5th Symposium
of the Swiss Clinical Trial Organisation (SCTO)
and the Bern University Hospital

Is there a future for Swiss Academic Clinical Research?

Wednesday, 18 June 2014, Inselspital Bern
Is there a future for Swiss Academic Clinical Research?

Dear Colleagues,

On behalf of the Swiss Clinical Trial Organisation (SCTO) and the Bern University Hospital we cordially invite you to the 5th SCTO Symposium devoted to the topic “Is there a future for Swiss Academic Clinical Research?”

The introduction of the law on research in humans (Human Research Act, HRA) and its ordinances changes the framework for clinical research in Switzerland considerably. Besides this new regulatory framework, academic clinical research is still facing challenges in terms of funding opportunities. This 5th SCTO Symposium intends to update you on currently discussed options to overcome at least some of these complex issues.

The first session is dedicated to the implementation of the HRA and its impact on clinical research. After a first appraisal of the status quo and an outlook to the future presented by the authorities, clinical research representatives will give an insight into the major improvements since the new law entered into force as well as its negative impact for clinical research. A patient’s view on the importance of (academic) clinical research and the role of patients will thematically close session one and at the same time build the bridge to the next session. This following part will namely focus on specific funding schemes from Germany, Norway and Italy, while clinical researchers will present case studies of projects funded by a foreign funding scheme.
The last session is devoted to the visions and perspectives for novel funding schemes for academic clinical research in Switzerland, giving different stakeholders the opportunity to share their views on the potential and limitations of academic clinical research in interactive short interviews.

We encourage you to participate in the discussion of these important aspects of future academic clinical research. Hopefully, this event offers a platform to successfully exchange ideas as well as a perfect opportunity to strengthen personal network. We are looking forward to lively discussions and invite you to contribute to the success of this event.

Yours sincerely,

Prof Pierre Dayer
President
Swiss Clinical Trial Organisation

Prof Matthias Gugger
Director of Teaching and Research
Bern University Hospital
## Scientific Programme

**Wednesday, 18 June 2014, Bern University Hospital**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:15</td>
<td>Opening, registration and coffee</td>
</tr>
<tr>
<td>09:45</td>
<td><strong>Welcome</strong></td>
</tr>
<tr>
<td></td>
<td>Prof Pierre Dayer, President SCTO,</td>
</tr>
<tr>
<td></td>
<td>Prof Matthias Gugger and Prof Peter Jüni, Bern University Hospital</td>
</tr>
<tr>
<td></td>
<td><em>Moderation of the symposium</em> Mathis Brauchbar, advocacy</td>
</tr>
<tr>
<td>10:00</td>
<td><strong>Session I</strong></td>
</tr>
<tr>
<td>10:00</td>
<td><strong>Half a year with the new legislation – a first appraisal</strong></td>
</tr>
<tr>
<td>10:00</td>
<td><strong>New Human Research Act: overview of implementation and status quo</strong></td>
</tr>
<tr>
<td></td>
<td>Brigitte Meier, Federal Office of Public Health (FOPH) and</td>
</tr>
<tr>
<td></td>
<td>Dr Françoise Jaquet, Swissmedic</td>
</tr>
<tr>
<td>10:40</td>
<td><strong>New Human Research Act: a major improvement</strong></td>
</tr>
<tr>
<td></td>
<td>Prof Christane Pauli-Magnus and Prof Mirjam Christ-Crain,</td>
</tr>
<tr>
<td></td>
<td>Dept Clinical Research, University Hospital Basel</td>
</tr>
<tr>
<td>10:55</td>
<td><strong>New Human Research Act: a major roadblock</strong></td>
</tr>
<tr>
<td></td>
<td>Prof Stephan Windecker, Department of Cardiology, University Hospital Inselspital Bern</td>
</tr>
<tr>
<td>11:10</td>
<td><strong>Academic clinical research – expectations of a patient</strong></td>
</tr>
<tr>
<td></td>
<td>Hansruedi Völkle</td>
</tr>
<tr>
<td>11:40</td>
<td><strong>Lunch buffet</strong></td>
</tr>
</tbody>
</table>
12:50 – 16:15  
Session II  
Funding for clinical research abroad

12:50  
The quality of funding schemes for clinical trials  
Dr Peter Wittman, PricewaterhouseCoopers (PwC)

13:20  
The German Research Foundation (DFG)  
Dr Frank Wissing, German Research Foundation (DFG)

14:00  
Neurostimulation for Parkinson's disease: a trial funded by the German Research Foundation  
Dr Michael Schüpbach, Bern University Hospital

14:30  
The Research Council of Norway  
Henrietta Blankson, PhD, The Research Council of Norway

15:00  
Coffee break

15:30  
The Italian Medicines Agency  
Dr Lorenzo Moja, University of Milan, Italy

15:50  
Albumin for severe sepsis: a trial funded by the Italian Medicines Agency  
Dr Pietro Caironi, University of Milan, Italy

16:15 – 17:15  
Session III  
A novel funding scheme for academic clinical research in Switzerland?

16:15  
It is time for a novel funding scheme  
Prof Peter Jüni, Institute of Social and Preventive Medicine (ISPM) and CTU Bern

16:35  
Different perspectives on academic clinical research and funding schemes  
Interactive short interviews with Prof David Nadal, SwissPedNet,  
Dr Peter Brauchli, Swiss Group for Clinical Cancer Research (SAKK),  
Dr Yvonne Gilli, National Council, Grüne, Dr Andreas Schiesser, santésuisse and delegates from the Swiss National Science Foundation (SNSF)

17:15  
Closing remarks and networking aperitif
About the Swiss Clinical Trial Organisation

Promoting a high-quality and nationally harmonised clinical research culture
The Swiss Clinical Trial Organisation (SCTO) is the central cooperation platform for translational and patient-oriented clinical research in Switzerland. Its primary objective is to position Swiss clinical research in an attractive and competitive way internationally with respect to innovation and quality.

A cooperation platform for (academic) clinical research
Through its founding members – the five Swiss university hospitals, the St. Gallen Cantonal Hospital, the Swiss Academy of Medical Sciences (SAMS) and the Collège des Doyens – the SCTO is closely connected to the six Clinical Trial Units (CTUs), which form a regionally established and nationally coordinated network for promoting academic clinical research. The CTUs are multidisciplinary study centres, serving as focal points for researchers and assisting in the planning, implementation, conduct and evaluation of studies in compliance with mandatory national and international standards.

Promoting a nationally harmonised study culture
The SCTO is assigned to enhance quality and harmonisation of the study culture within the CTU network and to specify common standards in the fields of quality, project and data management as well as education. The subject-specific working groups are composed of professional representatives of the individual CTUs and the SCTO. Moreover, the SCTO is the coordination platform for the CTU network and as such their representative and contact partner for authorities, industry and media.
National and international collaborations

As Swiss national information hub and cooperation platform, the SCTO is involved in the European Clinical Research Infrastructure Network (ECRIN), a not-for-profit organisation, which is primarily based on the collaboration with national coordinating networks of clinical research centres or units. www.ecrin.org

The SwissPedNet is the Swiss network for paediatric clinical research, a new initiative of the five Swiss university children's hospitals (Basel, Bern, Geneva, Lausanne, and Zurich) plus the three paediatric hospitals class A (Aarau, Lucerne and St. Gallen). The SCTO was assigned to coordinate the formation of this network and its activities with the existing CTU network. www.swisspednet.ch

To support patients empowerment, the SCTO is facilitating the launch of a EUPATI national platform (the European Patients' Academy on Therapeutic Innovation) to allow patients to become more involved in the development of innovative therapies and to be trained in the corresponding processes and regulations. www.patientsacademy.eu

Further close collaboration partners are the Swiss Group for Clinical Cancer Research (SAKK) and the Swiss Paediatric Oncology Group (SPOG). sakk.ch, www.spong.ch

Benefits

For researchers, the SCTO is the access point to multidisciplinary study centres, providing professional state-of-the-art support in the planning, implementation, conduct and evaluation of studies.

For industry, cooperative groups and other third parties, the SCTO facilitates the access to research infrastructures in Switzerland.

SCTO at a glance

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Non-profit institution, association, founded in 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>President</td>
<td>Prof. P. Dayer, HUG, Genève</td>
</tr>
<tr>
<td>Vice President</td>
<td>Prof. K. W. Grätz, Collège des Doyens</td>
</tr>
<tr>
<td>Director</td>
<td>A. Magnin</td>
</tr>
<tr>
<td>Members</td>
<td>CHUV Lausanne, Collège des Doyens, HUG Genève, Inselspital Bern, Kantonsspital St. Gallen, SAMW, Universitätsspital Basel, Universitätsspital Zürich</td>
</tr>
<tr>
<td>Advisors</td>
<td>Swissethics, SNSF, SwAPP, SGPM, SGKPT, scienceindustries, Interpharma</td>
</tr>
<tr>
<td>Network</td>
<td>CTU Basel, CTU Bern, CTU Genève, CTU Lausanne, CTU St. Gallen, CTU Zurich</td>
</tr>
<tr>
<td>Sponsors</td>
<td>SNSF, Members</td>
</tr>
<tr>
<td>Partners</td>
<td>ECRIN, SwissPedNet, SAKK, SPOG</td>
</tr>
</tbody>
</table>
General Information

Location
Inselspital Bern, Auditorium Ettore Rossi
Kinderklinik, Entrance 31B
Freiburgstrasse 31 B, 3008 Bern

How to get there
From train station SBB: Bus No 11, direction Güterbahnhof Bus stop Inselspital, see Bus 11 on the map

Parking
Insel-Parking, Murtenstrasse 10, 3010 Bern

Registration
By Friday, 30 May 2014
Online at www.scto.ch or by e-mail to scto2014@association-services.ch

Registration fee
CHF 200 Regular / CHF 100 Students
Free: Students enrolled at Bern University Hospital, University of Bern, MD-PhD Programme

Organisation
Swiss Clinical Trial Organisation
Petersplatz 13, CH-4051 Basel
Phone +41 (0)61 260 10 40
Fax +41 (0)61 260 10 49
event@scto.ch, www.scto.ch

Patronage
SAMS Swiss Academy of Medical Sciences
FNS Swiss National Science Foundation