Translational Research and Clinical Trials

Grand Challenges: Research infrastructures at the forefront

ICRI Copenhagen 2012

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Translational Research and Clinical Trials

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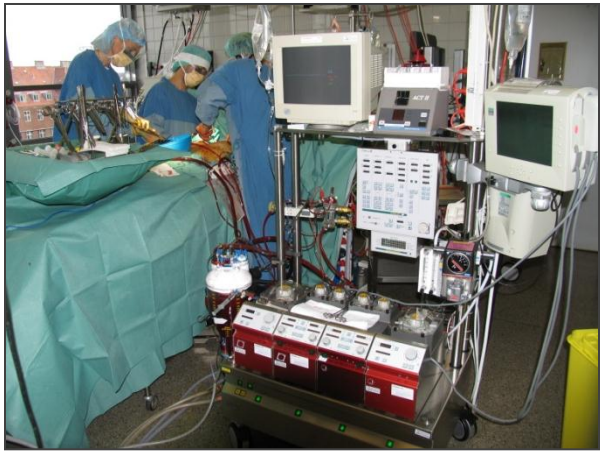
Chair: Liselotte Højgaard
Rapporteur: Cornelius Schmaltz, EC
DK: Anne Christiansen & Troels Rasmussen

Initial talks then debate among panel and participants

Why medical research?

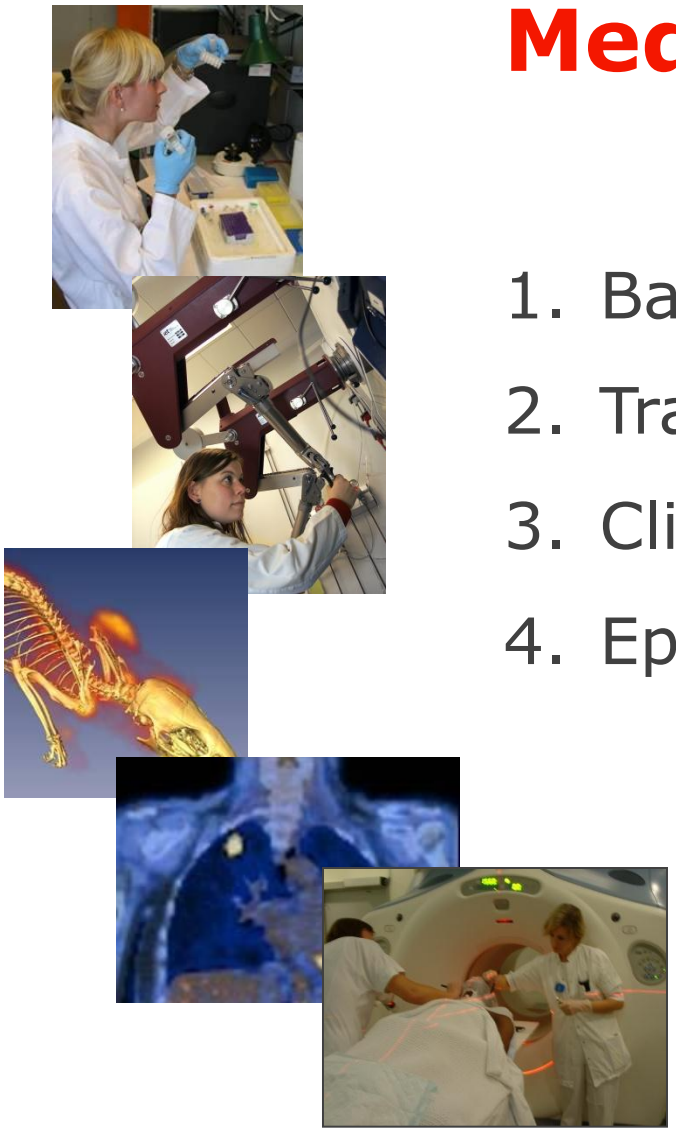


New knowledge

Research based educations

Research based patient treatment

Basis for European medical industry



Medical Research

1. Basic Research
2. Translational Research
3. Clinical Research
4. Epidemiology & Prevention

New mechanisms, pathophysiology, new drugs, methods, operations, diagnostics. As non commercial research, private-public partnership and industry sponsored R&D

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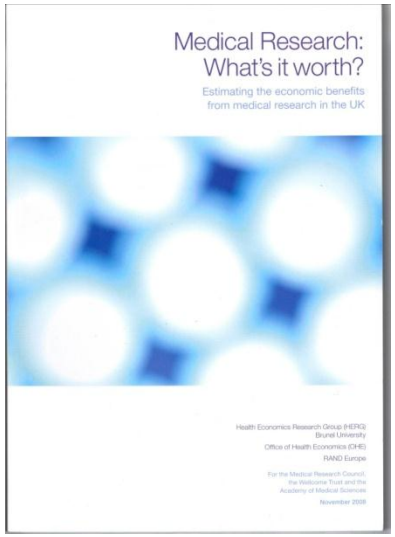
Medical research: What's it worth?



Investments in medical research gives a return of 39% for each of the following years

MRC Medical Research Council Leading science for better health

wellcome trust

ESFRI proposals in Medicine

- BBMR I- Biobanking and Biomolecular research
- ELIXIR – Life Science Biological information
- INFRAFRONTIER – Mouse genome
- **EATRIS – Translational research in medicine**
- **EURO - Bioimaging**
- **ECRIN - infrastructure for clinical trials**
- ERINHA - European high security BSL4 Laboratories
- MIRRI – Microbial Ressource Research Infrastructure
- ISBE - Infrastructure for Systems Biology Europe
- INSTRUCT - Infrastructure for structural biology

HEALTH 1:
Translational Research + Clinical Trials

„Personalised medicine": Revolution of modern medicine with re-writing of taxonomy and textbooks based on genomics and epigenetics. This increases the demand for large infrastructures, biobanks (e.g. BBMRI), data and therefore requires global collaboration and a new regulatory landscape.

- Simplified regulatory landscape in Europe and globally to assist and not impair clinical and translational research.
- Sustainable funding for investigator-driven clinical trials, e.g. ECRIN

HEALTH 1:
Translational Research + Clinical Trials

- **Regulatory issues**: make it possible to do multinational clinical trials = patient research !

- **Funding**:
  - Need to involve Health Ministries
  - Public-private partnership for infrastructure funding involving biobanks, eg.BBMRI

- **Quality, Transparency and Data sharing**:
  - Registration of protocols, open acces to protocols, data and publications. Publish both positive and negative results

Biological Ressource Centers

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Biological Resource Centers

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Joanne Daly, Australia

Dagmar Fritze, Germany

Judy MacArthur Clark, UK

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HEALTH 2:
Biological Ressource Centres

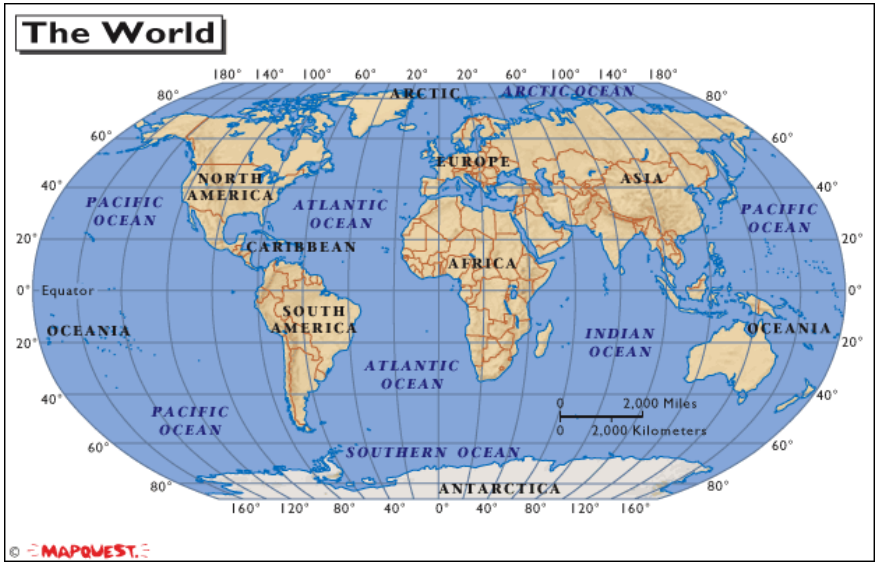
- **Biological Resources and the related data = indispensable tools for health research**
- **Harmonisation:**
  - Harmonisation & quality improvement
  - Accurate reporting essential
  - Keep „metadata“ (context) linked to data acquisition
  - Centres need to be drivers of harmonisation, developing standards!

HEALTH 2: Biological Ressource Centres

- **Funding:**
  - Sustainable funding
  - International infrastructures built on strong national infrastructures!

- **Animal studies:**
  - R,R, R, refine, reduce and replace
  - Harmonise standards and reporting
  - Meta-analysis/systematic review of animal research data
  - Follow example of human clinical trials: quality control, registration, reporting, access to raw data

Science is global, but adaptation is local



Proposition: OECD Global Science Forum on Preclinical Research