The SCTO-CTU network
Measures to increase value

Christiane Pauli-Magnus and Mirjam Christ-Crain, 01.06.2017
To what extent did the network increase value?

<table>
<thead>
<tr>
<th></th>
<th>Looking at numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Looking at perceptions</td>
</tr>
<tr>
<td>3</td>
<td>Telling success stories</td>
</tr>
<tr>
<td>4</td>
<td>Looking at quality indicators</td>
</tr>
</tbody>
</table>
The network.
An initiative fostered by the Swiss National Science Foundation

- > 180 staff members/ 100 FTE
- 2017-2020: 14 Mio CHF SERI investment

SERI: State Secretariat for Education, Research and Innovation
Our mission.
Increasing value through comprehensive support.

Training and Education

Project consulting and support

Quality and research infrastructures
Support tailored to study phase.
Good Operational Practice Guidelines

<table>
<thead>
<tr>
<th>CONCEPT</th>
<th>DEVELOPMENT</th>
<th>SETUP</th>
<th>CONDUCT</th>
<th>COMPLETION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study is feasible</td>
<td>Study is approved</td>
<td>Study is initiated</td>
<td>Last Patient Last Visit</td>
<td>Study is published</td>
</tr>
</tbody>
</table>
Looking at numbers...

In 2016, the network contributed to **>260 clinical research projects**
Looking at numbers…

In 2016, the network provided > 2700 services
Looking at numbers...

In 2016, the network provided > 200 courses to > 3000 participants

- 73%
- 19%
- 6%
- 2%

- GCP, Investigator
- GCP, Sponsor- Investigator
- Undergraduate e.g. MD, MSc
- Postgraduate e.g. CAS, DAS, MAS
Looking at perceptions...

- We collected feedback from 155 researchers about their experiences with services provided by the CTU network.

Main question:
- Did a specific CTU service positively influence the quality of your study?
- Feedback was collected as agreement/disagreement on a Visual Analogue Scale.
Looking at perceptions.

Concept phase

- Research question: n=87
- Sample size calculation: n=70
- Budgeting: n=37
Looking at perceptions.
Planning phase

- Protocol development: n=73
- Ethics committee submission: n=67
- Informed consent development: n=50
- Study registration: n=44
- Swissmedic submission: n=27
- Insurance management: n=22
Looking at perceptions.
Setup phase
Looking at perceptions.
Conduct phase
Looking at perceptions.
Completion phase
Telling success stories.

**Pneumonia:**
- very common disease
- Treatment: Antibiotics
- But: still high morbidity and mortality

- Question: Additional treatment options?

- Corticosteroids: most potent anti-inflammatory agents

**Clinical study:**

Corticosteroids for community-acquired pneumonia: the STEP Study

- double-blind, randomized, placebo-controlled study
- 800 patients in 7 hospitals in Switzerland
Telling success stories.

"De-centralized" statistical and epidemiological support

Regulatory affairs: no professional support

Budget: no professional planning

No feasibility check

Time until approval from Ethics and Swissmedic: 154 days

Costs: estimated 1.5 Mio CHF

Reality: 2.3 Mio CHF

Slower than anticipated patient recruitment

Time until inclusion of 800 patients: almost 5yrs
Telling success stories.

- Concept: Study is feasible
- Development: Study is approved
- Setup: Study is initiated
- Conduct: Last Patient Last Visit
- Completion: Study is published

Data management
Onsite management
Monitoring plan

CTU
Telling success stories.

Adjunct prednisone therapy for patients with community-acquired pneumonia: a multicentre, double-blind, randomised, placebo-controlled trial

Claudine Angela Blum*, Nicole Nigro*, Matthias Briel, Philipp Schuetz, Elke Ullmer, Isabelle Suter-Widmer, Bettina Winzeler, Roland Bingisser, Hanno Elsaesser, Daniel Drazdov, Birsen Arici, Sandrine Andrea Urwyler, Julie Refardt, Philip Tarr, Sebastian Wirz, Robert Thomann, Christine Baumgartner, Hervé Duplain, Dieter Burki, Werner Zimmerli, Nicolas Rodondi, Beat Mueller, Mirjam Christ-Crain

www.thelancet.com Published online January 19, 2015 http://dx.doi.org/10.1016/S0140-6736(14)62447-8

Planning of subsequent project
Telling success stories.

Clinical study: The KIDS-STEP Study: Corticosteroids for community-acquired pneumonia of hospitalized kids

- double-blind, randomized, placebo-controlled study
- 700 preschool and school kids in 8 pediatric centers in Switzerland
Telling success stories

"Centralized": Combined epidemiological & statistical support for protocol development

Professional regulatory support
Budget planning
Feasibility check

Support in funding application
Telling success stories

KIDS STEP Study funded by IICT call 2017


*Planned Study start: 1st of June 2017*
Looking at quality indicators...

What is our impact on

- Relevance of scientific question
- Adequacy of design and statistics
- Efficiency of study management
- Transparency and publication

"By ensuring that efforts are infused with rigour from start to finish, the research community might protect itself from the sophistry of politicians, disentangle the conflicted motivations of capital and science, and secure real value for money for charitable givers and taxpayers through increased value and reduced waste."

The Lancet, January 2014 und April 2016
Formulating an academic response.

Systematic review on clinical research quality among different stakeholders

1 von Niederhäusern et al; manuscript under revision

Deduction of a comprehensive quality framework and corresponding indicators

Finding consensus among stakeholders

2 von Niederhäusern et al; manuscript in preparation
Formulating an academic response.
4-Step consensus process

Number of involved expert: 142

Involved stakeholder groups 6
- Patient representatives
- Academia
- Pharmaceutical industry
- Ethics Committees
- Regulatory bodies
- Funding agencies

Number of involved countries: 16

Overall response rate: > 70%

Academic stakeholders: 47%
Swiss stakeholders: 23%
Formulating an academic response.

Research Stages:
- Concept
- Planning & Feasibility
- Conduct
- Analysis & Interpretation
- Reporting & Dissemination

Infrastructure:
- Ethics (Patient safety & rights)*
- Relevance / Patient centeredness
- Minimization of bias (Internal validity)
- Precision (Statistical validity)
- Transparency / Access to data
- Generalisability (External validity)

Sustainability / Education

* non-negotiable
Operationalisation and validation.
In conclusion.
To what extent did the network increase value?
Thank you for your attention.