essential part of our work. Such cooperation helps to fulfil our mission, because resources are used more efficiently and sometimes tasks can only be accomplished when we join forces with other CTUs. Collaborations exist on different levels. For example, the software licence of one of our major data-management systems is shared within the CTU network. Other examples include knowledge exchange via working groups, especially in the field of quality management. Finally, we are also collaborating on specific clinical projects to minimise costs, e.g. by decentralising on-site monitoring efforts.

The decade ahead for clinical research in Switzerland

Over the last two to three years, we have seen an increase in larger, multicentre randomised-controlled clinical trials that are supported by CTUs. This includes international trials that are initiated and coordinated from a Swiss centre for all participating countries. These trials often use a pragmatic approach to generate evidence that can be directly translated into clinical practice.

After completing her studies she opened her own practice, where she continued to work even after having two children. By doing this, she intended to demonstrate to her environment that her duties as a housewife didn't suffer because of her commitment to being a physician.

CTU BERN

Co-Heads
PD Dr Sven Trelle, Prof. Urs Fischer
Quality manager
Sarah Berner
Personal/administrative assistants
Anna Blättler, Simona Wanner

Statistics and Methodology Unit

Head
Dr Andreas Limacher
Head of cardiovascular health
PD Dr Dik Heg
Senior statisticians
Dr Lukas Bütikofer, Dr Niklaus Fankhauser, Dr Alan Haynes, Dr Alex Karagiannis, Dr Armando Lenz, Dr Marie Roumet
Statisticians
Martina Rothenbühler, Odile Stalder
Senior statistical consultant
Dr Georgia Salanti
Project manager
Dr Enrico Frigoli
Junior research assistant
Lena Maurer
Platform coordinator
Brigitta Gahl

Project Management Unit

Head
PD Dr Sven Trelle
Project managers
Dr Poorya Amini, Stefanie Hossmann, Dr Luca Tamò

Data Management Unit

Head
Muriel Helmers Walker
Clinical data managers
Hafeezul Adnan, Dr Steve Berger, Yves Bochud, Julie Rat-Wirtzler, Dominique Rubi, Miriam Wegmann, Priska Wölfli, Katrin Ziegler
Junior clinical data managers
Gian-Andrea Degen, Yannis Portmann

Monitoring and Regulatory Affairs Unit

Head
Dr Felix Rintelen
Senior clinical trial monitor
Lucia Kacina
Clinical trial monitors
Sereina Battaglia, Nathalie Schwab
Clinical trial monitor trainee
Dr Pia Massatsch
Junior research assistants
Stefan Künzler, Selina Wegmüller

Clinical Investigation Unit

Head
Prof. Urs Fischer
Clinical research coordinators
Renata Bünter, Madeleine Dähler, Regula Jaeggi, Ursina Sager Huber

SCTO MEMBER OF THE CTU NETWORK

UNIVERSITÄT BERN

With her decision to study, Marie Heim-Vögtlin called the traditional role of women radically into question.

“The quality of the application dossiers of IITs has improved markedly with the involvement of the CTUs.”

Swissmedic

Read more on what our partners say about the CTU network on pages 20 and 25.

CTU PORTRAIT
GENEVA

A highlight of the work conducted by the CTU Geneva

Three months after the World Health Organization alert on the Ebola epidemic, we started recruiting healthy subjects for the Geneva-based rVSV-ZEBOV study: an investigator-initiated combined phase I and II, placebo-controlled, double-blind trial, to determine the effect of dose on the safety and immunogenicity of the VSV Ebola candidate vaccine. Within 2 months, 115 patients were enrolled and then monitored for 2 years.

The phase III trials that followed confirmed efficacy of the candidate vaccine, which has been shown to provide 100% protection against this lethal disease. The vaccine has not yet been approved by any regulatory authority, but it is considered so effective that an emergency stockpile of 300,000 doses has already been created for use, should an outbreak recur.

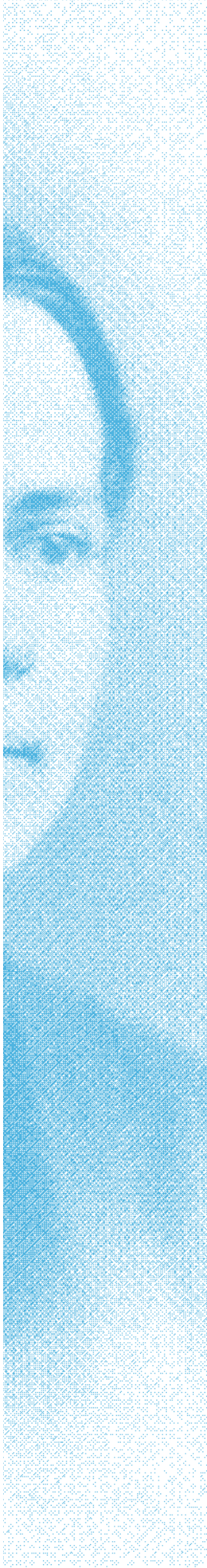
Learning gained from this collaboration

We learned from the challenges of setting up such a trial. Sourcing 115 healthy subjects to be recruited within 2 months and organising the first 7 visits within the first month leading up to 700 visits in 3 months called for outstanding capacities in organisation, communication, and delegation.

Testimonial

"We have developed a close collaboration with the CTU Geneva for the planning, conduct and closure of the phase I study, testing the vaccine candidate against the Ebola virus. Setting up and conducting this clinical trial was a fantastic experience, but also extremely difficult. This could not have been undertaken without the strong commitment and professionalism of the CTU, which was very resourceful for all kind of problems we faced, throughout the process! We appreciated the commitment and the kindness of the team and the participants, as shown by the results of an anonymous survey, where 103 of the 115 participants confirmed that the experience was positive, despite the difficulties encountered."

Prof. Claire-Anne Siegrist, Professor of Vaccinology and Paediatrics, University of Geneva and
Dr Angela Huttner, infectious disease physician and co-investigator, University Hospitals of Geneva



What makes the CTU Geneva unique

Our clinical trial unit is highly specialised in conducting early phase clinical trials and translational studies, in order to characterise the clinical pharmacology of new chemical entities. Nine beds are dedicated to these clinical trials run at the hospital, close to the Intensive Care Unit. The investigational unit is International Organization for Standardization (ISO) 9001-certified and ensures a high level of quality assurance. Our methodology unit provides investigators with advice on clinical trial design and performs data analysis. Furthermore, our methodology unit attempts to solve methodological problems through ad hoc research projects. The quality management group offers general consulting and services for any clinical research project.

We are proud of these recent clinical trials publications, illustrating the work done at our CTU:

- Agnandji, Selidji, et al. 2016. 'Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe.' *New England Journal of Medicine*, Vol. 374, No. 17. April, pp. 1647–60.
- Carpentier, M, et al. forthcoming. 'Kappa Statistic to Measure Agreement beyond Chance in Free-Response Assessments.' (revision in review, 2017)
- Cullati, Stéphane, et al. 2016. 'Patient Enrollment and Logistical Problems Top the List of Difficulties in Clinical Research: A Cross-Sectional Survey.' *BMC Medical Research Methodology*, Vol. 16, Article No. 50. May.
- Huttner, Angela, et al. 2017. 'Safety, Immunogenicity, and Preliminary Clinical Efficacy of a Vaccine against Extraintestinal Pathogenic Escherichia Coli in Women with a History of Recurrent Urinary Tract Infection: A Randomised, Single-Blind, Placebo-Controlled Phase 1b Trial.' *Lancet Infectious Diseases*. February.
- Marsousi, Niloufar, et al. 2016. 'Coadministration of Ticagrelor and Ritonavir: Toward Prospective Dose Adjustment to Maintain an Optimal Platelet Inhibition Using the PBPK Approach.' *Clinical Pharmacology & Therapeutics*, Vol. 100, No. 3. September, pp. 295–304.
- Poncet, Antoine, et al. 2016. 'Normality and Sample Size Do Not Matter for the Selection of an Appropriate Statistical Test for Two-Group Comparisons.' *Methodology: European Journal of Research Methods for the Behavioral and Social Sciences*, Vol. 12, No. 2. June, pp. 61–71.

Benefits the CTU offers

The CTU offers expertise and means to conduct clinical trials with professionalism and quality, in a safe environment. Additionally, it enables investigators to save time.

Synergies gained from being a member of the CTU network

Synergies that benefit us include the exchange of scientific and clinical expertise. These include the SCTO's Guidelines for Good Operational Practice (GGOP), Standard Operating Procedures (SOP), clinical trial data management software, common training (on audits and ISO 9001), and visibility.

The decade ahead for clinical research in Switzerland

We hope to see enhanced harmonisation among the CTUs, including simplifying the multicentre study set-up and the harmonising of contracts. We also expect to see the poles of expertise within the CTU network highlighted (such as early phase I trials in Geneva), both within our field and externally.

With this, she triggered a storm of protest not only in her family, but throughout the country. The public was convinced that women were physically too weak to undertake a course of study.

CTU GENEVA

President
Prof. Jérôme Pugin
Scientific deputy
Dr Françoise Lascombes
Management assistant
Corinne Chaudet

Clinical Investigation Unit

Manager
Prof. Jules Desmeules
Medical doctor
Dr Alain Matthey
Pharmacist and pharmacovigilance manager
Dr Victoria Rollason
Clinical research associate (CRA) and monitoring manager
Jocelyne Chabert
CRA and medical device expert
Mariagrazia Di Marco
CRAs
Ninon Horie, Emmanuelle Lelong Favre
Data managers
Serenella Ferro Rojas, Khaled Mostaguir
Study nurses
Donatienne Cordier, Nathalie Isidor, Roselyne Merlet
Auxiliary nurse
Teuta Cajani-Ajdini

Methodology Unit

Manager
Prof. Thomas Perneger
Management assistant
Sandrine Rudaz
Statisticians
Dr Christophe Combescure, Dr Elise Dupuis-Lozeron, Antoine Poncet

Quality Management Unit

Manager
Dr Françoise Lascombes
Secretary
Marlène Mischler
Quality officers
Isabelle Mercier, Isabelle Semac

SCTO MEMBER OF THE CTU NETWORK

UNIVERSITÉ DE GENÈVE
FACULTÉ DE MÉDECINE

HUG Hôpitaux Universitaires Genève

Q&A

The CTU network's anniversary provides an opportunity for us to reflect on our past and to envisage the future. For this purpose, we have asked some of our key partners to comment on the CTU network.

Q1 From your perspective, what has changed significantly thanks to the introduction of CTUs and their network?

Swissmedic

The quality of the application dossiers of investigator-initiated trials (IIT) has improved markedly with the involvement of the CTUs. Thanks to the CTUs, the sponsor-investigators now have access to a contract research organisation (CRO) they can trust and afford, and with whom they share a common mindset, because they belong to the same academic environment. Another important benefit is the involvement of the CTUs in the training of clinical trial teams on GCP and legal requirements.

Division Clinical Trials
Swissmedic

Swiss Academy of Medical Sciences

The common standards, also passed on in shared trainings, have clearly improved the quality of clinical research, from the quality of the applications, to the implementation of research projects, right through to their publication.

Daniel Scheidegger
President Swiss Academy of Medical Sciences

swissethics

The expertise of the CTUs has considerably improved the quality of the applications of IIT to all ethics committees. Given that human research is only ethical if the scientific, legal, and ethical requirements are fulfilled, CTUs are contributing a great deal towards this progress. The CTUs have not only improved all the regulatory aspects as regards trials, but have also resulted in scientific questions being much more rigorously addressed. This is a result of skilled biostatisticians calculating and identifying the relevant endpoints for the respective scientific and/or clinical questions. The CTUs have contributed considerably to the key issues of increasing scientific value and reducing scientific waste.

Dr Susanne Driessen
Chair swissethics

European Clinical Research Infrastructure Network (ECRIN)

The SCTO is ECRIN's national scientific partner, and as such, we have the opportunity to collaborate regularly with the network and its individual CTUs. These centres play an active role in the implementation of the multinational (academic) clinical trials that ECRIN supports. We are honoured to partner with such high-quality research centres, devoted to excellence in all areas of research, and we believe that their contribution has a direct and positive impact on the quality of ECRIN-supported trials.

Marie Heim-Vögtlin
After her father granted the necessary permission, 23-year-old Marie Heim-Vögtlin began her medical studies at the University of Zurich in 1873, and thus became the first Swiss woman university student.

OVERVIEW
CONTACTS

CTU network members

CTU Basel
University of Basel
Department of Clinical Research
c/o University Hospital Basel

Schanzenstrasse 55, 4031 Basel
+41 (0) 61 328 77 17
https://dkf.unibas.ch

CTU Bern
Department of Clinical Research
University of Bern

Finkenhubelweg 11, 3012 Bern
+41 (0) 31 631 33 72
www.ctu.unibe.ch

CTU Geneva
Centre de recherche clinique
University Hospital Geneva and Medical
Faculty of the University of Geneva

Rue Gabrielle Perret-Gentil 4, 1211 Geneva 14
+41 (0) 22 372 91 34
http://crc.hug-ge.ch

CTU Lausanne
Centre de recherche clinique
Department of Education and Research

Rue du Bugnon 21, 1011 Lausanne
www.chuv.ch

CTU St.Gallen
Kantonsspital St.Gallen

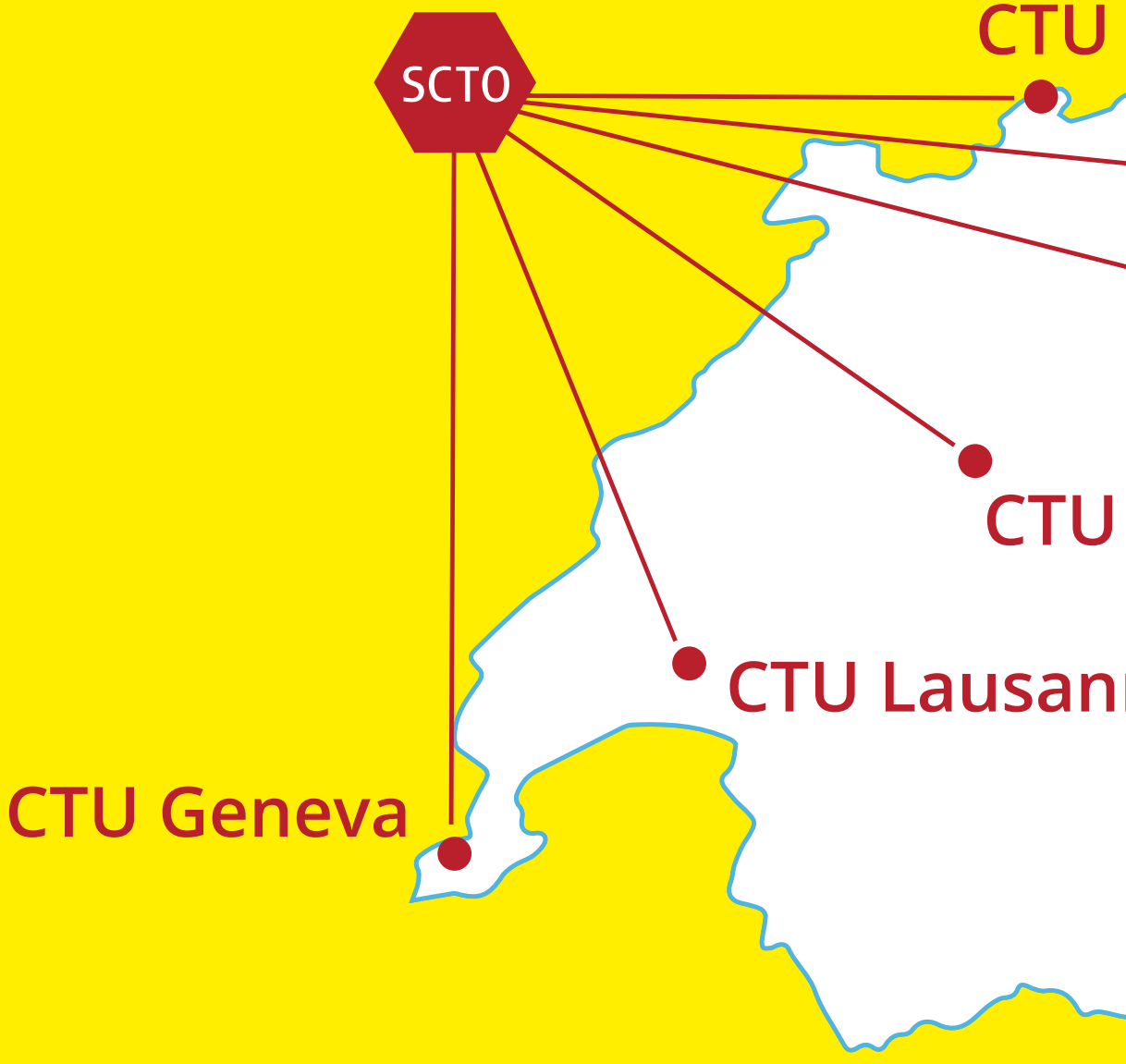
Rorschacherstrasse 95, 9007 St.Gallen
+41 (0) 71 494 35 12
www.ctu.kssg.ch

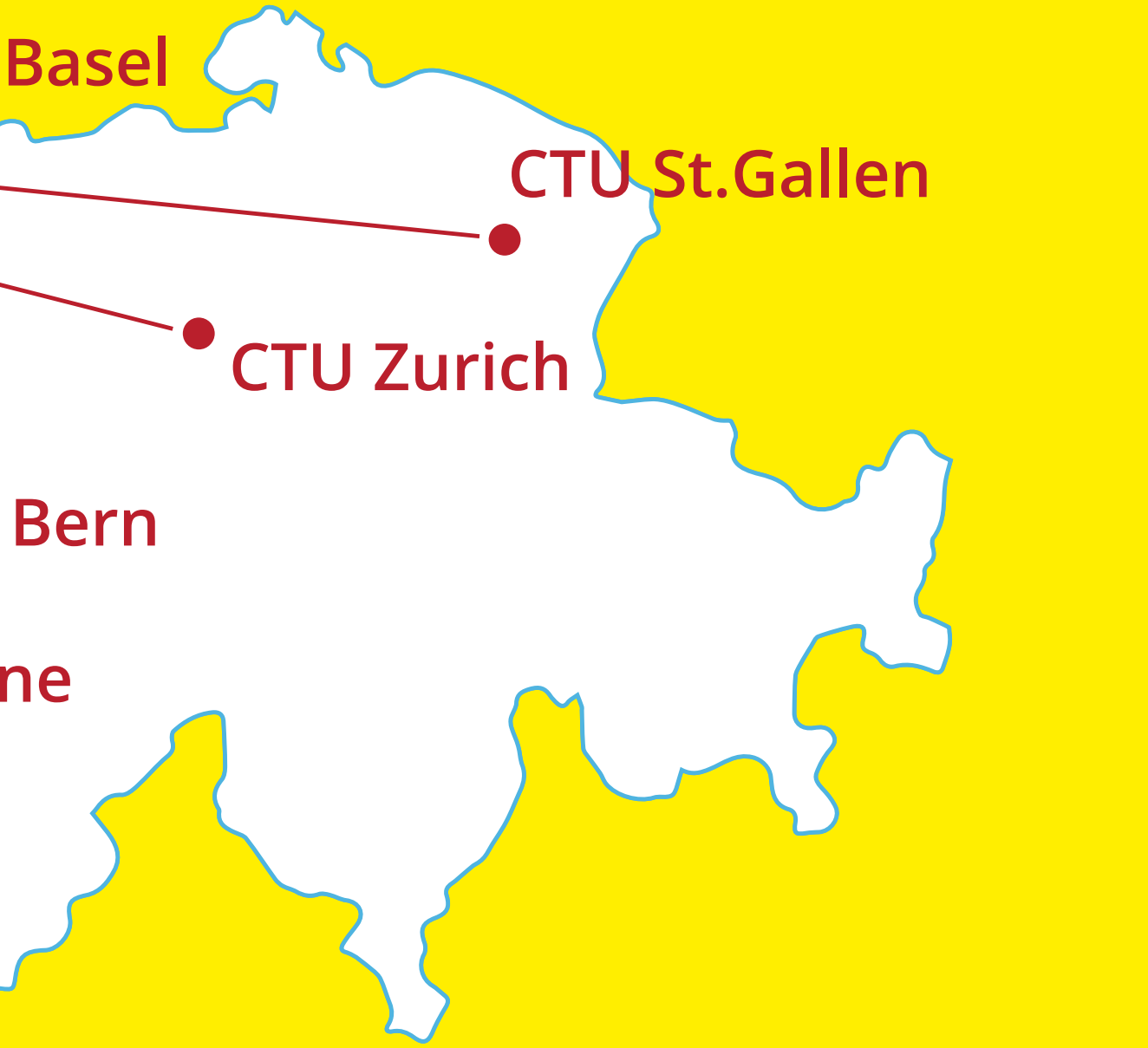
CTU Zurich
Clinical Trials Center
University Hospital Zurich

Raemistrasse 100 / MOU2, 8091 Zurich
+41 (0) 43 253 02 47
www.en.ctc-zkf.usz.ch

SCTO MEMBER OF THE CTU NETWORK

The SCTO is an independent organisation and is based on a joint initiative of the Swiss National Science Foundation (SNSF) and the Swiss Academy of Medical Sciences (SAMS). As of 2017, the SCTO is a research institution of national importance funded by the State Secretariat of Education, Research and Innovation (SERI) and the SNSF.


SCTO
CTU
CTU
CTU Lausan
CTU Geneva


Basel
CTU St.Gallen
CTU Zurich
Bern
ne

OVERVIEW
PLATFORMS

CTU platforms

Platform	Coordination
Data management	Dr Michael Scharfe, CTU Basel
Biostats/methods	Brigitta Gahl, CTU Bern
Monitoring	Dr Jocelyne Chabert, CTU Geneva
Regulatory affairs	Dr Laure Vallotton, CTU Lausanne
Project management	Dr Synove Otterbech / Mareen Reiter, CTU St.Gallen
Auditing	Dr Regina Grossmann, CTU Zurich
Education	SCTO Executive Office

Coordination of the CTU network

Executive Office of the Swiss Clinical Trial Organisation (SCTO)
Petersplatz 13, 4051 Basel
Phone +41 (0) 61 260 10 40
Web *www.scto.ch*

Collaboration

ECRIN: European Clinical Research Infrastructures Network
SwissPedNet: Swiss Research Network of Clinical Paediatric Hubs
PedCRIN: Paediatric Clinical Research Infrastructure Network

Funding

- State Secretariat of Education, Research and Innovation (SERI)
- Swiss National Science Foundation (SNSF)
- cantons and/or university hospitals/universities to which the CTUs are linked
- revenues from certain services subject to a fee
- private institutions (such as foundations)

FNSNF
Swiss National Science Foundation

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Education,
Research and Innovation SERI

Q&A

While reflecting on the developments of the past decade, we asked our key partners to comment on what they see as the future priorities for the CTU network.

Q2 From your perspective, what should the CTU network mainly focus on?

Swissmedic

The CTU network should focus on harmonising the training on GCP and legal requirements relating to clinical trial teams (investigators, study nurse, etc.) in the different CTUs.

It would also benefit from implementing an audit programme for the investigator-initiated trials that are running in the centres they are responsible for. This audit would not be limited to the trials where the CTU is involved as the CRO, but to all running IIT trials.

Finally, the network should aim to reach agreements with the hospital pharmacies to get reasonable prices for the preparation of investigational medicinal products (IMPs) according to GMP, for investigator-initiated trials. While these prices are generally very high for the typically small budgets of trials, high pricing cannot be avoided, because GMP is essential to guaranteeing the quality and safety of the IMP.

Division Clinical Trials
Swissmedic

Swiss Academy of Medical Sciences

Thanks to the training and regular meetings of the CTU directors, the network is well established within itself. Now it should position itself outwards as an "entrance gate" for international studies, which would then be carried out simultaneously at all CTUs.

Daniel Scheidegger
President Swiss Academy of Medical Sciences

swissethics

Reducing waste and increasing value should be the main areas of focus, to help young scientists to start their careers. The recent years have witnessed an enormous increase in efforts to reduce incrementally any potential study-related risks (not only potential medical risks, but also risks pertaining to data protection, for example). The majority of these risks have a very low likelihood of occurring. Similarly, the maximum level of risk mitigation by increasing regulatory efforts has probably been reached (or even surpassed). The only feasible alternative to this additional regulatory activity would be if the CTUs were – among others – mandated to establish an audit function to control data and sample research on the national level for the projects of biobanking and personalised health.

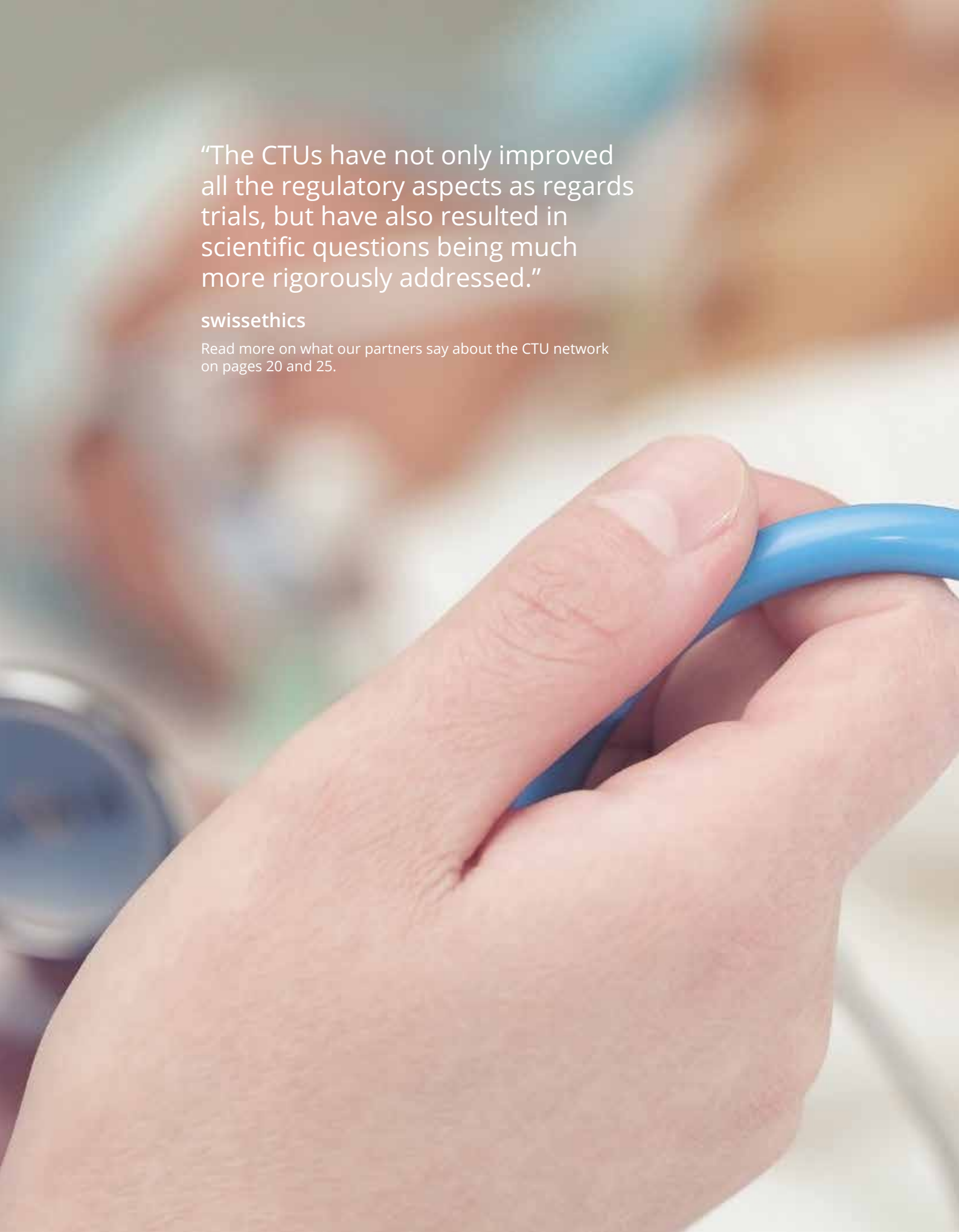
Therefore, as a general rule, the CTU network should prioritise scientific issues over regulatory aspects. As regards improving research in Switzerland, the SCTO and its CTU network have the opportunity to become a major academia-driven stakeholder. Because pharmaceutical research is intended to develop new markets for novel drugs, the generation of medical evidence is usually driven by economic reasoning. The SCTO should promote that academic, scientific, and medical reasoning become important drivers of the generation of medical evidence in future.

Dr Susanne Driessen
Chair swissethics

Patient representative

I find it particularly impressive to see how thoroughly the SCTO is involving patients in its work. They are tirelessly committed to the Swiss EUPATI platform. We are very grateful that we can continue to count on such a strong partner.

David Haerry
Vice-Chairman Positive Council Switzerland



“The CTUs have not only improved all the regulatory aspects as regards trials, but have also resulted in scientific questions being much more rigorously addressed.”

swissethics

Read more on what our partners say about the CTU network on pages 20 and 25.

CTU PORTRAIT
LAUSANNE

A highlight of the work conducted by the CTU Lausanne

Our CTU was contacted in early September 2014, when the World Health Organization declared the Ebola outbreak spreading in West Africa an international health emergency. WHO mandated Prof. Blaise Genton as principal investigator for a combined phase I and IIA (first-in-human) clinical trial, testing the safety and immunogenicity of one of the few vaccine candidates in the pipeline.

We contributed to the setup, implementation, and completion of this trial as sponsor representative. Our activities included: coordinating all stakeholders overall, discussing the study design, managing study budgets and contracts (the Clinical Trial Agreement with GlaxoSmithKline/GSK and the National Institute of Allergy and Infectious Diseases/NIAID, plus a Horizon 2020 grant agreement), writing the protocol and other study-related documents, developing the electronic Case Report Forms (eCRF via secuTrial®), submitting the dossiers to the competent authorities with extremely tight deadlines (the dossiers were submitted to the ethics committee and Swissmedic less than 3 weeks after the first contact with the principal investigator and the study was authorised just one month later), registering the clinical trial, organising the shipping of vaccines, managing the Trial Master File, overseeing the monitoring and safety management including organising Data and Safety Monitoring Board (DSMB) meetings, amendments, contributing to writing of the publication, and finally, writing the final Clinical Study Report.

All study visits were performed at the clinical investigation unit of our CTU. The recruitment and vaccination of 120 healthy volunteers was completed in 1.5 months and these participants were followed up for 6 months. Our study nurses were involved in recruiting participants, organising and conducting study visits, obtaining and processing biological samples, collecting and administering study data on eCRF, and managing the participants' study files.

To conclude, the results of the study were then published in this article:

De Santis, Olga, et al. 2016. 'Safety and Immunogenicity of a Chimpanzee Adenovirus-Vectored Ebola Vaccine in Healthy Adults: A Randomised, Double-Blind, Placebo-Controlled, Dose-Finding, Phase 1/2a Study.' *The Lancet Infectious Diseases*, Vol. 16, No. 3. March, pp. 311–20.

Learning gained from this collaboration

Our participation in this study was a real challenge, due to the urgency of the Ebola outbreak. We had to meet extremely tight timelines for obtaining regulatory approval and completing recruitment. In order to fulfil these requirements, we had to put this study on our top-priority list and postpone less urgent projects. Several fully dedicated collaborators of the CTU had to work exclusively on this project for weeks. The Ebola project permitted us to develop and implement new activities, such as that of sponsor role and study coordination.

This project was also the first for us that simultaneously involved almost all the staff and type of activities at the CTU (regulatory affairs, project management/coordination, data management and clinical operations). It led to very close and fruitful collaboration among our CTU staff members, helping greatly to build our team spirit.

Finally, the CTU network has offered us international collaborations (such as with Horizon 2020, and NIAID) with promising results which gave our CTU national and international visibility.

Testimonial

"Our collaboration with the CTU Lausanne for the conducting of our 'express' Ebola vaccine phase I/II trial was invaluable in several respects. Of especial value were the design and writing of the protocol, case report and informed consent forms, the development of regulatory documents for Swissmedic, as well as for the in-depth scientific investigation, to responding rapidly and appropriately to the regulatory authorities' comments on the product.

But certainly, the most important contribution of the CTU Lausanne was to have developed a fantastic working environment with fully dedicated staff, ready to address the numerous challenges that occurred during this trial. Thanks to the professionalism and commitment of the staff, we were all able to achieve at an incredible speed what was so much awaited to fight the dramatic Ebola virus disease epidemic in Africa."

Prof. Blaise Genton, principal investigator of the Ebola study,
University medical centre Lausanne

What makes the CTU Lausanne unique

The CTU Lausanne benefits from a small, yet highly dedicated and rapidly growing, multi-disciplinary team. Our team members have various and complementary career backgrounds, having being involved in different types of organisations and projects. Consequently, they are able to cover almost all aspects of clinical research. Combined, our skills include: interventional and observational studies, public academic and institutional research as privately funded and corporate industry research, drug development, translational research, biomarkers, medical devices and vaccine-related projects. Within the 2017–2020 SCTO development plan, funded by the State Secretariat for Education, Research and Innovation (SERI), the CTU Lausanne is in charge of developing a national regulatory affairs platform.

Benefits the CTU offers

Our multidisciplinary team is offering an *à la carte* service, to support all aspects of clinical research studies, from the concise advice to extensive support, through all steps: from concept and design to the final publication of a study. In addition to this direct support, the CTU Lausanne offers more transversal services such as GCP trainings – recognised by swissethics – for principal investigators and sponsor-investigators. These training courses are developed in partnership with the centre of clinical epidemiology (Centre d'épidémiologie clinique/CepiC). Our CTU is thus now the one-stop shop for clinical research in Lausanne.

With this, scurvy was eradicated almost completely from the Royal Navy.

Synergies gained from being a member of the CTU network

Being a member of the CTU network is a major advantage, in terms of our impact and visibility. A clinical research organisation like ours benefits from being part of a national network, having identified counterparts in all main academic areas, from sharing common definitions, missions, procedures, and tools (such as a risk-based evaluation tool that helps us advocate for adequate practices in monitoring). Moreover, the federal recognition of the added value of such a network endorses its credibility, when implementing high-quality procedures that promote the excellence of clinical research in Switzerland.

The decade ahead for clinical research in Switzerland

Research is competitive by nature; clinical research cannot escape such pressure. On the other hand, quality and efficiency present in clinical research are also the driving forces that preserve our founding principles of ethics and safety. Thus, in an increasingly complex and demanding environment (with its constraints of regulations, safety, procedures, traceability, transparency, costs and swiftness of reactions required), the only way for Switzerland to stay internationally competitive will be for us to maintain this excellence, by always striving for improvement. This is why we need the CTU network, a specialised network of professionals who share their knowledge, skills, and returns on experience – to maintain clinical research at its best.

CTU LAUSANNE

Head
Prof. Jean-Daniel Tissot
Director
Prof. Marc Froissart
Medical coordinator
Dr Laure Vallotton
Portfolio manager, project coordinator
Dr Isabelle Guilleret
Senior clinical research managers
Aude Erdmann-Voisin, Dr Aurélie Mello, Dr Loane Warpelin-Decrausaz
Clinical research associate
Sonia El Hamdi
Biostatistician
Dr Pierluigi Ballabeni
Clinical laboratory biologist
Dr Marc Maillard
Study nurses
Christiane Pellet, Laura Pezzi, Françoise Secretan, Loredana Sene
Research data project head
Ali Maghraoui
Database manager
Fady Fares

SCTO MEMBER OF THE CTU NETWORK

UNIL | Université de Lausanne
Faculté de biologie et de médecine

Although the importance of Lind's findings on scurvy were recognised at the time, it was not until more than 40 years later that an official Admiralty order was issued on the supply of lemon juice to ships.

"We are honoured to partner with such high-quality research centres, devoted to excellence in all areas of research."

ECRIN

Read more on what our partners say about the CTU network on pages 20 and 25.

CTU PORTRAIT
ST.GALLEN

A highlight of the work conducted by the CTU St.Gallen

The CTU provided project and safety management, medical writing, biostatistics, and monitoring services for an international investigator-initiated trial conducted by PD Dr Ulrich Mey (Trial chairperson, Kantonsspital Graubünden/KSGR), in cooperation with Prof. Christoph Driessen (Sponsor-investigator and co-trial chairperson). The clinical trial was successfully conducted, involving 50 patients at 17 active haemato-oncological study sites in Switzerland and Germany, from April 2012 to December 2015.

The CTU services provided covered all stages of the trial, from set-up (budget calculation, contract negotiation, medical writing, biostatistics, and submissions to ethics committees as well as Swissmedic) to its implementation (including full oversight, remote control of the study data, safety management and reporting, monitoring, and investigator meetings), and the conclusion of the study (data cleaning and analysis, the Clinical Study Report, and archiving). Liaison took place with external service providers in Switzerland; for monitoring there was a cooperation with the CTU Zurich. In Germany, project management and monitoring was conducted by a German CRO (iOMEDICO AG).

This open, multicentre, phase II study evaluated the efficacy and safety of Bendamustine, Revlimid, and Dexamethasone (BRd) in patients with relapsed/refractory Multiple Myeloma (rrMM) after first-line treatment. Study patients received 6 cycles of BRd (induction therapy) followed by 12 cycles of standard treatment of care with Revlimid and Dexamethasone (Rd).

The primary endpoint investigated the combined complete and very good partial response (CR/VGPR) rates achieved within or over 4 weeks, after the treatment with BRd-treatment. The study aimed to demonstrate a CR/VGPR rate of >40% after induction therapy. Of 45 evaluable patients, 23 (51%) achieved a CR/VGPR. Grade 4 neutropenia or thrombocytopenia occurred in 17 (34%) and 8 (16%) patients, respectively. Thus, study results demonstrated that treatment with BRd has a high efficacy in patients with advanced rrMM. However, dose-limiting haematotoxicity restricts its use in those patient populations that are extensively pretreated. To summarise the findings, BRd is a safe and efficacious regimen in the second-line treatment for rrMM, leading to high-quality responses in a considerable proportion of patients.

Study results were published in October 2016 in the *British Journal of Haematology* and the Clinical Study Report was filed in November 2016.

Learning gained from this collaboration

This collaboration embodied the first proof of concept of different CTUs working together in the monitoring of a multicentre, multinational drug trial. In this particular case, while the sponsor role and lead of the study was based in St.Gallen, monitoring tasks for patients treated and recruited in the Zurich area were taken over by the CTU Zurich. To enable this, a mutual agreement about monitoring conduct and practice in this trial was required and established between both CTUs.

Of high value were the various management plans, developed in advance of the study, such as the safety and data management plan. For future projects, more time needs to be allocated to the contract negotiations and communication required to support the study sites. We observed that the level and experience of the study site staff will determine the extent of monitoring required.

Testimonial

"The trial was a multicentre, international, phase II study for testing a novel drug combination in an oncology indication. All regulatory and safety aspects for the conduct of clinical trials had to apply and had to be met from an organisational point of view. This meant that a structure was required to perform, in particular, the relevant sponsor's tasks. The CTU network of the SCTO provided an ideal environment and was, in the context, the only option enabling this study, which was subsequently published in the *British Journal of Haematology*. Without the CTU and the SCTO network, this trial would not have been possible."

PD Dr Ulrich Mey, Medical Oncology and Haematology,
Kantonsspital Graubünden, Chur

What makes the CTU St.Gallen unique

The CTU provides professional support to investigators across all phases of their clinical trials, starting at the concept phase, covering project and data management, and accompanying the study throughout its completion. Members of the CTU team share their knowledge and expertise with the clinical researchers and offer access to the broader resources of the CTU network and the SCTO. Moreover, principal investigators of investigator-initiated trials receive efficient feedback on their study design and elaboration, before submitting it to the ethics committee. Because the pre-submission process encompasses both regulatory and scientific assessments, it covers the essential aspects of a clinical trial protocol. Finally, the CTU St.Gallen has established a comprehensive biobank environment, for registering and storing study-related biological material. The CTU biobank team manages all tasks relating to biobanking on behalf of the investigator, including the coordination and exchange with the Swiss Biobanking Platform (SBP).

Benefits the CTU offers

The CTU offers project and site management services through all stages of single- and multicentre clinical trials in all medical fields, for national and international settings. Our project managers initiate and manage the trial and coordinate the communication among all parties involved, to ensure project objectives are met in a timely fashion. Having the facilities on campus, the CTU offers expertise on and easy access to local infrastructure and study activities. Moreover, through the CTU network and the SCTO, with their contact to European clinical research infrastructure, the CTU supports efficient coordination with other investigational sites. Depending on the needs of the clinical trial, on-site or remote risk-based monitoring is performed to ensure protocol and regulatory compliance.

Another pair was given vinegar, and the last pair two oranges and one lemon per day.
Those sailors fed citrus fruits experienced a remarkable recovery.

Synergies gained from being a member of the CTU network

Our CTU creates synergies through cost-effective trial management and our in-depth knowledge on study harmonisation. We can ensure cost-effectiveness in multicentre trials, by allocating monitoring and auditing tasks to partner CTUs, based on proximity. For example, in a multicentre international investigator-initiated trial led by the CTU St.Gallen, the monitoring of Bern and Fribourg trial sites was carried out by a monitor of the CTU Bern. An exceptional benefit for us is the know-how sharing that occurs within the CTU network, promoting a harmonised and up-to-date elaboration of national quality standards that are compliant with ethical and regulatory obligations.

The decade ahead for clinical research in Switzerland

The accelerated growth of knowledge in biology and medicine, together with the discovery of novel disease mechanisms and personalised treatment options, have led to an increased demand for national and international multicentre trials. Such studies require comprehensive skills and knowledge, which cannot be provided by small and specialised clinical research units. Hence, to be competitive in clinical research on the international level, clinician scientists will benefit from the well organised research infrastructure provided by the CTU network of the SCTO. It will be crucial for clinical research in Switzerland to remain compatible with international regulations and to collaborate closely with clinical research infrastructures in neighbouring countries.

CTU ST.GALLEN

Co-head, scientific/medical
Prof. Lukas Flatz
Co-head, operational
Dr Reinhard Maier
Quality manager and Swiss Biobanking Platform (SBP) hub coordinator
Dr Synove Otterbech
Administrative assistant
Christina Brem
Project managers/monitors
Dr Elke Hiendlmeyer, Christina Jodlauk, Mareen Reiter
Project manager/monitor and GCP course manager
Dr Simone Kaelin
Biostatistician
Sabine Güsewell
Data managers
Daniel Lengwiler, Andreas Szabo
Study nurses
Roman Aliesch, Caroline Dietrich, Nicole Kradolfer, Sigrid Patzl
Trainee
Burim Zulfiu

SCTO MEMBER OF THE CTU NETWORK

Kantonsspital St.Gallen

"Given that human research is only ethical if the scientific, legal, and ethical requirements are fulfilled, CTUs are contributing a great deal towards this progress."

swissethics

Read more on what our partners say about the CTU network on pages 20 and 25.

Lind selected 12 sailors aboard ship, all suffering from scurvy, and divided them into six pairs, giving each pair different additions to their basic diet. Some received cider, others seawater, some "elixir vitriol", and yet others a mixture of garlic, mustard, and horseradish.

CTU PORTRAIT
ZURICH

A highlight of the work conducted by the CTU Zurich

The CTU Zurich (also known as the Clinical Trial Centre/CTC) has been engaged in a number of local, national, and international clinical research projects, such as EuroSkinGraft (funded by the European Union Seventh Framework Programme, also known as FP7).

EuroSkinGraft produced a fully autologous skin graft, first grown in the lab and then transplanted in a single procedure to human patients. Being part of a project that dealt with a novel generation of skin substitutes was one of the highlights of the recent years for us. The extraordinary dedication of the sponsor Prof. Ernst Reichmann of the Tissue Biology Research Unit and the principal investigator Prof. Martin Meuli and his team at the University Children's Hospital Zurich were an inspiration for CTC staff. Headlines in the media, such as "Schweizer Forscher verpflanzen Kunsthaut" (Swiss researchers transplant artificial skin) and "Der Hautmacher" (The skin-maker), might illustrate the impact of this project.

Learning gained from this collaboration

The CTC is continuously benefiting from the experiences gained, especially with projects relating to novel processes and procedures, e.g. with skin transplantation. We adapt, improve, and provide procedures and processes continually, as necessary.

Testimonial

"The CTC Zurich was involved with the EuroSkinGraft FP7 project, from the beginning. The consortium benefited enormously from the expertise of the CTC, in all relevant aspects. The professional support provided by the CTC staff in trial management, data management, and lessons learned from monitoring made us full professionals, regarding our GCP compliance. This competence was confirmed during the Swissmedic inspection of our project. Together with the specialists from CTC, we continue to improve GCP adherence, in order to focus on what is driving us: providing our patients with the best and safest future therapies developed by our research."

Prof. Ernst Reichmann, Head of the Tissue Biology Research Unit,
University Children's Hospital Zurich

What makes the CTU Zurich unique

At the CTC, we offer a comprehensive range of services to clinical researchers, not only from the University Hospital Zurich, but also from the University Children's Hospital, the Balgrist University Hospital, the Psychiatric University Hospital Zurich, the Federal Institute of Technology (ETH) Zurich, and many more clinical institutions in the Canton of Zurich.

At the CTC, we collaborate with an impressive range of Swiss clinical trial institutions and our centre serves as a founding member of the International Clinical Trials Center Network (ICN), of which it is the current chair institution. We operate a quality management system (certified according to ISO 9001), and share our expertise with partners who intend to establish their own quality management (QM) system for clinical research. Besides providing services to clinical researchers, the CTC offers a range of educational opportunities, from weekly seminars and scientific meetings to GCP courses and advanced studies programmes.

Benefits the CTU offers

The specialists at the CTC support researchers in the planning and execution of clinical trial projects, in compliance with Swiss laws and regulations, approved guidelines and the international GCP Standards (ICH-GCP-Standards), published by the Swiss Academy of Medical Sciences (SAMS). We focus primarily on academic research (investigator-initiated clinical trials), but also support industry-sponsored projects.

Our **Regulatory Affairs Unit** experts offer competent advice and support in the preparation of clinical trial documents (e.g. study protocol, informed consent and patient information). They assist researchers in dealing with ethics committees and regulatory authorities. Submission documents are scrutinised for compliance with regulations and standards (including GCP).

Our **Monitoring Unit** specialists provide support in routine monitoring and undertake pre-study visits, initiation visits and close-out visits. They support site management, ensuring that all activities are performed in accordance with GCP standards and that all investigational sites comply with protocol and applicable regulations.

The **Data Management Unit** specialists offer support or conduct for all procedures related to the handling of clinical data, in particular of electronic clinical trial data. The unit uses and maintains validated electronic database management systems (secuTrial® and RedCAP®) for data capture, storage, and retrieval.

The **Clinical Research Ward** supports clinical researchers in the running of clinical trials. Its specialist staff (physicians, bio-medical scientists, study nurses, and coordinators) perform comprehensive site management of common structures and resources, and provide dedicated research facilities (a fully equipped research ward), logistics (controlled storage), and manpower.

The **Quality Management Unit** assures the currency and accuracy of all process documents (Process Documents, Standard Operating Procedures, and Working Instructions), and other forms and templates for internal and external use, such as for reporting on safety. The team offers on-demand quality consulting and auditing. A service of the unit offers a set of instructions and templates that enable external partner hospitals to build their own system and clinical research ward.

All of our units are also involved in the **educational programme of the CTC**. The CTC offers a range of teaching events, such as GCP courses at all levels (accredited by the SGPM, SwAPP, and swissethics), courses leading to Certificates of Advanced Studies, issued by the University of Zurich, in clinical trial management, clinical monitoring, and clinical data management. The CTC is an FMH/SIWF, category-A specialist training site allowing an accredited 3 years training leading to the Pharmaceutical Medicine specialist title for physicians. Qualification for the SwAPP diploma can also be obtained.

We offer a range of courses on various aspects of clinical research and organise lectures and scientific meetings. The CTC is engaged in the ICN, an international collaborative network of CTUs, for which it is the current chair institution.

In 1747, while serving as surgeon on *HMS Salisbury*, James Lind carried out experiments to discover the cause of scurvy, the symptoms of which included malaise, joint pain, bleeding gums, loose teeth, and poor wound healing.

Synergies gained from being a member of the CTU network

The CTC is engaged in numerous activities of the CTU network, including task forces and working groups on various topics. We enjoy the exchange of ideas and the combined efforts to promote the advancement of clinical research in Switzerland.

The decade ahead for clinical research in Switzerland

The CTC envisions nationwide opportunities for industry-independent clinical research of the highest standards, not only in university-associated institutions, but also in district or private hospitals and at primary health care service institutions, such as general practices and health maintenance organisations. Additionally, the CTC hopes a general system of financing quality and regulatory support efforts in publicly funded investigator-initiated clinical trials will be established. Finally, we would also welcome a national financing program for industry-independent clinical research.

CTU ZURICH

Head
Prof. Gabriela Senti
Head of regulatory affairs
Dr Annette Widmann
Head of monitoring
Karin Huber
Head of clinical research ward
Dr Natalie Leu-Möckli
Head of advanced studies
Silke Ludwig
Head of quality management
Dr Jürg Lustenberger
Head of data management
Dirk Smolinski
Head of education and international affairs
Dr Fabian Tay

SCTO MEMBER OF THE CTU NETWORK

UniversityHospital Zurich

SCTO CONTACTS

SCTO Executive Office

Annette Magnin, Managing Director
a.magnin@scto.ch

Dr Caecilia Schmid, ECRIN Correspondent, Project Manager Data Management
c.schmid@scto.ch

Rosine Mucklow, Project Manager Quality
r.mucklow@scto.ch

Pascale Wenger, Network Coordination
p.wenger@scto.ch

Jadranka Knezevic, Administration, Communication
j.knezevic@scto.ch

Cornelia Morel, Administration, Accounting
c.morel@scto.ch

To learn more about these two pioneering scientists, Marie Heim-Vögtlin and James Lind, visit:

Marie Heim-Vögtlin

https://www.ebg.admin.ch/ebg/de/home/dokumentation/persoenlichkeiten-aus-der-schweizer-gleichstellungsgeschichte/marie-heim-voegtlin--1845-1916-.html

James Lind

http://www.bbc.co.uk/history/historic_figures/lind_james.shtml

Editor / Author

SCTO, Annette Magnin, Jadranka Knezevic

CTU portraits provided by the CTUs

Design and layout

Howald Fosco Biberstein

Imprint

SCTO, Petersplatz 13, 4051 Basel, Switzerland
Tel +41 (0) 61 260 10 40, Fax +41 (0) 61 260 10 49
info@scto.ch, www.scto.ch

Patronage

FNSNF
Swiss National Science Foundation

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Education,
Research and Innovation SERI

James Lind
Lind was a Scottish doctor, a pioneer of naval hygiene and expert on the treatment of scurvy. He was born in Edinburgh in 1716. He also pioneered the first controlled clinical trial.

Swiss Clinical Trial Organisation
Petersplatz 13, 4051 Basel, Switzerland
www.scto.ch