Medical Research in Europe: Strengths, Weaknesses and Future

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"The Grand Challenges"

An aging population in Europe with
- obesity & the metabolic syndrome
- mental health disorders
- allergy & chronic diseases
- cancer & cardiac diseases as the big "killers"

Rising health care expenditures, as we can do more, and populations expect more
Why medical research?

New knowledge
Research based educations
Research based patient treatment
Basis for European medical industry

We need research to cope with the Grand Challenges
Medical Research

1. Basic Research
2. Translational Research
3. Clinical Research
4. Implementation, ”translation mode 2”
5. Epidemiology & Prevention

New mechanisms, pathophysiology, new drugs, methods, operations, diagnostics.

*Researcher initiated non commercial research, private-public partnership, industry sponsored R&D.*
"The special case of medicine"

More than 50% of all research publications in Europe are from medicine and life science.

The University Hospitals / Academic Medical Centers produce more than half.

EU and national legislation + organisation are crucial. Innovation – new ways of doing something useful - is facilitated by PPP. IMI The Innovative Medicines Initiative is a fine example.
Science is global

Results are made by scientists, spread by scientific publications and conferences, and used by the whole world.

It is important that the results can be trusted (Research integrity).

It is important with “Open Access”, so that all can read the results.
Medical research: What’s it worth?

Investments in medical research give a return of 39% for each of the following years.
Research is a great benefit to patients

Research in USA and Europa in the last 50 years have changed Survival for children with cancer. Now more than 85% survive
How is it organised?

**Health care:**
Clinics and hospitals
GPs, specialists
hospitals, private and public
*doctors, nurses etc.*
*Hospital Directors*

Different system in the European countries: Often organisation + regional level + ministry

Ministries and national authorities

EU DR Research Horizon 2020
EU Health is a local matter in each country.
Other EU DGs are also important

**Research**
Universities, hospitals, ESFRI, EMBL, institutes etc.

**Education pre- & postgraduat**
Doctors, nurses, physicists, chemists, molecular biologists,
System biology, IT & computer scientists

*University deans, health and institute directors,
Professors and younger scientists, MD PhD*

**INDUSTRY** for new drugs and products

The press and the public
new media, blogs, facebook, twitter

**Funders:** public and private
Research Funding in Europe

Horizon 2020 70 bio €

- ERC for excellent research
- Industrial leadership
- Societal challenges with health 1:6

90% of research funding in Europe national funding DFG, BMBF, MRC, NHS, INSERM, CNRS

Charities: Welcome Trust, Robert Bosch Stiftung, Novo Nordisk Foundation etc.

EU DGs for health, research, industry.

DG Research Health: Programme Committees from each country + AG.

New Advisory Group for EP.
8th Call for New Centers of Excellence

Excellence – Trust - Transparency

60 mio € per year for Centers of Excellence in all types of research. 10 year grants, 6+4, up to 20 mio € for each, almost unlimited freedom. Output – publications of the highest quality and important for Denmark.
EMRC The European Medical Research Councils was the membership organisations for the medical research councils in Europe, under ESF, The European Science Foundation.

Now ScienceEurope Medicine. Again the major funders in Europe.

Collaboration between countries and exchange of information and knowledge. Open access, animal research, funding, ethics, peer review etc.
Copenhagen Research Forum

What
Aiming to be the top researchers’ unbiased and unfiltered voice in Europe

Why
Deliver “out of the box” recommendations on Horizon 2020 from an important stakeholder’s position

Who
Active top scientists from across Europe Invited in their personal capacity.
The Alliance for Biomedical Research in Europe is a unique initiative representing 21 leading research-oriented medical societies that include more than 400,000 researchers across Europe.

The BioMed Alliance is committed through its actions to promote excellence in European biomedical research and innovation with the goal of improving the health and well-being of all European citizens.
- Universities, LERU and other university organisations

- Academies, Belgian Royal Academy of Medicine

- EuroScience – for with ESOF conference, June 2014 Copenhagen
WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

WHO Europe has an advisory group for research.
The ICMJE is a group of general medical journal editors whose participants meet annually.

*Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals.*

ICMJE developed these recommendations to review best practice and ethical standards in the conduct and reporting of research in medical journals, and to help authors, editors publishing accurate, clear, unbiased medical journal articles.
All stakeholders in Europe worked together to secure a new EU directive on animal research.

The ESF-EMRC Position on the Proposal for a Directive on the Protection of Animals used for Scientific Purposes

Introduction

The position paper of the European Medical Research Councils (EMRC), the Standing Committee for Medical Sciences at the European Science Foundation (ESF-EMRC), was adopted on Oct 26th, 2009 in Copenhagen, Denmark. In its position paper, the EMRC asks the European Commission and the European Parliament to adopt a new directive to replace the outdated Directives 86/609/EEC (Amended 2010) on the protection of animals used for scientific purposes.

The stakeholders at the EMRC meeting were from Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Switzerland, and the United Kingdom. They highlighted the need for a new EU directive to protect animal welfare, address scientific advances in research, and ensure the protection of animals used for scientific purposes.
Research initiated by the researchers

- Improve education, training and career structure
- Increase funding for IDCT.
- Risk-based approach for regulation of IDCT.
- Easy procedure for authorization for IDCT.
- Improve IDCT quality to statistically reliable results
OECD Global Science Forum

International Cooperation in Non-Commercial Clinical Trials

Paradigm shift with individual tailormade treatment: Stratified medicine or precision medicine.
Personalised Medicine

Doctor: If this doesn’t help, then come again, and we will get you something else.
Patient: Couldn’t I get the something else right away?
Clinical research is complicated

Ethical committee
Medicinal Agency
Data protection agency
EudraCT
ClinicalTrials.Gov
GCP units
Hospital and university rules & limitations

Study plan and protocol
Patient information
Informed consent
SOPs
Databases and archiving
Quality control also for drugs

EC Clinical Directive 2001
There is a new EU directive on data protection on its way linked to data security. Will the new one harm research?
Implement the results of research in patient treatment

National authorities, HTA
Scientific societies – guidelines
Doctors, conferences and journals
Industry.
Patients, public and press.
Research is genes and new drugs, but also medical technology
The Blind Men and The Elephant

It was six men of Indostan,  
To learning much inclined,  
Who went to see the elephant  
(Though all of them were blind),  
That each by observation might  
satisfy the mind.

The first approached the elephant,  
And, happening to fall  
Against his broad and sturdy side,  
At once began to bawl;  
'God bless me! but the elephant  
Is very like a wall!'  

The sixth no sooner had begun  
About the beast to grope,  
Than, seizing on the swinging tail  
That fell within his scope,  
'I see', quoth he, 'the elephant  
Is very like a rope!'  

And so these men of Indostan  
Disputed loud and long,  
Each in his own opinion  
Exceeding stiff and strong,  
Though each was partly in the  
right  
And all were in the wrong

John Godfrey Saxe
Health care and medical research from above

It is complex, complicated, heterogeneous, varied between European countries, research areas, cultures.

Many people are engaged in research strategy and policy, as leaders, burocrats attending many meetings.

Translational research is in the center and collaboration between basic and clinical research is needed.
"Grand challenges"

Hospitals are busy and costs are rising. Many hours on administration, as bureaucrats have proliferated.

Less time and energy for research.

Infrastructures and institutes and large strategic investments create movement.

Top Down strategy and then – leave the rest to the very best.
Public funding of health R&D in % of GDP (2008)
Share of EU15/25 & USA in total biomedical ISI publications

World share of both US and EU tends to decrease which is a consequence of the growing output of the emerging economies (above all China, but also Brazil, India, Turkey and others).
Share of EU15/25 & USA citations
(100% = citations to all worldwide biomedical publications)

- The share of the world citations to biomedical publications remained about 50% and 40% for USA and EU15 or EU25 publications, resp.
- All citation analyses in favor of USA vs. EU15/EU25.
EMRC White Paper for stronger medical research 2007

How to strengthen European medical research and increase the return on investment in public and private health research. The research field is complex and requires a long-term strategy. The EMRC proposes a programme of action to address the main challenges in research, development, and innovation in the field of medical research. The programme is designed to achieve the following objectives:

1. To increase the public and private investment in medical research.
2. To improve the efficiency and effectiveness of medical research.
3. To enhance the collaboration between researchers and stakeholders.

The programme includes specific actions to achieve these objectives, such as:

- Increasing the funding for medical research.
- Improving the regulatory and ethical framework for medical research.
- Enhancing the infrastructure for medical research.
- Strengthening the international collaboration in medical research.

The EMRC recommends that these actions be implemented in a coordinated and coherent manner at both national and European levels. The programme is open to all stakeholders, including researchers, patients, industry, and policymakers. The EMRC encourages all countries to participate in the implementation of these actions and to report on their progress.
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
- European high security BSL4 Laboratories

Research infrastructures are most often large institutions, like CERN, ESRF, PSI, ILL, ESS.
New EU data protection directive - avoid to make it worse

Top down strategy with investments and infrastructures to push translational research.
Conclusion

Health care and health research is highly complex. Not one final common pathway. Europe is complex and diversified.

Sometimes things **can** be moved, it takes collaboration, will power, a lot of work and collaboration between many dedicated groups.

Every time we in healthcare and biomedicine disagree someone else will hijak the agenda and win the race for funding.
New EU Clinical Directive – to make it easier
New EU data protection directive - avoid to make it worse
European Medical Research Councils (EMRC)
White Paper II
A Stronger Biomedical Research for a Better European Future
"Domus Medica Europa" in Bruxelles

Science Europe Medicine, The Biomedical Alliance, EMBO, Academies, EORTC, EU DG Health, medical schools, HTA and guidelines, doctors, nurses, Health and hospitals & Patients.