Funding of patient-oriented clinical research by the German Federal Ministry of Education and Research (BMBF)

Dr. Steinmüller/ Dr. Jacobs

PT-DLR

July 8th, 2011, Cologne
Health research programme of the Federal Ministry of Education and Research

• General information
• The framework programme 2011 - 2019

BMBF/ DFG funding activity
“Clinical trials (and systematic reviews)“

• Overview
• Summary of survey results
Project Management Agency in the German Aerospace Center (PT-DLR)

- Non-governmental, non-profit project management organisation
- Department of Health Research
- 71 scientific & 64 administrative staff
- Mandated by the Federal Ministry of Education and Research (BMBF)
- Administrates the Health Research Programme of BMBF
  (implementation, administrative & scientific controlling, monitoring, evaluation, participation in planning of funding initiatives)
Health Research Framework Programme: Criteria for constituting new funding priorities

- **Societal need**: number of people affected, mortality and morbidity
- Obvious **gaps in health care**, economical and individual burden
- Significance for the **health care system**
- Potential for **scientific and technological innovations**
- Potential to **strengthen top-level research**
- Potential for **economic exploitation**
Health Research Framework Programme: General information

• Cross-departmental framework programme of the German Federal Government managed by BMBF

• Valid for the next 8 years (2011 - 2019)

• Planned budget of BMBF 2011-2014:
  ~ 5,5 billion Euro
  (includes institutional funding, project funding, federal share of the German Research Foundation (DFG))

• Additional budgets of other federal departments
Health Research Framework Programme: Six fields of action

- Focussed research into major diseases
  (e.g. Health research centres, rare diseases)
- Individualised medicine
  (e.g. basic/preclinical/clinical research, specific diseases relevant for certain population groups)
- Research into prevention and nutrition
  (e.g. Epigenetics, environmental-related health research, vaccine development)
- Research into health care
  (e.g. centres for research in health economics, young scientists programme)
- The health care industry
  (e.g. medical technology, telemedicine, part of high-tech strategy)
- International cooperation in health care
  (e.g. ERA-Net, Joint programming, neglected and poverty-related diseases)
BMBF strategy for patient-oriented clinical research: Research infrastructures

KKS

PaedNet  KKS network office

ChirNet  Clinical study centre
BMBF/DFG funding activity “Clinical trials”:
General information

- BMBF and DFG have launched a joint initiative for patient-oriented medical research in Germany – a novelty

- For the first time clinical trials and systematic reviews can be financed independently of specific thematic funding programmes

- In 2010: 30 million € p.a. by BMBF + DFG (15 mio. € each)

- Joint reviewing process for clinical trial applications

- Separate reviewing of systematic review applications
BMBF/DFG funding activity “Clinical trials”:
Objectives

• To further improve the quality and safety of health care for patients

• To implement international state-of-the-art expertise and methodology in clinical trial research in Germany

• To increase awareness and acceptance of evidence-based medicine in science and the population
BMBF/DFG funding activity “Clinical trials”: Which types of proposals are eligible?

Prospective multicentre clinical trials with patients

Systematic reviews according to international standards

- Systematic reviews
- Individual patient data analysis
- Prognostic reviews
- Network analysis
- Meta-meta-analysis
- Reviews on drug safety/ adverse events
- Diagnostic reviews
- Reviews including non-RCT or qualitative trials
- Updates on systematic reviews

→ Cooperation with the Cochrane Collaboration is recommended, but not mandatory
BMBF/DFG funding activity “Clinical trials”:
Evaluation criteria for systematic reviews

- **Need** for the group of patients

- Impact of the results on **clinical practice**

- **Methodological progress** in the field of systematic reviews

- Design and **methodology** of the proposed review

- **Expertise** of the applicants
**BMBF/DFG funding activity “Clinical trials”: History**

<table>
<thead>
<tr>
<th>Year</th>
<th>Proposals</th>
<th>Funded proposals</th>
<th>Funding rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005/ 2006</td>
<td>16</td>
<td>11</td>
<td>70%</td>
</tr>
<tr>
<td>2006/ 2007</td>
<td>16</td>
<td>5</td>
<td>30%</td>
</tr>
<tr>
<td>2007/ 2008</td>
<td>38</td>
<td>15</td>
<td>40%</td>
</tr>
<tr>
<td>2008/ 2009</td>
<td>42</td>
<td>15</td>
<td>36%</td>
</tr>
<tr>
<td>2009/ 2010</td>
<td>50</td>
<td>20</td>
<td>40%</td>
</tr>
<tr>
<td>2010/ 2011</td>
<td>56</td>
<td>12</td>
<td>31%</td>
</tr>
</tbody>
</table>
BMBF/DFG funding activity “Clinical trials”: Survey

- Based on an online-questionnaire in March/ April 2011
- Addressed to all funded projects
- Presented at an evaluation workshop on May 31st/ June 1st, 2011

Return rate

- 61 of 78 BMBF-funded systematic reviews answered the questionnaire (Return rate: 78%)

→ Summary of the results
Medical fields of funded systematic reviews

- Psychiatry / Psychology: 20
- Haematology / Oncology: 16
- Surgery: 10
- Other: 7
- Cardiology: 6
- General medicine: 4
- Pharmacology: 3
- Dermatology: 2
- Neurology: 2
- Anaesthesiology: 2
- Radiology: 1
- Ophthalmology: 1
- Gynaecology: 1
- Gastroenterology: 1

Other medical fields include:
- Gastroenterology
- Gynaecology
- Neurology
- Dermatology
- Pharmacology
- General medicine
- Cardiology
- Surgery
- Other
Types of funded systematic reviews

- Standard review: 36
- Individual patient data (IPD) analysis: 8
- Other: 4
- Prognostic review: 2
- Network analysis: 2
- Inclusion of qualitative primary studies: 2
- Meta-meta-analysis: 2
- Review on drug safety/ adverse events: 2
- Diagnostic review: 1
- Update of a systematic review: 1
### Delay in conduct of the review in the following steps:

<table>
<thead>
<tr>
<th>Step</th>
<th>Delay (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publication (peer-review process)</td>
<td>17</td>
</tr>
<tr>
<td>Data extraction</td>
<td>10</td>
</tr>
<tr>
<td>Literature search and evaluation</td>
<td>10</td>
</tr>
<tr>
<td>Preliminary steps (Definition of search algorithms, In-/Exclusion criteria of studies etc.)</td>
<td>9</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>6</td>
</tr>
<tr>
<td>Collection of individual patient data</td>
<td>5</td>
</tr>
</tbody>
</table>
Contribution of international collaborators

- Support by methodological expertise: 16
- Support by clinical expertise: 12
- Support in literature search: 12
- Peer-review of protocol and manuscript: 11
- Transfer of individual patient data: 8
- Support in quality rating of primary studies: 5
- Support in data extraction from primary studies: 4
82 publications arouse from the funded systematic reviews (until today)
Long-term effects of funding: infrastructures and cooperations

- Constant/active collaboration with respective Cochrane Review Group: 30
- Cooperation with the German Cochrane Center: 12
- Establishment of new research group for syst. reviews at own institution: 11
- Cooperation with authors from primary studies: 9
- Expansion of international cooperations: 8
- Strengthening of research group for syst. reviews at own institution: 7
- New external, national cooperation: 6
- Cooperation with Cochrane Methodological Group: 4
Relevance of the funding activity for the personal career of project leaders/ review authors:

- High importance for **scientific career** in general

- Establishment of **international cooperations**

- Authors achieve **national and international reputation**

- Significant impact on **expertise in systematic review methodology** in work group

- Implementation of **research infrastructures und promotion of young scientists** at institutions of the review authors
  (e.g. EBM-working group, young scientists group, master thesis, PhD thesis, “Habilitation”, publications, professorship)

- Funding highly contributes to awareness and acceptance of **evidence-based medicine in Germany**

- Contribution of German scientists to the international entities of the **Cochrane Collaboration**
Thank you for your attention!

Further information:
http://www.gesundheitsforschung-bmbf.de/
Results from funded systematic reviews had an impact on national and international (S3-) guidelines

• Haematology/ Oncology (many)
• Psychiatry (some)
• Surgery
• General medicine/ Pain therapy
• Neurology
• Rehabilitation after neurological diseases
• Nursing care