Simulation Exercise for Joint Programming

Effective Health Services for European Citizens

“Improved Management of Cardiovascular Diseases and their Socio-Economic Costs based on Medical Research”

November 2008 – updated August 2009
Background of the exercise

The European Commission (EC) has invited the European Science Foundation (ESF) and the European Heads of Research Councils (EUROHORCs) to draft a simulation exercise of a Joint Programming proposal. The aim of the simulation is to provide Commissioner Potočnik with an example of how a Joint Programme could be designed and implemented. This version was submitted to Commissioner Potočnik on 25 November 2008.

The Health Research sector and “Improved management of cardiovascular diseases and their socio-economic costs based on medical research” was chosen as a test case, based on the following arguments:

- Cardiovascular disease is the foremost killer of European citizens.
- National efforts have not been able to manage the cardiovascular disease, and the economic costs are increasing exponentially.
- Strong research teams in many European countries have agreed to form the core consortium.
- 30 European countries have committed to collaborate in Medical Research, as documented in the EMRC White Paper “Present Status and Future Strategy for Medical Research in Europe” published in November 2007.
- ESF and EUROHORCs and relevant national, European and international organisations have already accomplished background work in the form of analyses and foresight, facilitating the simulation effort (Table 1).

The selection of cardiovascular disease as a pilot for simulation should not be taken as an indication that it is necessarily the priority area for joint programming within the Medical Research sector. The simulation was kept as broad as possible to serve as a working template for further work in different areas of medical research.

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Authors and Contributors
I. Objectives

The aim of this exercise is to develop a joint research strategy to promote an effective health care system for cardiovascular disease (CVD) in Europe, for prevention, diagnosis and treatment of the diseases, and management of their socio-economic costs. This case can serve as a model for other Joint Programmes for medical research on other major diseases (such as cancer, infectious diseases, neurological and mental illnesses, musculoskeletal disorders, metabolic diseases such as diabetes, and neurodegenerative and ageing-related diseases for example Alzheimer's disease) and even beyond this as a model for Joint Programming in all scientific areas.

II. Rationale

Cardiovascular disease is the main cause of death in the European Union (EU), killing more than 2 million people a year. It costs the EU more than €192bn annually, equivalent to nearly €1,000 per citizen. In addition, the 2008 CVD statistics show considerable variation all over Europe, with eastern parts particularly affected. Corresponding data would be useful for planning medical treatment across the EU, since for high-risk and low-risk countries different strategies are needed.

CVD leads to significant reductions in life expectancy and often to considerable impairment of quality of life of patients over a prolonged period. Preventative measures are important, but due to the long time-spans that lifestyle changes of populations take, immediate measures on development of early diagnosis and individualized therapy with improved treatments are crucial. The advances in prevention, diagnosis and therapy rely on analysis of lifestyle, nutritional, environmental and genetic risk factors. The analysis can be accomplished using European biobanks and registers that have already been largely assembled for Western Europe and still need to be constituted for Central and Eastern Europe.

III. Vision

The Vision is a virtual European Institute of Health, which structures, institutionalizes and synergises joint efforts to meet challenges that cannot be met in national silos.

A virtual Institute of Health would realise the following specific Vision points:

* Significant reduction in cardiac mortality over ten years. A 10% reduction would lead to 200,000 lives saved per year.
* A sustainable change in the lifestyle of individuals, reducing the risk of cardiovascular diseases and other diseases with similar risk factors.

IV. Strategic Research Agenda

Examples of major research challenges for CVD

* To increase the understanding of the molecular and physiological basis of health and disease: use that understanding to improve diagnosis, treatment and prevention; integrate all sequences of activities from gene identification to functional studies and genomic clinical trials leading to personalized medicine with data acquisition in this case on the European population.
* To leverage the potential of cardiovascular imaging as a cornerstone in the therapeutic decision making process: comprehensive information about the heart and coronary arteries, from anatomy to function and perfusion, according to agreed criteria and standards, fully integrated in the entire patient work-up from diagnosis to prognosis.
* To develop new drugs and reduce drug-induced pathologies: prediction of toxicity of drugs and drug candidates using bioinformatics tools, and validation of biomarkers for drug safety.

Added value of Europe-wide Joint Programming

National research efforts alone have not been able to come up with sufficiently strong results to assure the best and most efficient research based health care in heart diseases in Europe. A pan-European effort is needed, as the cardiovascular research area and the interaction with health care in clinical cardiology are very complex, large and demanding. The present serious development in heart diseases with an ageing population, a rising incidence of diabetes and obesity, an increased number of patients with heart insufficiency, and new aspects for women and heart disease make it a ‘Grand Challenge’.

Pan-European joint activities will provide researchers from small countries and the new EU Member States access to globally competitive facilities and infrastructures, and to the best researchers’ networks.

The success of such a pan-European initiative with high economic and societal impacts relies on the a priori definition of the research priorities among the various stakeholders and end users, in particular the health services of the Member States.

Cardiovascular medicine: a success story

There has been a marked decline in the incidence of cardiovascular disease in the western world over the past 25...
years. In fact, the vast majority of the estimated gains in life expectancy are related to progress made in cardiovascular disease (Figure 1). It has been demonstrated that these gains in life expectancy related to cardiovascular disease are due to improved prevention and management of cardiovascular risk factors (accounting for approximately half of the gain) and to improved pharmacological or surgical treatments (accounting for the other half). Among the critical research programmes which have led to these advances, a prototypical example of advance in prevention is the management of hypercholesterolemia with statins. Likewise, a good example of advance in treatment is the role of reperfusion therapy in acute myocardial infarction.

Research translating into improved prevention

The management of hypercholesterolemia has been revolutionised by the discovery of statins, which not only lower effectively LDL-cholesterol but also have been demonstrated to reduce markedly cardiovascular morbidity and mortality in secondary prevention and high-risk primary prevention patients. The key to the discovery of statins was the isolation and functional characterisation of the LDL-receptor by Brown and Goldstein (which led to their subsequent Nobel prize), a typical example of successful basic research discovery, followed by good translational research into development of a drug, and a series of successful large collaborative international clinical trials.

Another good example was quoted in a workshop of the December 2008 Informal meeting of Ministers for Competitiveness – Research organised on the issue of Joint Programming, and refers to the possible benefits of improved prevention of hypertension, since it is the cause of cerebrovascular disorders, which cause 30% of cognitive disorders of the elderly.

Research translating into improved treatment

The management of acute myocardial infarction has been revolutionized by the demonstration that timely reperfusion of the myocardium in patients with ongoing acute myocardial infarction was associated with myocardial salvage, improved cardiac function, but, more importantly, improved survival. Two of the key studies in establishing this were the large cooperative academic clinical trials ISIS-2 and GISSI, which demonstrated that timely use of thrombolytics reduced mortality in acute myocardial infarction. This is another “success story” of large academic clinical trials.

Cardiovascular disease: a persisting global problem

Yet, despite all the progress made, cardiovascular disease remains a major threat to the health of Europeans as well as globally. First, cardiovascular disease remains the number one cause of death in Europe when all ages and gender are considered. Cardiovascular disease alone represents approximately 40% of all causes of mortality before the age of 74 in Europe. To quote Sans et al., “in spite of decreasing age-specific cardiovascular disease mortality rates in Western European countries, there has been no decrease in the absolute number of people who die from cardiovascular diseases. The number of chronically ill cardiovascular patients may even be increasing in these countries due to the ageing of the population.”

In addition, the WHO MONICA (World Health Organisation – Multinational MONitoring trends and determinants in CARDiovascular disease – www.ktl.fi/monica) project has shown that the decline observed in the incidence of cardiovascular disease in Western Europe has been counterbalanced by a substantial increase in Eastern Europe (Figure 2) and a genuine epidemic of cardiovascular disease in “emergent countries” 13. Because of this, estimates are that, by 2020, the number 1 and 2 causes of death worldwide will remain ischemic heart disease and cerebrovascular disease (Figure 3).
Cardiovascular research: an important investment for improving the health of European citizens

Therefore, continued investment in basic, translational and clinical research in cardiovascular disease is key to continued improvement in the health of Europeans. In this respect, translational research and cooperative academic large clinical trials are two areas which are in need of support from public funding in order to address the population’s needs (as opposed to the drug or device industry research agenda).

Examples of pre-existing commitment of national and European organisations

Funding Agencies and Medical Research Councils: The 37 medical research councils of all 30 countries represented within ESF (listed in Table 2) adopted the White paper document ‘Present Status and Future Strategy for Medical Research in Europe’ in November 2007, where enhanced collaboration, implementation of best practice and sharing of research projects and results were agreed upon. 23 of these organisations belong to EUROHORCs.

Learned Societies – European Society of Cardiology (ESC): The European Society of Cardiology is in the process of setting up a European Heart Research Foundation specifically with the aim of promoting transnational research across national boundaries in order to leverage the best European research rather than hitherto confining research to individual countries. The ESC is totally committed to the concept of European-wide joint programming for research, particularly as the scientific questions are becoming increasingly complex.

Cohorts and Biobanks: Below we give a real example of projects and consortia that are being considered for joint funding across Europe. As the projects are still under consideration for funding they will be subject to peer review process and there can be no guarantee that they will be implemented. However, they illustrate the principle of cross border working between national funding agencies. The main project is known as EPIC-Heart and is based on the existing prospective European cohort known as EPIC.

The European Prospective Investigation into Cancer and Nutrition (EPIC), coordinated by the International Agency for Research on Cancer/World Health Organisation (IARC/WHO) was established in the 1990s and has collected information on over 500,000 individuals whose health and lifestyle have been monitored. It involves 10 participating countries (Denmark, France, Germany, Greece, Italy, Norway, Spain, Sweden, the Netherlands and the United Kingdom). EPIC-Heart is a subset of the EPIC cohort and comprises information on about 10,000 individuals who have developed cardiovascular disease. The EPIC-Heart core database will form the basis of a study to correlate genes and lifestyle. Currently, the main EPIC-Heart proposal is being considered for funding in the UK. Through ESF the 10 EPIC countries are also involved in a proposal to jointly fund projects addressing this issue.

The European Society of Cardiology and the relevant national institutes and academic societies can act as platforms for strengthening pan-European cardiovascular research, and implementing the best practices in health provision. A list of biobanks and registers should be composed for Europe, similar to the one established by the P3G consortium for North America.

Pre-existing and new Infrastructures: Six ESFRI 1st Roadmap programmes in the biomedical area are to be capitalized by this Joint Programme, i.e., BBMRI – Biobanking and Biomolecular Resources Infrastructure, INSTRUCT – Integrated Structural Biology Infrastructure, Infrafortress – Functional Genomics in the Mouse as a Model of Human Disease, EATRIS – European Advanced Translational Research Infrastructure, ECRIN – Clinical Trials and GMP biotherapy facilities, ELIXIR – Bioinformatics, and IMI-JU – the Innovative Medicines Initiative Joint Undertaking, with their respective roles shown in Figure 4 (following page).


Some of these networks have become the true materialisation to which they were intended. However, the life cycle of discovery in biology is much longer than that of EC instruments, making it almost impossible to perpetuate after the end of the EC contract. The future of the invaluable networks could be consolidated in the context of Joint Programming and a virtual European Institute of Health.

Knowledge transfer

Knowledge created by medical research is transferred to benefit society in the form of new and improved practices in patient care, and as commercial activity based on new drugs, diagnostic methods, medical instruments and services. The Innovative Medicines Initiative (IMI) provides a platform to develop joint research agendas between the European Community and the Pharmaceutical Industry. Research findings from Joint Programmes should be actively provided for development and commercial exploitation, taking advantage of private technology transfer companies, as well as public ones created in several Member States to enhance the economic impact of research on society. Ownership and management policies of Intellectual Property (IP) should be agreed upon beforehand taking into consideration national legislation and the recommendations provided by the Commission.

The civil society, through e.g. patient organisations and other NGOs, should be part of the knowledge transfer chain, and the transfer and sharing of knowledge should occur in both directions, from knowledge creators to users and vice versa.

Work packages and other activities

Research work packages:

- Fundamental research on genes, proteomics, lipiddomics, metabolomics, pathophysiology and molecular imaging
- Creation of tools (platforms) enabling genomic analysis of epigenetic programmes and changes in individual or small groups of cells in integrated contexts
- Translational research which brings basic research results into clinical practice. Research on translational...
models, as well as on cellular and soluble biomarkers. In many earlier physiological and pathological animal models advances have been made, but need to be better explored in the human. To fill the gap between current experimental models and applicability in human biological and pathological issues, there is a need for “humanized” in vitro and in vivo models and for biomarkers both in the diagnostic and the follow up therapeutic fields.

- Clinical research with focus on diagnostic imaging, and treatment of diabetes, obesity, hypertension and hypercholesterolemia, coronary heart disease and heart insufficiency.
- Implementation of research results into daily clinical practice – to obtain “best practice” within clinical cardiology in Europe. To speed up this implementation is fundamental.
- Research on preventive measures, with common goals to modify citizens’ life styles and nutrition, based on research data from gene and life style interaction and survival.
- Research on health economics.

Other work packages:
- Organisation of structured sharing of infrastructures, biobanks and registers and streamlining Legislation and Guidelines for best practices and ethical issues for their use.
- Reaching out to less developed areas and underserved populations i.e. children, women, the elderly in Europe and the rest of the world
- Developing policy and organise knowledge transfer to industry, and manage IP issues taking advantage of the European Commission’s recommendations for universities and other research organisations
- Organisation of researcher and student mobility taking into account the European Commission Communication on careers and mobility
- Dissemination of the outcome and impact measures presented at the ESC annual congress which gathers tens of thousands of cardiologists. Make use of the current information technologies for dissemination of outcome and impact measures, set up a highly respected website which is peer reviewed and provides information free of charge. Improved models to apply the advances of genetics, genomics, transcriptomics and proteomics to the study of gene and protein functions

**Expenditure on cardiovascular research in Europe**

The EMRC White Paper concluded that medical research in Europe is underfunded and highly fragmented. This is corroborated for diseases such as cancer and brain diseases as shown in Figure 5 presented in the EC Communication on Joint Programming.

For the sake of the specific case of CVD, there is a need to acquire data on public funding of research on Cardiovascular Disease in Europe, as compared to the US, as well as to assess the degree of coordination/fragmentation of this research. In their recent view on Joint Programming, EUROHORCs is prepared to contribute actively to this process by providing information on nationally funded research.
V. Implementation

Joint Programmes should be focused on a few areas addressing issues of high societal urgency, and which cannot be addressed in national silos. The perspective should span 10-15 years to produce the necessary conditions for a decisive impact.

From a more practical perspective, the following modus operandi could be proposed:

1. Identification of the topics for Joint Programmes (0.5-1 year)
   • Ministries (i.e. of Health/Research/Environment….) identify the areas of urgent societal needs.
   • Members of the ESF – Standing Committees, in this case members of the EMRC, coordinate the consultation of the best scientific experts. The experts could use the ESF Foresight Instruments, i.e. Science Policy Briefings, Exploratory Workshops or Forward Looks, to map the existing research initiatives and gaps, and to identify the relevant existing and lacking infrastructure.
   • Ranking and presentation of the evaluated topics channeled through ESF/EUROHORCs to representatives at the Ministerial level.
   • Selections of themes ratified at Ministerial level.

2. Self-assembly of participating funding organisations (1 year)
   • It is important that fresh funding be put forward by both national governments and the European Commission in order to incite participation of research funding and performing organisations (hereafter “organisations”) and to give the programmes the means to achieve their ambitious goals.
   • The organisations participate on a voluntary basis, confirm binding financial commitment, and enter into self-governance.
   • The participating organisations select a Lead Agency amongst themselves to coordinate the Programme or nominate the ESF to do so.
   • The organisations or the Lead Agency select(s) a Steering Committee, and nominate(s) an independent Scientific Council.

3. Call, terms of reference and peer review (1 year)
   • The Steering Committee defines the objectives of the Joint Programme based on the data and documents developed under (1) and the Terms of Reference for the participating research teams, and launches the call. One of the incentives for researchers to participate in Joint Programming could be privileged access to the best research infrastructures.
   • Applications could be submitted by national programmes, consortia or institutes, or bi- or multilateral initiatives, either pre-existing ones or created for this purpose, or both.
   • Acceptance of research consortia should be based on excellence and relevance only.
   • The Lead Agency/ESF organises a centralized and harmonized peer review process, under the surveillance of the Scientific Council. The quality of the peer review should be so high that national funders trust it.
   • The Steering Committee ranks the applications according to the Scientific Council’s recommendations and submits its proposal to the participating organisations for ratification.
4. Funding and running of the Joint Programme (10-15 years)

- Other funders such as philanthropy and patient organisations should be invited to participate in the Health domain. The Lead Agency/ESF could seek for novel funders at the respective national level.
- The money could be accumulated into a virtual 'common pot' like in the case of the ESF EUROCORES scheme, or to a real 'common pot', according to the practices of the different types of funders.

Organisation and running of the research work packages and other activities will vary according to the research domain.

5. Monitoring and Impact Assessment (during and after completion of the programmes)

- Each Joint Programme should have a Scientific Advisory Board (SAB) maybe independent from the Scientific Council, nominated by the Steering Committee, to perform evaluation of progress at regular intervals and provide advice on research, organisational issues, funding, infrastructure and transfer of knowledge to end-users. Continuation of funding should depend on the progress. The biomedical research outputs will be made available through a Europe-wide open repository similar to the UK PubMed Central.
- Each Programme should be the subject of impact assessment after a proper time period. The impact studies in the health sector could be similar to that carried out by the Health Research Board (HRB) in Ireland. The study consisted of assessing the cumulative outcomes of a selection of HRB-funded research projects over time to demonstrate the impact the funding on people’s health and the Irish economy. Using a pioneering approach called the ‘Payback Framework’ the HRB worked with the Health Economics research group in Brunel University (UK) and RAND Europe to identify and assess these benefits\textsuperscript{22}. OECD could contribute to developing such a study for Europe in an international perspective.

The overall process is summarized in the Figure 6 below.

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VI. Outcome and Societal Impact

Health research plays a key role in improving citizens’ quality of life, health and prosperity\textsuperscript{23}. The most important outcomes of medical research are better prevention strategies and better health care for individuals. The impact should be a healthier population and improved management of the economic cost of health care. A recent survey demonstrated an eight-fold return on investments in cardiovascular research\textsuperscript{15}.

There is an absolute need for a European Institute of Health since translational research today is unlikely to be successful in a single country, let alone a single institution. The pooled resources in terms of expertise, facilities and cohorts of patients available across Europe are a unique opportunity to introduce effective investigations and
treatments that would benefit the health of the people of Europe. Already the pharmaceutical industry has learnt this and in cardiovascular disease no longer are clinical trials, to introduce new treatments, ever conducted in a single country but are invariably conducted across Europe. In fact the pooling of resources described would be much more financially effective in delivering these goals. Moreover, other than the plans of the European Society of Cardiology and EU Networks of Excellence there are very few opportunities if any for collaboration across Europe, unlike the great success achieved by the Americans through the National Institutes of Health – NIH in the US.

The aim of such a virtual European Institute of Health (EIH) would be to structure, institutionalise and synergise national and European efforts and to address important health challenges in the global context.

References

15. EMRC White Paper at: www.esf.org/emrc/whitepaper
17. A similar approach has been initiated in research on oncology – The Stockholm Declaration, Science Direct, Molecular Oncology 2 (2008) 10-11.
23. Medical Research: assessing the benefits to society, Academy of Medical Sciences, MRC, Wellcome Trust (UK), May 2006

Table 1: Pre-existing analyses and foresights

European Science Foundation (ESF) – European Medical Research Councils (EMRC)

ESF has coordinated the development by the best experts in European countries of numerous documents analysing the status quo and the future developments and needs of health research in Europe.

• White paper ‘Present Status and Future Strategy for Medical Research in Europe’ (published November 2007). This document, endorsed by 30 European countries, advocates a strong medical research based on enhanced research collaboration across Europe. More at: www.esf.org/emrc/whitepaper
• Forward Look ‘Investigator-Driven Clinical Trials’. To develop a strategy and recommendations on how to best address health needs in Europe in an international perspective (to be published December 2008). More at: www.esf.org/emrc/icdt
• Forward Look ‘Implementation of Medical Research

The EUROHORCs and ESF vision on a Globally Competitive ERA and their Road Map for Actions to Help Build It, Science Policy Briefing No30 (June 2008)

EUROHORCs view on Joint Programming (14 November 2008)

European Commission (EC) – DG Research

Mission Statement
The mission of EMRC is to promote innovative medical research and its clinical application towards improved human health.

EMRC offers authoritative strategic advice for policy making, research management, ethics, and better health services.

In its activities, EMRC serves as a voice of its Member Organisations and the European scientific community.

EMRC disseminates knowledge and promotes the socio-economic value of medical research to the general public and the decision makers.

Member Organisations
EMRC is the membership organisation under the ESF of 37 national medical research councils in 30 European countries. 23 of them belong to the association of the European Heads of Research Councils (EUROHORCs*) – their names are underlined*.

- Austria
  - Austrian Science Research Fund (FWF) Professor Christoph Kratky* – President
  - Austrian Academy of Sciences (ÖAW) Professor Peter Schuster – President

- Belgium
  - Research Foundation Flanders (FWO) Dr. Elisabeth Monard* – Secretary General

- Bulgaria
  - Bulgarian Academy of Sciences (BAS) Professor Naum Yakimoff – Secretary General

- Croatia
  - Croatian Academy of Sciences and Arts (HAZU) Professor Milan Mogus – President

- Cyprus
  - Cyprus Research Promotion Foundation (RPF) Mr. Achilleas Patzinakos – Director General

- Czech Republic
  - Czech Science Foundation (GAČR) Professor Josef Syka* – President

- Denmark
  - Danish Medical Research Council (FSS) Dr. Lars Fugger* – Chair

- Estonia
  - Estonian Science Foundation (ETF) Professor Jüri Allik* – President

- Estonia Academy of Sciences Professor Richard Villems – President

- Finland
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- France
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- National Institute for Health and Medical Research (Inserm) Professor André Syrota* – President

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  - German Research Foundation (DFG) Professor Matthias Kleiner* – President

- Greece
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Table 2: The European Medical Research Councils (EMRC)

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<th>Country</th>
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<td>Austria</td>
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ESF
The European Science Foundation (ESF) was established in 1974 to provide a common platform for its Member Organisations to advance European research collaboration and explore new directions for research. It is an independent organisation, owned by 80 Member Organisations, which are research funding organisations and research performing organisations, academies and learned societies from 30 countries. ESF promotes collaboration in research itself, in funding of research and in science policy activities at the European level.

EMRC
The European Medical Research Councils (EMRC) is the membership organisation for all the medical research councils in Europe under the ESF. Its mission is to promote innovative medical research and its clinical application towards improved human health. EMRC offers authoritative strategic advice for policy making, research management, ethics and better health services.

EUROHORCs
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