

Alliance for Biomedical Research in Europe

EUROPEAN COUNCIL FOR HEALTH RESEARCH CONCEPT PAPER

Introduction: Urgent need for a pan-European strategic platform for health research

In health, research is the key to identifying causes of disease and developing strategies for health promotion and prevention, as well as diagnosis and treatment. It helps save lives.

New treatments, drugs and technologies are a result of many years of study, trials, promise and investment. But in this golden age of genomics and biomedical research, why aren't many promising discoveries benefiting patients as rapidly as expected? Why are Europe's innovators increasingly relocating outside Europe? And how are EU Member States going to tackle the challenge of ever increasing healthcare costs given the demographic trends of an ageing population, in a time of economic gloom?

The EU's 'Innovation Union' initiative¹ aims to create an environment in Europe that supports the translation of novel ideas into products and services and can generate growth, jobs and social well-being. Biomedical research represents an outstanding example of research-driven innovation which, through health promotion and prevention, the development of diagnostic and medicinal products, the improvement of medical treatments, and advances in health services research may boost scientific excellence and knowledge as drivers of future growth in the European Research Area (ERA).

We, representatives of the health research community in Europe, are convinced that strategic long-term planning is needed to ensure basic science discoveries promote better health for citizens. To achieve this, the scientific community needs to be in the driving seat, together with other stakeholders in the health continuum, including patient representatives.

Presently, scientific collaboration in health in Europe lacks a strong strategic framework. It is frustrating for European researchers to see opportunities being lost, with excellent breakthroughs in basic science not being pursued. Moreover, the innovation cycle in this field is long – approximately 10 years – yet current health research opportunities in Europe tend to focus on short-term collaborative projects of 3-5 years. Thus excellent collaborations are often discontinued once the project funding is completed.

For the first time, the European biomedical community has come together as an Alliance representing 20 health research organisations and around 250,000 biomedical researchers, to deliver on their societal responsibilities by calling on EU and national decision-makers in Europe for urgent action to help science achieve true innovation that can create a healthier and prosperous environment for Europe's citizens.

Horizon 2020 (H2020), the Framework Programme for Research and Innovation 2014-2020, needs to integrate a strategic approach across the entire health spectrum.

The creation of a 'European Council for Health Research (EuCHR)' can provide the best strategic scientific leadership to EU programmes in health research.

The EuCHR can bring together and consult with all health stakeholders. The objective is to ensure that Europe's frontline research groups and laboratories are supported with the resources and people they need to make their innovative ideas a reality. This strategic action will guarantee that high-quality research outcomes reach Europe's citizens as quickly as possible.

¹ The Innovation Union is one of the seven flagship initiatives of the Europe 2020 strategy for a smart, sustainable and inclusive economy. For more information on the Innovation Union, go to http://ec.europa.eu/research/innovation-union/index_en.cfm?pg=home.

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The BioMed Alliance has been joined in this call for coordinated action by several stakeholders including leading actors in the pharmaceutical industry² and the broader scientific community³. The BioMed Alliance has also been working closely with key opinion-leaders in research and policy including Nobel Laureates and patient advocates⁴. Health is unquestionably wealth; yet there is unanimous agreement that Europe is falling far behind its competitors in terms of innovative health research, and recognition of the economic benefits of investing in and co-ordinating this field at EU and national level.

The European Council for Health Research will:

- ✓ Focus on accelerating excellent biomedical research in Europe and promote Europe as a centre for health research innovation.
- ✓ Seek better coordination and strategic planning of biomedical research funding programmes at European level.
- ✓ Define and support high-level health research programmes in order to achieve translation of findings into innovative outcomes.
- ✓ Promote deeper and longer-term collaborative initiatives that address the current gaps in the Innovation Cycle and deepen cross-talk and collaboration across all relative disciplines.
 - ✓ Have a bottom-up structure and be led by excellent scientists.
 - ✓ Provide strategic advice on the steering of European health research to policy-makers.
- ✓ Incorporate all relevant stakeholders, not only biomedical scientists but also patient representatives and leading investigators from other fields, in order to boost creativity and innovation in this sector and promote a healthier Europe.

² EFPIA, the European Federation of Pharmaceutical Industries and Associations, has endorsed the concept of a EuCHR. EFPIA represents approximately 2000 companies on the EU scene.

³ 600 European researchers from across all scientific disciplines were invited to contribute their comments and ideas on Horizon 2020 by the Copenhagen Research Forum. The final recommendations, including the call for a European platform for all health stakeholders, were published in the 2012 report "Visions for Horizon 2020 – from Copenhagen Research Forum". www.crf2012.org/

⁴ The BioMed Alliance has created a multidisciplinary, multi-professional 'Core Group' of top-level biomedical experts, political advisors, patient advocates and industry representatives, who were nominated by the Alliance member societies and can bring the concept of a EuCHR forward.

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1.

The Grand Challenge

Healthcare represents the biggest expense to Europe's national budgets after pensions, and will be the fastest growing item of government expenditure in the coming decades due to the ageing population⁵. Europe's decision-makers are facing tough choices. Aside from the declining working population, there is an increasing prevalence of non-communicable and chronic diseases, such as cancer, cardiovascular disease, neurodegenerative and respiratory diseases, autoimmune diseases and diabetes amongst others, most of which are often coupled with co-morbidities in the elderly. How can this be sustained?

'Health is Wealth'

The figures facing Europe are disturbing. According to the World Health Organisation (WHO), the major non-communicable diseases⁶ are the cause of 86% of deaths and 77% of the disease burden. Under status-quo prevention and treatment trends, estimates indicate that non-communicable diseases worldwide will cause an output loss of \$47 trillion (€35 trillion) over the next two decades⁷. Yet, such diseases are largely preventable and are linked by common risk factors. There is an urgent need for intervention: more effective coordination of research at national and EU level, increased cross-disciplinary interaction, research advancements, and research-informed policies to promote healthier behaviours, are needed in order to tackle this grand challenge.

But despite the critical need to advance in health research, **Europe is progressively falling behind as global competition in research becomes stronger**. According to a recent report by the European Commission (EC), innovation performance growth is slowing down and the European Union (EU) is not closing the persistent gap with global innovation leaders such as the United States (US), Japan and South Korea⁸. Many biomedical companies are finding drug development in Europe economically challenging and as a result are moving their operations from the region, mainly to Asia.

Europe is also behind in its investment in research generally. Between 2002 and 2007, European investment in research stagnated⁹; in the same period China increased research and development (R&D) spending by a staggering 160%. This is worrying, as healthcare is a driving factor for different industries in most European countries. Investments in research and innovation related to health will pay off for Europe as new concepts in therapy can be exported worldwide. The UK's Medical Research Council, for example, looked at investment in cardiovascular research, and estimated the return on investment to be up to 39%¹⁰. Clearly, investment creates employment and improves health, as well as providing innovative cost-saving technologies, thus reducing the growing economic burden Europe faces.

Biomedical research investment and coordination will advance innovation and help patients, ultimately driving down costs. With our global competitors increasingly focusing on biomedical research, it is high time for Europe to step up its efforts in this field, through consultation with scientific experts on necessary strategic actions.

⁵ Standard & Poor's, 2012. Mounting Medical Care Spending Could Be Harmful To The G-20's Credit Health.

⁶ This refers to cardiovascular diseases, cancer, mental health problems, diabetes mellitus and chronic respiratory diseases in the WHO Europe region.

⁷ World Economic Forum and the Harvard School of Public Health Report, 2011.

⁸ European Commission, 2012. Innovation Union Scoreboard 2011: The Innovation Union's performance scoreboard for Research and Innovation

⁹ Actual spending on all R&D increased by just 29%, whereas GDP increased 27% in that time, meaning there was virtually no real-terms spending increase. China increased its investment by 160%, although its GDP grew by 97%. The Lancet, 2011. Volume 377, Issue 9765.

¹⁰ Medical Research Council, 2008. 'Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK'.

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The main obstacles to overcome in European health research include:

a) The Complexity of the Innovation Cycle

Scientific breakthroughs often occur at basic science level, and the success of the European Research Council (ERC) in particular is a good indicator of the quality and dimension of frontier research in Europe. But the road that brings discoveries from bench to bedside is notoriously bumpy and complex as it involves many phases, stakeholders and regulatory barriers at all stages. For advances in the molecular understanding of disease to actually improve human health, there is a need for a broad and systematic effort to be made.

In the biomedical field, the Innovation Cycle involves mainly the following steps:

- Developing ideas into novel concepts starting from basic and clinical research findings;
- Translating novel concepts into clinical practice;
- Taking findings to the market, and
- Evaluating treatment strategies by monitoring outcomes.

Figure 1 illustrates the complexity of the Innovation Cycle in the biomedical field.



Figure 1: The complex Innovation Cycle from research to market in the biomedical field.

While the existing model of collaborative short-term projects being funded has made important contributions to science its limitations are to be recognised. Fruitful collaborations are often disbanded because their grant has expired, and it is very difficult to achieve sustainability under the current conditions. At EU, national, and regional level, no instrument currently exists to extend funding of projects which have accomplished unique results and which need to be continued to maximise the potential of real successes and innovations. This results in a major loss of knowledge, in its transfer, in potential opportunities for innovation AND in its implementation into the health system.

There is an urgent need to go beyond the current model of funding of individual projects, and move towards a long-term strategic definition of research programmes at European level, accommodating flexibility and sustainability and steering the translation of research to promote a healthier Europe.

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As Europe has not been able to adequately address the complexity of the Innovation Cycle in the biomedical field, we are losing competitive ground.

b) A fragmented biomedical community of potential innovators

Medical disciplines in Europe have traditionally worked independently of each other and there has been little cross-talk as there is presently no suitable instrument to do so. Yet, different diseases often share similar basic mechanisms such as ageing, inflammation and abnormal repair, and thus wasteful duplication of research takes place.

In addition, the entire scientific community often share common technological and infrastructural resources: several technological tools such as bioinformatics, systems biology, genomics, clinical trial design and statistical analysis are common to all disciplines. Moreover, the large medical centres at national level are not collaborating efficiently across borders and there is still a need to partner with relevant industries on health research advances made, in order to ensure society benefits.

Furthermore, we are moving away from the often inefficient 'one-size-fits-all' approach to an era of individualised/stratified medicine, which is increasingly becoming the cornerstone in biomedical research. Personalised medicine means delivering the right treatment, to the right patient, at the right time, promising a future where disease is detected at the earliest possible time, with treatments that are tailored to an individual patient's genetic composition. To implement personalised medicine means that large-scale comprehensive studies under common regulatory frameworks will be essential.

Scientific careers can also be boosted if more attention is paid to innovation in biomedical research. Europe needs to be a more attractive centre for creative thinking in biomedical research, where the best and brightest talents are encouraged to remain and reap training opportunities. In addition, Europe's investigators need to keep up with the rapid changes in biomedical research; new technologies, new experimental approaches and the associated bioethical and social repercussions call for a focus on continuing cross-disciplinary, multi-professional training programmes.

A major hurdle in this fragmentation of research efforts is the lack of strategic programmes and coordinated funding that support research across borders and disciplines in a long-term perspective. As long as this situation continues, it will hamper information flow and will prevent the full exploitation of the wealth of experience, of achieving the required critical mass, as well as the identification and taking up of best practices.

Accelerating research in the biomedical field in Europe can only be achieved through long-term strategic research programmes capable of triggering global multidisciplinary partnerships and that address the full innovation cycle.

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2. Top Scientists Taking the Lead: the EuCHR

It is said that in a recession, innovation thrives. The European biomedical community is reacting to the alarming economic and health challenges by speaking with 'one voice' for the first time.

The EU proposes that the Innovation Union will move discoveries quicker to the market and promises 'More Jobs, Improved Lives and Better Society'. Yet, this ambitious task does not provide strategic action for health innovation. To truly make a difference, a multi-professional, multidisciplinary context which covers a continuum from basic research through translational research to clinical application is needed.

To realise this goal, the BioMed Alliance proposes the creation of the European Council for Health Research (EuCHR). This strategic initiative will boost innovation in health research-it will contribute to defining biomedical research and translation programmes based upon the best scientific leadership and by ensuring expert input on policy from the outset.

Following the model of the ERC, a bottom-up 'Scientific Council' within the EuCHR would be created. This independent body of excellent biomedical scientists would have a mandate to set long-term, sustainable, research programmes based on the likelihood of achieving translations of findings into innovative outcomes that will improve the health of citizens. Its guiding principle will be to contribute to effective progress by funding research at the highest level and exploiting in full the benefits of coordination and co-operation across Europe and beyond, thus avoiding fragmentation and providing savings for national health systems.

The proposed EuCHR would be mandated to consult with all relevant stakeholders and to process adequately their contribution and initiatives in its own independent decision-making process. In this more directed, strategic approach, **excellence still remains the most important selection criterion**. The structure and governance of the EuCHR, including rules on analysis, follow-up, monitoring and transparency criteria for Scientific Council members and review panels will be defined according to best practice.

The EuCHR will aim to achieve timely and cost-effective translation of research into practice by:

- ✓ Promoting strategic planning and synergy with other European programmes at national, regional, and EC level, including the ERC, the Innovative Medicines Initiative (IMI), the Marie Curie actions, relevant infrastructural initiatives as well as the other five societal challenges outlined in Horizon 2020;
- ✓ Reinforcing H2020 determination to implement simplification in its design, rules, financial management and implementation ;
- ✓ Providing incentives to encourage the contribution from other science and technology (S&T) fields (such as nanotechnology, engineering, information and communications technology (ICT), environmental research, nuclear physics or space research), as well as the economic and social science fields;
- ✓ Providing authoritative advice on the steering of EU-funded research;
- ✓ Providing scientific advice for new regulatory measures needed to ensure progress of health research in Europe.

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3. Why is the EuCHR needed?

1. Because the European added-value of H2020 in health-related areas can only be exploited if:
 - a) strategic top-level scientific leadership can be achieved in defining and supporting the best and most relevant research,
 - b) strategic long-term action at European level can be pursued in order to successfully translate research into health benefits and,
 - c) strategic collaborations and cross-talk amongst health research stakeholders at EU level are efficiently organised.
2. Because the major challenges facing health research and innovation in the EU cannot be met without coordinated action. By establishing H2020 internal strategic coordination, based upon top-level scientific steering, a EuCHR will provide the impetus and instruments needed to promote voluntary interaction and synergies at a larger scale, namely: a) strategic specific partnership, at EU level, between industry, national agencies and the EC and b) strategic convergence at programme level involving regulatory bodies and national health authorities.
3. Because European funding for health research and innovation is scattered across several funding instruments and strategic science-based coordination is required in order to create collaborations with all related sectors, and achieve a responsible and effective framework for action.
4. Because large medical research centres at national level need to work closer together across borders due to this huge societal challenge facing Europe. There is an urgent need to increase networking and joint initiatives in translational medicine.
5. Because Europe needs to be more proactive in encouraging 'science for society' initiatives that promote research in health. By boosting health research, opportunities can be provided for up-and-coming innovators to avoid the current 'brain drain' and rather support a 'stairway to excellence' for young health research investigators that exemplify the multidisciplinary workforce of the future.

4. The Added-value of a EuCHR with Scientific Leadership

- ✓ The EuCHR will **aim to reinforce excellence** at the heart of European health research. Only scientists can set scientific priorities to promote a healthier Europe and ensure innovations that benefit society.
- ✓ The EuCHR will promote an **'innovation-friendly' environment, and encourage the containment of healthcare costs, promote health and research competitiveness and aim to reduce inequalities**. To do this, a new dynamic for networking between academia, clinical practitioners, industry and the regulatory agencies will be promoted, in an effort to encourage public-private **partnership**.
- ✓ **Patient empowerment** will be an important element of the EuCHR. Patients are at the centre and a vital part of the research and innovation process. Thus, maintaining a patient-centric view and optimally involving patients in this endeavour will be central to the activities of the EuCHR.
- ✓ The EuCHR can **assess the value of crucial research findings** and ensure continuity and a mechanism that would allow for investment and funding for strategic European-wide clinical trials, in order to close the current basic-translational research gap.
- ✓ The EuCHR will help **promoting coordination of biobanks, data standardisation, harmonisation** and integration, database interoperability and easy access to such resources.

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- ✓ The EuCHR can ensure that **advances in one clinical area may benefit others** through closer cooperation and cross-fertilisation of resources and expertise. Moreover, young investigators interested in studying the interconnectiveness of diseases and resources will be encouraged.
- ✓ The EuCHR will **allocate adequate resources for bottom up initiatives of research networks to foster newly emerging topics** and to facilitate innovations in research fields not covered in well-defined strategic top down programmes.
- ✓ The EuCHR **will attract competence** from other science and engineering fields.
- ✓ **The significant regulatory pressures** placed on the biomedical community¹¹ are slowing down innovation. The EuCHR can create strategies to support biomedical researchers streamline the increasing red tape.
- ✓ The EuCHR can help to **foster a culture where excellent biomedical scientists can bring their ideas to fruition in order for civil society to benefit**. By accelerating private-public partnerships in health research and encouraging science for society, the EuCHR gives hope to the next generation of scientists. The opportunities that such a structure can provide offer new hope and opportunities to talented up-and-coming biomedical researchers.¹²
- ✓ **Deeper and longer-term collaborative research platforms** will be promoted. It is only by doing so that novel and efficacious therapies and strategies can be developed to promote both a healthier European population and a healthier economy.

Conclusions

Coordinated and strategic planning of health research is urgently needed in order to tackle the major health challenges facing Europe. Coordination can address fragmentation and improve the use of technological and infrastructural resources by the entire biomedical research community. Success and innovation in health research moreover requires a long-term commitment to sustain excellent research.

A scientific-led strategy can promote a healthier and more productive Europe. A European Council for Health Research (EuCHR) under scientific leadership can ensure expert input on policy from the outset, advance innovation and competitiveness by understanding the complexity of the innovation cycle, encourage participation from more researchers across borders and ensure savings for national health systems.

The Biomed Alliance, on behalf of the biomedical research community in Europe, believes that through such an integrated and coordinated multidisciplinary strategy, involving all stakeholders including patients, the cost curves in health can be addressed. This call for action by the biomedical community comes at a time when EU and national policymakers are identifying how to accelerate EU research and innovation through the 'Horizon 2020' initiative, despite the increasing economic difficulties facing Member States.

¹¹ The EU Clinical Trials Directive (2001/20/EC) is an example of legislation that has provoked much criticism amongst the biomedical research community for severely hampering academic-led research.