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' initiative[1] aims to create an innovative environment in Europe by supporting the translation of novel ideas into products and services that generate growth, jobs and social well-being. Biomedical research represents an outstanding example of research-driven innovation which, through the development of diagnostic and medicinal products and the improvement of medical treatments, 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 is long in this area – approximately 10 years – yet the EU research framework programmes tend to focus on short-term collaborative projects of 3-5 years, and 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 21 health research organisations and around 250,000 biomedical researchers, to deliver on their societal responsibilities and to sound alarm bells.

Horizon 2020[1], 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 the stakeholders, to ensure that high-quality research outcomes reach Europe's citizens as quickly as possible. Providing the 'missing link' between researchers and other key stakeholders and creating a platform to coordinate funding, such a body can support Europe's frontline research groups and laboratories with the information and people they need to make their innovative ideas a reality.

The BioMed Alliance has been joined in this call for coordinated action by several stakeholders including leading actors in the pharmaceutical industry[2] and the Copenhagen Research Forum, which involved over

[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.

[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.

600 researchers from across all scientific disciplines. We have also been working closely with key opinion-leaders in science and policy including Nobel Laureates and patient advocates[3]. There is unanimous agreement that Europe is falling far behind its competitors in terms of innovative research, and recognition of the economic benefits of investing in biomedical research both at EU and national level, as health is unquestionably wealth.

[3] 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.

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 population[4]. 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, and diabetes amongst others, 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 diseases[5] are the cause of 86% of deaths and 77% of the disease burden in the WHO European region. 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 decades[6]. Yet, such diseases are largely preventable and are linked by common risk factors. There is an urgent need for intervention through cross-disciplinary interaction, research advancements, and research-informed policies.

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 US, Japan and South Korea[7]. 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 stagnated[8]; 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%[9]. Clearly, investment creates employment and improves health, as well as providing innovative cost-saving technologies, thus reducing the growing economic burden Europe faces.

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

[4] Standard & Poor's, 2012. Mounting Medical Care Spending Could Be Harmful To The G-20's Credit Health.
[5] This refers to cardiovascular diseases, cancer, mental health problems, diabetes mellitus and chronic respiratory diseases.
[6] World Economic Forum and the Harvard School of Public Health Report, 2011.
[7] European Commission, 2012. Innovation Union Scoreboard 2011: The Innovation Union's performance scoreboard for Research and Innovation
[8] 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.
[9] Medical Research Council, 2008. 'Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK'

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 and stakeholders. 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 at European level.

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

- Developing ideas into novel concepts starting from basic research and clinical 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.

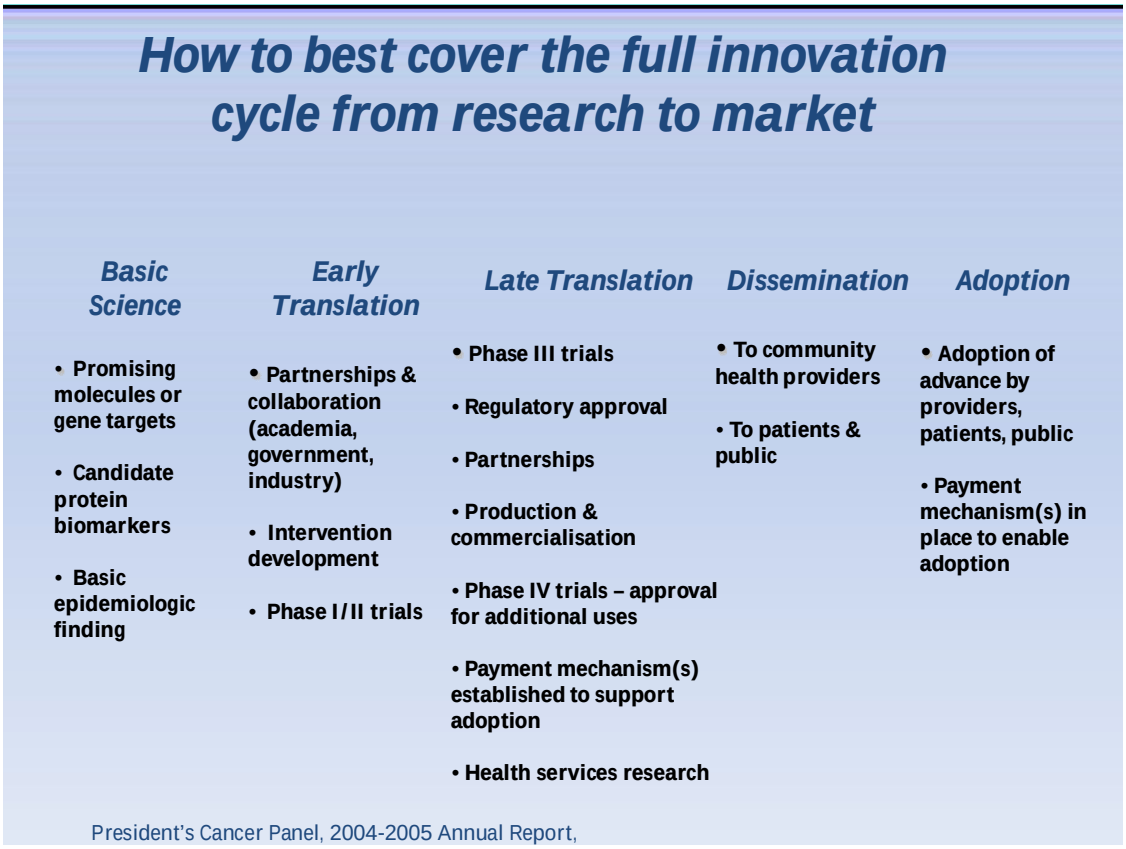

Figure 1: The complex innovation cycle from research to market in the biomedical field.

We recognize that the existing model of collaborative short-term EU-funded projects is of great importance. However, 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. There is no instrument in place 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 EU level,** accommodating flexibility and sustainability at project level and steering the translation of research to promote a healthier Europe.

To date, Europe has not been able to adequately address the complexity of the Innovation Cycle in the biomedical field. As a result, 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, and thus wasteful duplication of research takes place.

The variability in research activity and ultimately patient care is a consequence of many factors, the most significant being the social and cultural differences among countries, differences in clinical governance, and lack of structured networks of interested parties with commonly agreed goals.

Aside from the commonality of basic mechanisms involved in conditions such as ageing, inflammation and abnormal repair between different diseases, there are also technological tools such as bioinformatics, systems biology, genomics, clinical trial design and statistical analysis that are common to all disciplines. The entire scientific community often share common technological and infrastructural resources and face similar challenges such as the administrative complexity and lack of sustainability of excellent research projects. 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.

As long as this situation continues, it will hamper information flow and will prevent the full exploitation of the wealth of experience, of gaining the required critical mass, as well as the identification and taking up of best practices.

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. **The era of personalised medicine** means that large-scale comprehensive studies under common regulatory frameworks will be essential.

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

2. An Innovative Solution: 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 and calling on EU decision-makers for urgent action to help science achieve true innovation that can create a healthier and prosperous environment for Europe's citizens.

The EU proposes that the Innovation Union will moves 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), a bottom-up initiative that will have a structural effect in contributing to defining biomedical research and translation programmes based upon the best scientific leadership and that should ensure expert scientific input on policy from the outset.

This scientific expert leadership (a EuCHR 'Scientific Council') focused on improving the health of Europe's citizens and encouraging innovation will warrant savings for national health systems.

Why is the EuCHR needed?

1. Because the EU 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 EU 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 at EU level.
   By establishing H2020 internal strategic coordination at EC level, 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 EU 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 health research and innovation increasingly require networking of many other science and technology (S&T) research and innovation areas (such as nanotechnology, information and communications technology (ICT), environmental research, nuclear physics or space research) as well as of EU horizontal policy instruments (including the 'Marie Curie Actions', 'International Co-operation' activities and 'Research Infrastructures'). Conversely, new challenges in health research provide fresh opportunities for innovation and progress in many other S&T fields, namely in the physical sciences and engineering, but also in the economic and social sciences.

5. 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.

3.Top Scientists taking the lead

Currently the process underlying the EU research framework programme and subsequent 'calls' of the 'Health' theme is neither sufficiently inclusive nor sufficiently tailored to address biomedical research challenges. Under the current scheme, there are no noteworthy incentives that encourage the contribution from other S&T fields to help combat the current health burden. This leads to a fragmented approach in the process of identifying what the research priorities should be and where the EU added-value will best be achieved.

In addition, the selection of EU-funded biomedical research projects needs to be optimised and based upon excellence of the project coupled with the likelihood of delivering innovations and better health outcomes. More direct involvement of the biomedical community in the development of funding strategies and in the process of priority-setting is essential, in order to move to a new paradigm based upon long-term strategic programmes.

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.

The EuCHR would incorporate the following:

- ✓ establish well-defined programmes
- ✓ provide authoritative advice on the steering of EU-funded research
- ✓ achieve timely and cost-effective translation of research into practice, and
- ✓ help to provide scientific advice for new regulatory measures needed to ensure progress of health research at EU level.

For many scientists, the EU-funded research opportunities available are confusing and complicated with an overuse of jargon and burdensome red tape. It is often unclear to the scientific community of how to become involved and suggest research topics for new calls. However, the scientific community will welcome and support changes in a system that is scientific-led by prominent experts who understand the obstacles faced by the health research community and who will aim to ensure a simpler and less bureaucratic system.

In this more directed, strategic approach, **excellence still remains the most important selection criterion**. Appropriate rules and stipulations, including rules on analysis and transparency criteria for Scientific Committee members will be defined.

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. Its guiding principle will be to contribute to effective progress in promoting research at the highest level and exploiting in full the benefits of co-operation across the EU and beyond.

6. The Added-value of 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 health 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 created, similar to how the EU's Innovative Medicines Initiative (IMI) has attempted to provide a platform for public-private **partnership**.[10]

- ✓ **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 and its 'Scientific Council' could **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 **promote the need for coordination of biobanks, data standardisation, harmonisation** and integration, database interoperability and easy access to such resources.

- ✓ The EuCHR can ensure that **advances in one clinical area may benefit others** through closer co-operation and cross-fertilisation of resources.

- ✓ **The significant regulatory pressures** placed on the biomedical community,[11] are slowing down innovation. The EuCHR can create strategies to support biomedical researchers streamline the increasing red tape.

- ✓ **The EuCHR will promote science for society** and aim 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.

- ✓ **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.

[10] The Innovative Medicines Initiative (IMI) is an example of a public-private partnership in the health field. The IMI is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe

[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.

Conclusions

Common strategic planning of health research is urgently needed in order to tackle the major health challenges facing Europe. The Alliance for Biomedical Research in Europe (the BioMed Alliance), a unique initiative involving key biomedical research organisations in Europe, considers that success and innovation in health research requires a long-term commitment.

The BioMed Alliance recognises that not only is health research truly fragmented in Europe, the entire scientific community often uses the same technological and infrastructural resources and face the same challenges such as the administrative complexity and lack of sustainability for excellent research projects.

A scientific-led strategy can promote a healthier and more productive Europe. This European Council for Health Research (EuCHR) can ensure expert scientific 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.

We, the biomedical research community in Europe, believe that through such an integrated 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.