



Infrastructures for patient oriented clinical research and investigator-initiated clinical trials: Funding Measures of the German Federal Ministry of Education and Research (BMBF)

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The German Funding system

The Health Research Programme

Patient oriented clinical research and clinical trials: the challenge

Funding Programmes for patient oriented clinical research

- Infrastructures: Clinical coordination Units/Clinical Trials Centers
- Project funding the clinical trials programme
- Others

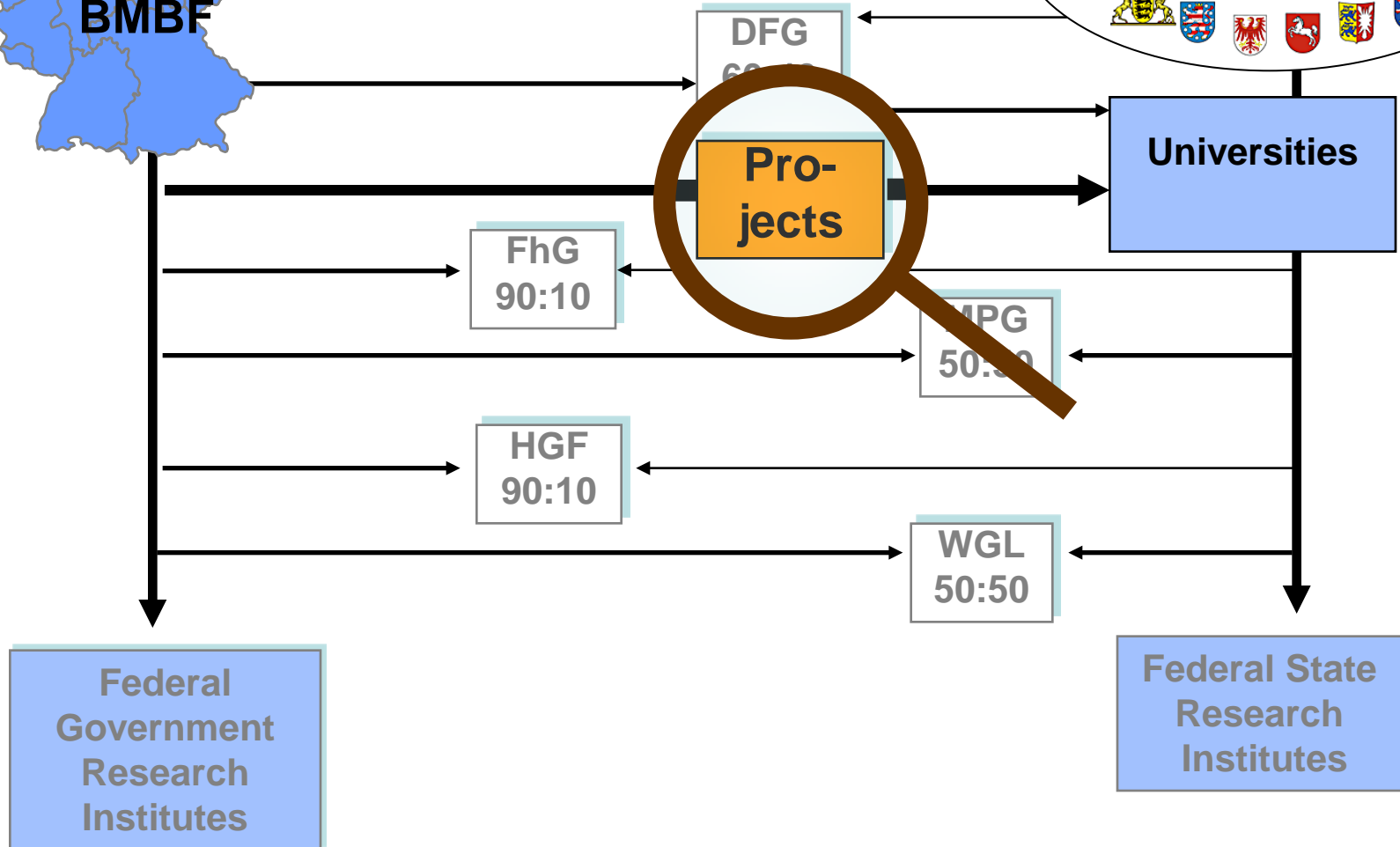
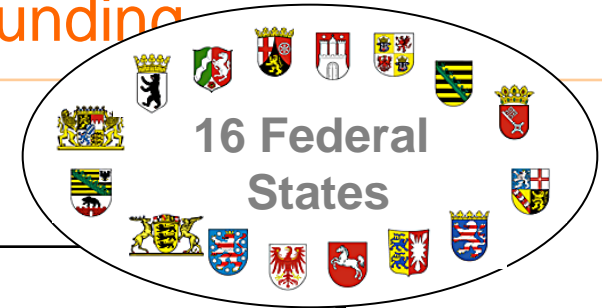
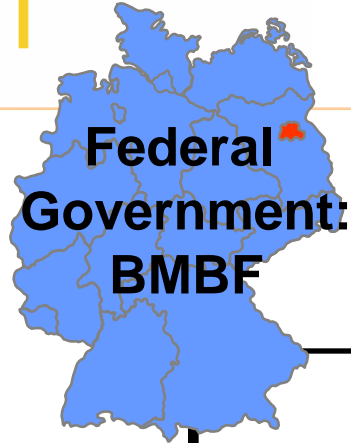
Conclusion



Federal Ministry
of Education
and Research

Shared responsibilities

Project and Institutional Funding





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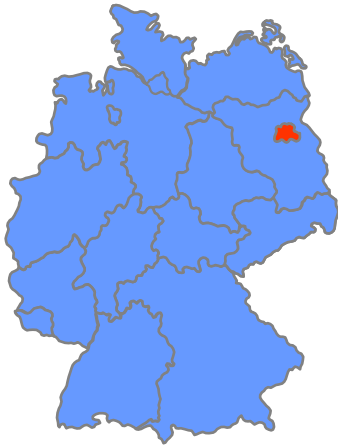
Conclusion



The Health Research Programme

conducted and implemented
by the

**Federal Ministry of
Education and Research
(BMBF)**



Health Research Programme
160 million € in 2009



Health Research Programme

„Research for the People“

Aims of the Programme:

- To examine the causes of diseases and to **develop effective treatment**
- To **improve prevention and health precaution**
- To contribute to a **productive and affordable health care system**
- To improve **translational research** and the transfer of research results into the health care system and the economy
- To **foster the research landscape**



German Health Research Programme

Clinical Trials

- neurological disorders
- cardiovascular disorders
- metabolic disorders
- cancer
- inflammatory disease

Effective Disease Control



Health Care System Research



- public health
- patient care
- psychotherapy

core areas

Clinical Coordination Units – KKS

Clinical Study Centres

Integrated Research and Treatment Centres - IFB

Research Structures



4

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Private Enterprises and Science

3



- medical devices
- innovative drug
development
- innovative therapies



German Health Research Programme

... implementation

- Identification of novel subject areas
- Uncovering subject-related deficits (i.e. infrastructure)
- Analysing gaps in health care system
- specifically-tailored instruments developed **Clinical Trials**
- Significance for the health care system
- Potential for scientific and technological innovations and for economic exploitation



Agenda

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Patient oriented clinical research/ non commercial clinical trials

The situation ten years ago in Germany

- Low acceptance in medical faculties
- Too few studies are performed and published
- Lack of infrastructures, lack of funding
- Too few young investigators
- study quality in comparison to the international standards too low

**Implementation of funding instruments: project funding,
funding of infrastructures**



Agenda

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Infrastructures for Clinical trials: Clinical Coordination Units - KKS

... are service units to support the development of clinical trials

Were started in 1998:

12 **“Coordinating Centers for Clinical Trials”** were funded which

- establish a sustained infrastructure at university hospitals/medical faculties to conduct a clinical trial
- Improve standards
- Train physicians and nurses
- support designing and governing clinical trials

KKS (except CHIR-Net) have been funded over 10 years

12 units were supported by BMBF with a total of 38 Mio. €



Clinical Coordination Units

CHIR-Net

... is specifically tailored to support clinical scientists in surgery

- improve quality and number of clinical trials in surgery
- provide support for clinical trials intended by surgeons
- are small service units mostly appended to KKS (except one)
- develop training modules motivating surgeons to conduct clinical trials
- provide a network structure essential for knowledge exchange and patient recruitment

coordination unit (appended to SDGC) plus 5 regional centres

total funds: approx. 5 Mio. €. Initiation of funding: 2005



Clinical Coordination Units

PAED-Net

- ... aims at enhancing evidence-based medicine in children to increase safety of diagnostic and treatment schemes
- intend to motivate paediatricians to conduct clinical trials
- offer support in the design, particularly in consideration of strict regulations
- are small modules appended to KKS at 6 sites
- network structure is essential for recruitment of small numbers of patients and for the transfer of expertise

coordination unit plus 6 regional modules funded with approx. 5.4 Mio. €

BMBF funds were provided from 2002 to 2008



Clinical Coordination Units - KKS

- Funding has terminated, KKS are now integral part of most university
- Sites have joined to form the KKS alliance

Funding has been a great success

BUT

... could not solve all problems

- support limited to administrative and theoretical advice
- lack of professional staff to conduct clinical trials on site



Clinical Trial Centres

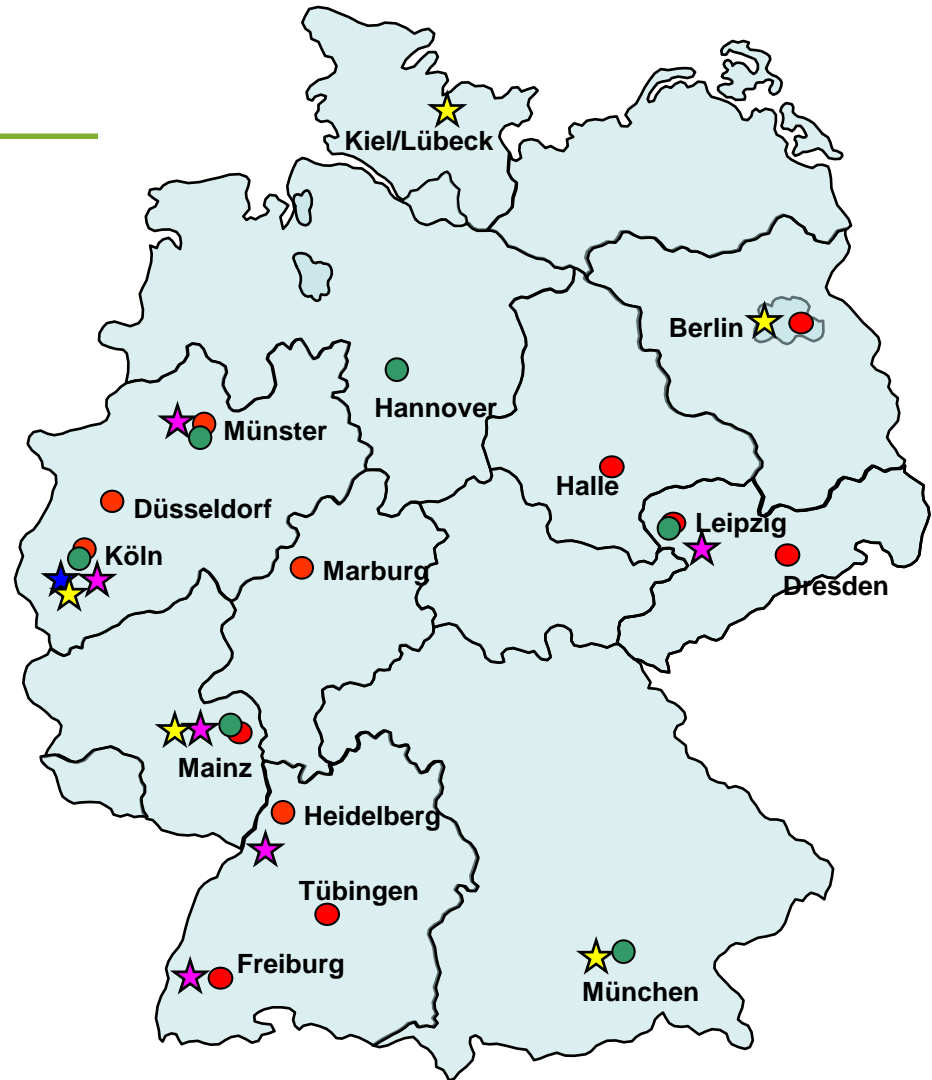
... provide infrastructure and competence to conduct a clinical trial at the clinics

- comprehensive concept for the establishment of **study units at the clinics**
- **supply of staff** trained on performing clinical trials
- **development of comprehensive programmes for training medical staff**
- interface to industry

Initial funding period of 4 years with the potential of another 4-years period
6 centres granted since 2007 with a total of 24 Mio. € (First funding period)



Infrastructures for clinical trials



● KKS ● Clinical Trial Center

★ PaedNet

★ ChirNet



Project funding: Clinical Trials Programme **DFG**

... is a joint Programme of the German Federal Government and the German Research Foundation (DFG)

- support multicentric clinical trials in academia
 - non-profit therapeutical studies
 - diagnosis/prevention
- open to any discipline
- selection is purely based on quality criteria:
 - innovation/originality
 - relevance to German Health System

annual calls since 2005, annual budget actually 30 Mio



Which types of trials are eligible in the programme?

Prospective multicentre clinical trials with patients

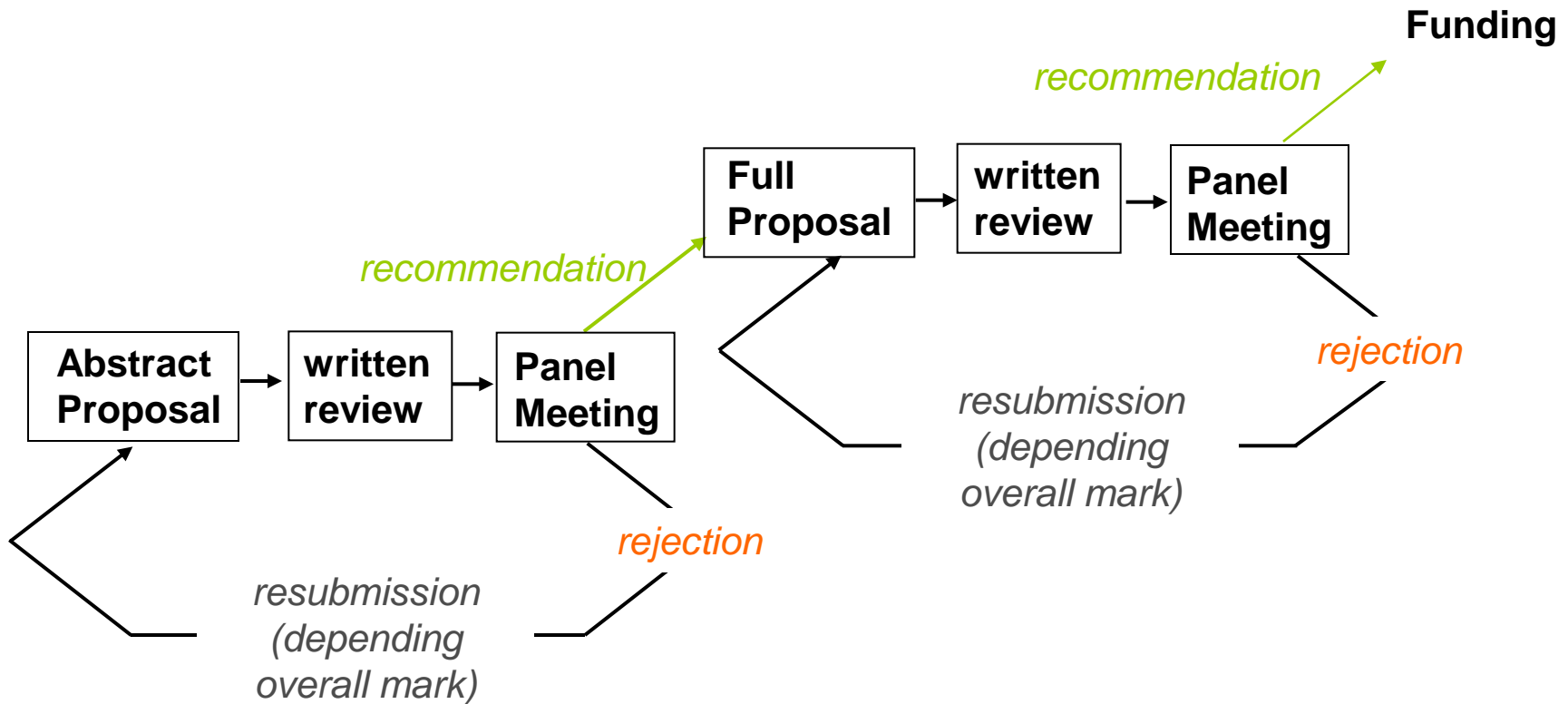
- a) controlled interventional therapeutical trials
- b) diagnostic studies (Phases II-IV according to Sackett)
- c) controlled interventional trials on secondary prevention
- d) prognostic studies

- e) systematic reviews

Not: Trials where companies have direct commercial interest in the results

Clinical Trials Programme

... aims to improve quality of academic trials according to ICH-GCP standards



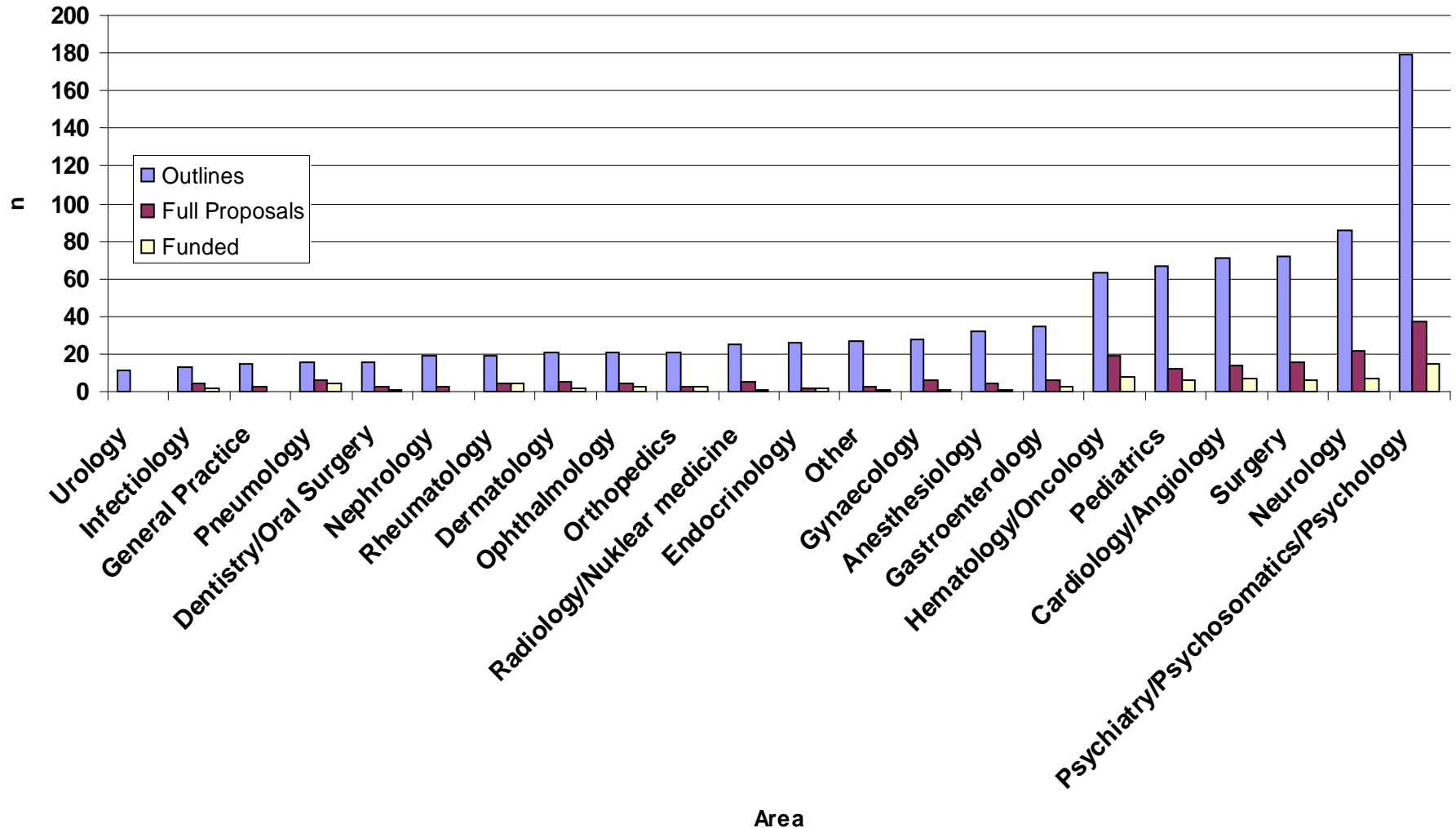


How many trials funded so far?

	1. Call	2. Call	3. Call	4. Call	5. Call
total budget	10 Mio €	20 Mio €	20 Mio €	30 Mio €	30 Mio €
database entries	416	230	204	197	202
outlines	335	193	173	175	178
full proposals	42	32	41	63 (+4)	54(+3)
average budget	850.000 €	876.000 €	1.55 Mio €	1.52 Mio €	1,89 Mio €
granted	17 (41%)	18 (58%)	21 (51%)	23 (35%)	
rejected	24 (59%)	13 (42%)	20 (49%)	42 (65%)	



Fields of funded trials





Accompanying Measures

Infrastructures

National Trial Register (WHO, since 2008)



Research Networks/Consortia

37 Clinical Research Units

Competence Networks in Medicine

Cancer Trials

DFG



Training

Junior Training Academy “Clinical Trials”

DFG



Outlook and Conclusion

- The implementation of funding programmes in the field of patient oriented clinical research in Germany has improved the quality and the number of non- commercial clinical trials

BUT

- There still remain further challenges
 - quality, number and acceptance of patient oriented research in Germany has still to be improved, funding has to be continued
 - high costs due to high regulatory burden: activities at european and international level towards a risk based approach (OECD initiative) and harmonization
 - public funding and infrastructure especially for multinational clinical trials is needed (ECRIN)



Activities at european and international level



A Road Map Initiative for Clinical Research in Europe



FORWARD LOOK

Investigator-Driven
Clinical Trials



Thank you!

Dr. Kirsten Steinhausen

Bundesministerium für Bildung und Forschung

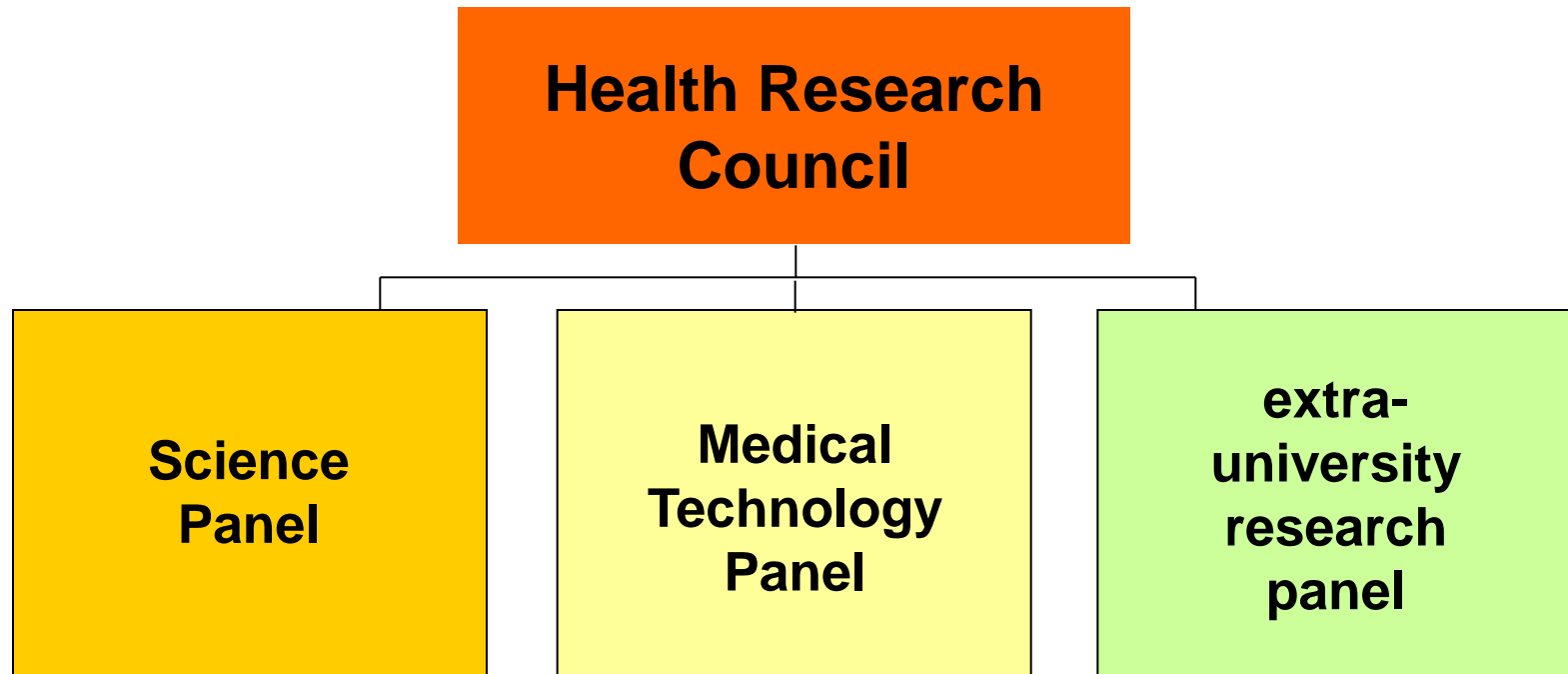
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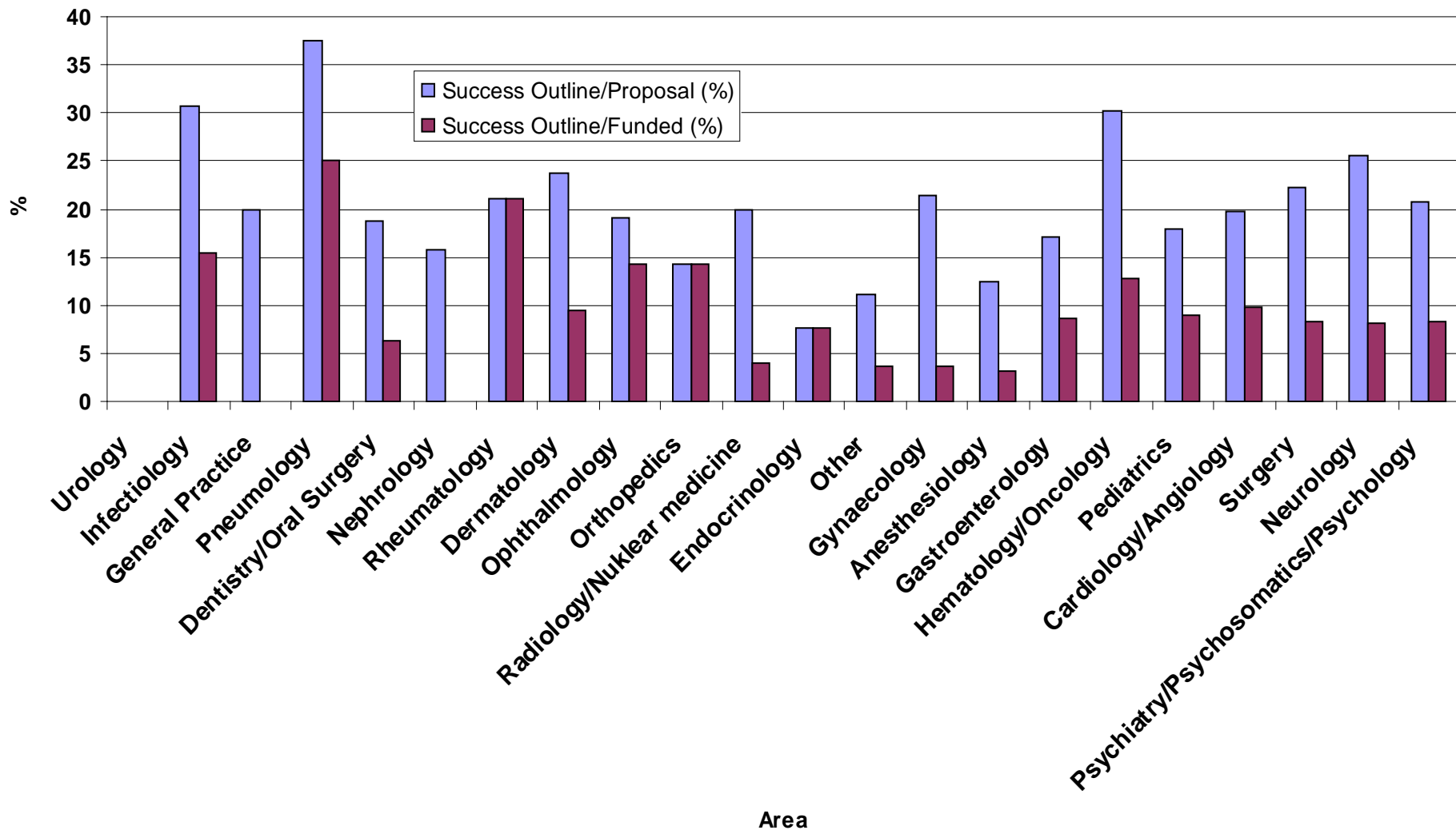
Health Research Council

... consists of various experts to cover all aspects in health research





Successrates of funded trials





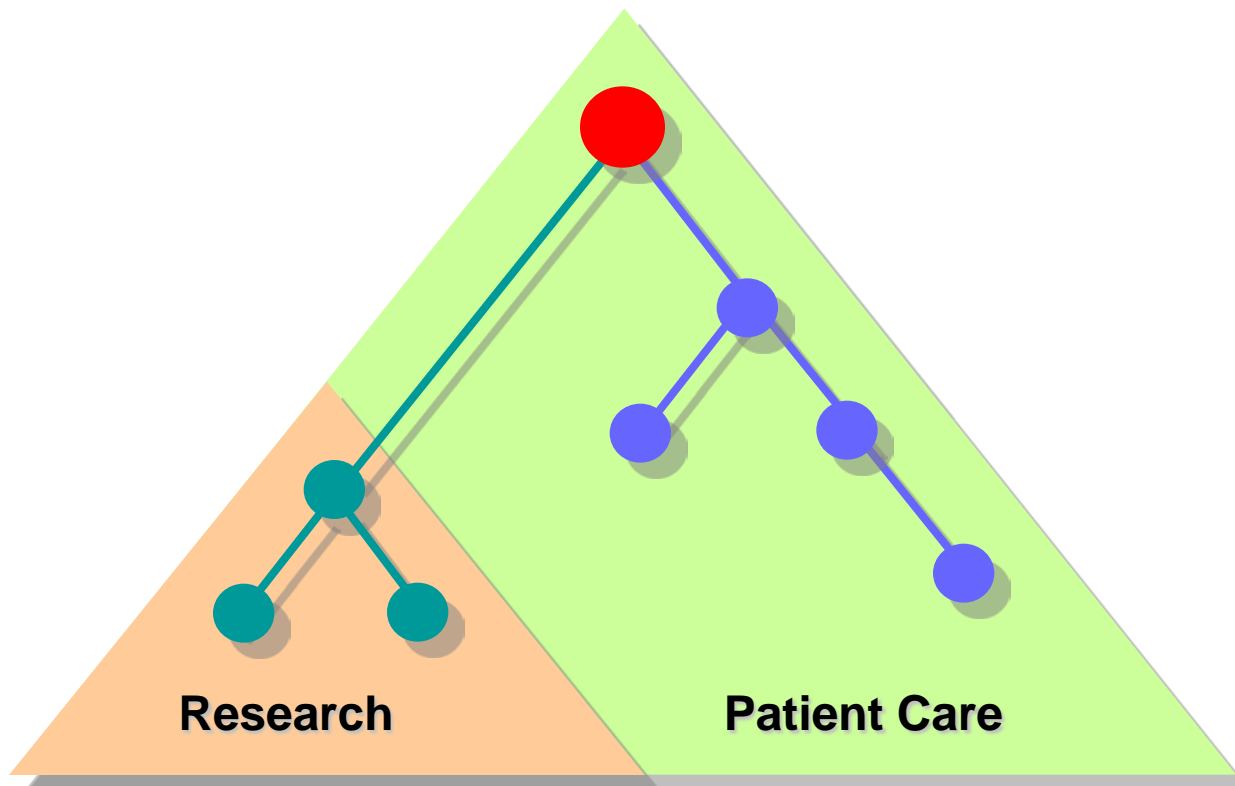
Long-Term Studies in Health Research

- Demand for high quality population-based studies as well as patient-based studies in many medical fields.
- Funding initiative by the German Federal Ministry for Education and Research to support long-term prospective cohort studies.
- Announcement in April 2007
- Funding duration: up to 12 years
(initial phase of 6 years)
- Financial volume: 4.5 Mio € per year
(total of 27 Mio € for first 6 years)



Current Situation in Medical Faculties

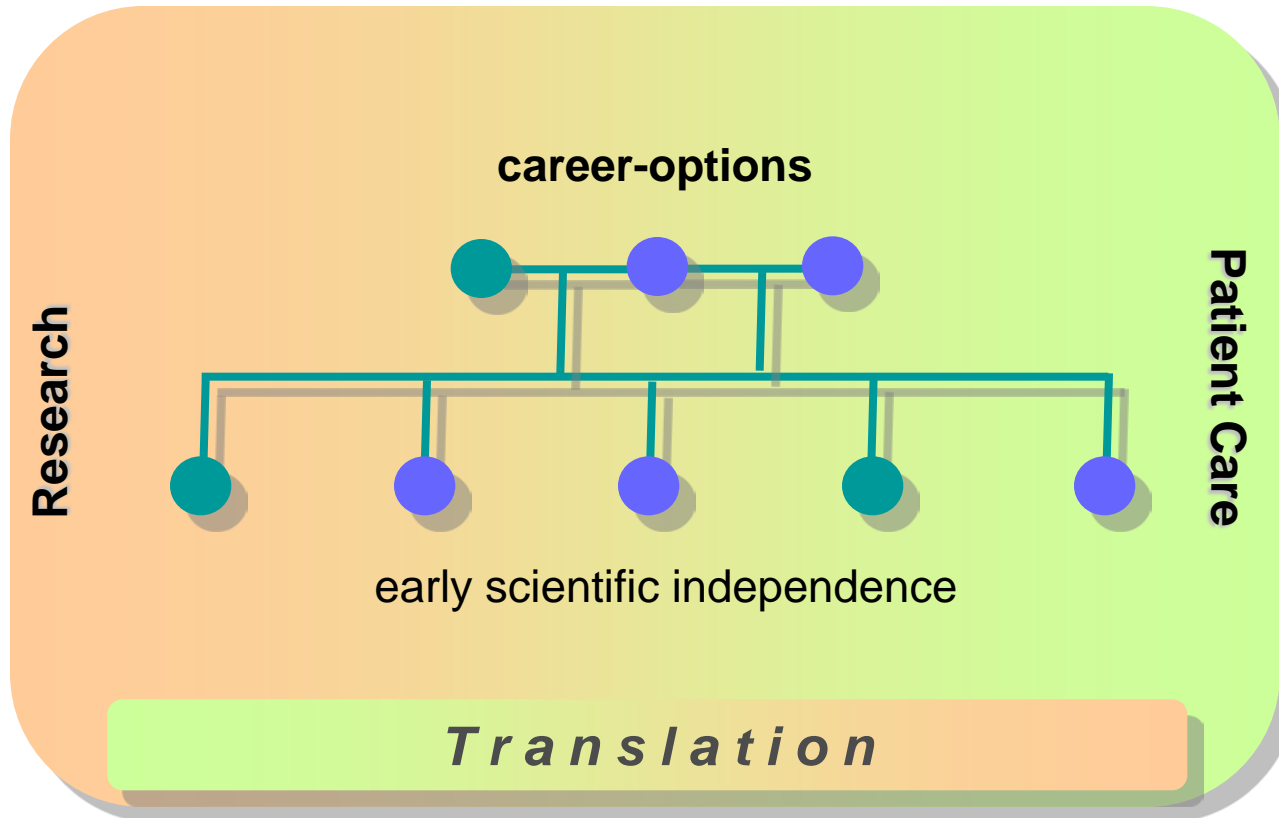
... is characterised by hierarchical structures and little interaction between basic scientists, clinical researcher and attending doctors





Integrated Treatment Centres - IFB

...improve the co-operation between scientists and clinicians and offer novel career-options through flat hierarchies





Integrated Treatment Centres - IFB

... have great potential to realise the vision of an integrated approach to patient-oriented research

- **improvement of patient-oriented research**
 - direct interaction of basic and clinical scientists
 - protected time for medical doctors
 - IFB-specific core-units
- **strengthen the role of young academics**
 - junior professorships
 - junior group-leaders
 - MD/PhD-programmes
- **projects related to the IFB's subject area**

Two calls in 2005 & 2007: 4 IFBs being funded for 5 ys. with a total of 100 Mio. €
another 3 centres are expected to receive funding (approx. 60 Mio. € in total)



Instruments to improve patient-oriented research

... aim at enhancing the bench-to-bedside transfer of knowledge

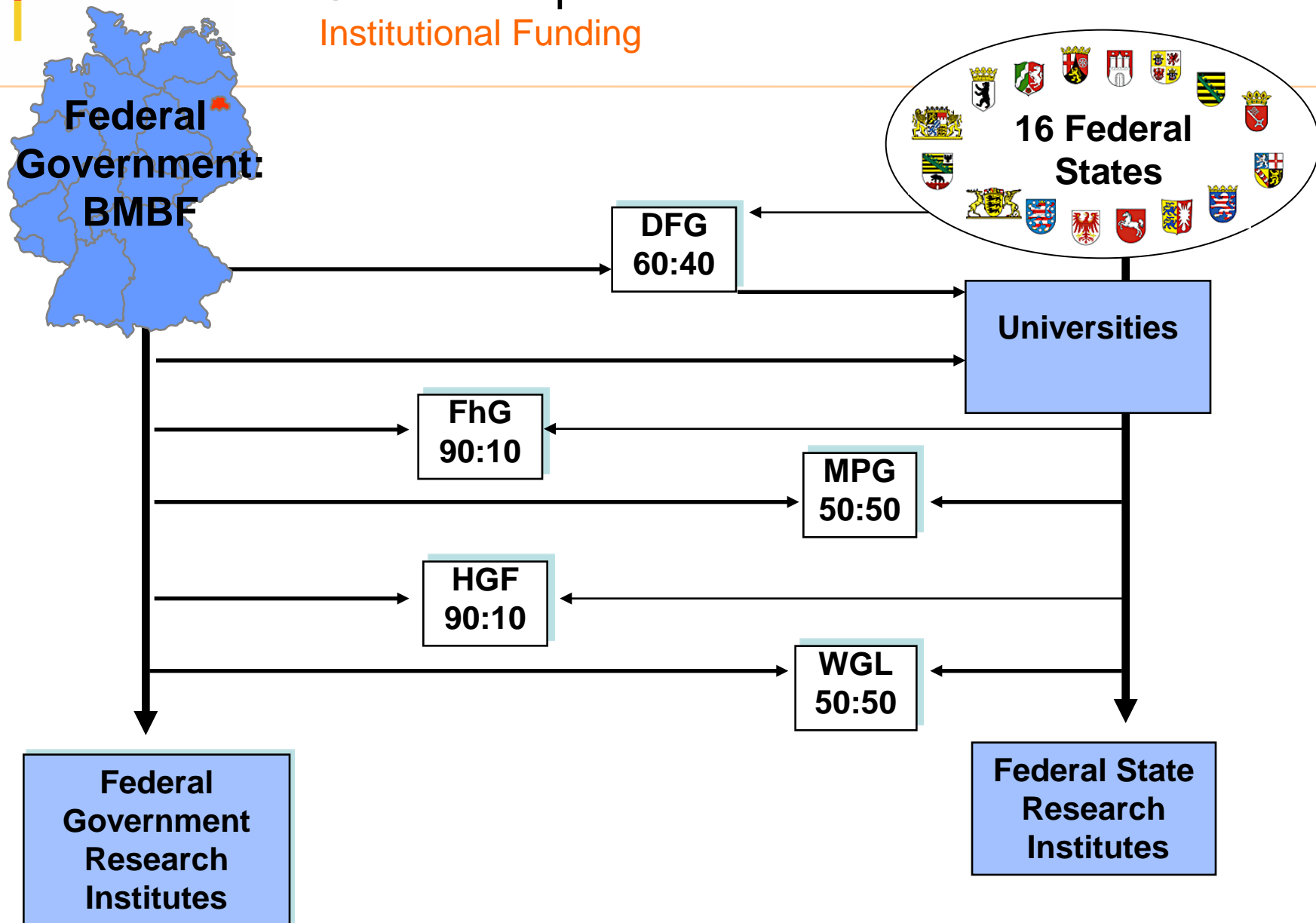
- **Clinical Trials Programme**
- **Clinical Coordination Units - KKS**
- **Clinical Trials Centres**
- **Integrated Research and Treatment Centres - IFB**



Federal Ministry
of Education
and Research

Shared responsibilities

Institutional Funding





The German Research System

Sites of Research

Universities

...are sites of basic research and training

MPG Max Planck Society for the Advancement of Science e.V.

...institutes perform basic research in all disciplines

HGF Hermann von Helmholtz Association of National Research Centers

...research centers perform basic research in the public interest, especially using extensive large-scale equipment and develop new technologies

WGL Wissensgemeinschaft Gottfried Wilhelm Leibniz

...institutes provide service for research, perform research in selected fields of science and are links between basic and applied research

FhG Fraunhofer Gesellschaft

...institutes develop and implement new technologies by means of goal oriented basic and applied research