Adding Value in Clinical Research

8th Symposium of the Swiss Clinical Trial Organisation

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Ayşim Yılmaz
Clinical Research @ SNSF

1. Retrospect
2. Present challenges
3. Future perspectives
Clinical Research – main success factors

• specialised infrastructures and infrastructure networks
• multicentric studies and coordination
• training and standards - study design, GCP, statistics
• high data quality, data accessibility
• young clinician investigators
• time for research studies
SNSF action plan since 2004 (1)

Infrastructures

• multicentric cohort studies
• network of non-pathology oriented clinical trial units
• Swiss Clinical Trial Organisation (ECRIN)
• Swiss Biobanking Platform (BBMRI)
SNSF action plan since 2004 (2)

Projects and Careers

• MDPhD stipends
• Fellowships for young advanced clinical researchers
• SNSF Clinical Professorships
• Protected research time for young clinicians
• Special Programme University Medicine (translational research projects conducted by young clinicians)
• Special Programme IICT (investigator initiated clinical trials)
A short look at IICT – a new special programme

Investigator initiated clinical trials

- **research topic**: free, clinically relevant, under-researched, not in the industry focus, and of public interest

- **study type**: prospective, randomised, multicentric, interventional studies, novel or existing treatments

- **multicentric setting**: more than 2 centers. Non-university and international recruitment centers can be involved as «project partners»;

- collaboration with SCTO/CTU network
A closer look into IICT

Call 2015:

• 112 letters of intend
• 75 applications for CHF 116 Mio
• 9 grants for CHF 12.6 Mio (start 2016)

Call 2016:

• 59 letters of intend
• 35 applications for CHF 51 Mio
• 7 grants for CHF 9.7 Mio (start 2017)
Centres involved in SNSF financed studies

- All University Hospitals
- 6 Cantonal Hospitals
- 7 other research institutions
- 15 foreign hospitals outside CH
- **7180 patients**
Ongoing challenges in project funding

• Success rates of clinical research projects still at max 40% (overall average 50%)

• High rate of discontinued RCTs

• Discontinued studies not published
# Challenges revealed by the IICT programme

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Percentage of evaluated proposals</th>
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<tbody>
<tr>
<td>Rationale for treatment/hypothesis not convincing</td>
<td>35%</td>
</tr>
<tr>
<td>Inadequate study design</td>
<td>30%</td>
</tr>
<tr>
<td>Methodology (partly) insufficiently elaborated</td>
<td>25%</td>
</tr>
<tr>
<td>Inadequate primary endpoint</td>
<td>20%</td>
</tr>
<tr>
<td>Sample size / power calculation incomplete or insufficient</td>
<td>15%</td>
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<tr>
<td>Feasibility questioned (practical or ethical reasons)</td>
<td>10%</td>
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<tr>
<td>Confounding factors not controlled/addressed</td>
<td>5%</td>
</tr>
<tr>
<td>Study premature</td>
<td>5%</td>
</tr>
<tr>
<td>Dosing of IMP not justified/not clear</td>
<td>3%</td>
</tr>
<tr>
<td>Study potentially biased</td>
<td>2%</td>
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<tr>
<td>Effect size unrealistic or not well justified</td>
<td>2%</td>
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<tr>
<td>Study is risky for patients or safety issues are not addressed</td>
<td>1%</td>
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<tr>
<td>Inadequate patient population</td>
<td>1%</td>
</tr>
<tr>
<td>Commercial interest and/or role of industry partner unclear</td>
<td>1%</td>
</tr>
<tr>
<td>Issues with drop out rate</td>
<td>1%</td>
</tr>
<tr>
<td>Study is too ambitious</td>
<td>0%</td>
</tr>
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Knowledge is the key to the future
Future perspectives@SNSF (1)

Data quality, data accessibility, impact

→ Open access to publication

_signed LERU “Christmas is over. Research funding should go to research, not to publishers!”
(LERU: League of European Research Universities)

_all SNSF funded research should be published open access until 2020
Future perspectives@SNSF (2)

Data quality, data accessibility, impact

→ Open Research Data

“The SNSF values research data sharing as a fundamental contribution to the impact, transparency and reproducibility of scientific research. In addition to being carefully curated and stored, the SNSF believes research data should be shared as openly as possible.”

- data management plans to be submitted as integral part of the grant proposal

- data underlying a publication have to be shared on FAIR, digital and not-for-profit repositories; no embargos except for legal, ethical, copyright etc constraints.
Thank you for your attention