



WRITTEN RESPONSE TO THE GREEN PAPER

FROM CHALLENGES TO OPPORTUNITIES: TOWARDS A COMMON STRATEGIC FRAMEWORK FOR EU RESEARCH AND INNOVATION FUNDING

DATE OF SUBMISSION	Friday, 20 May 2011
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NUMBER OF PAGES	11

EXECUTIVE SUMMARY

The Alliance for BioMedical Research in Europe* (hereafter, BioMed Alliance) welcomes the opportunity to provide comments on the European Commission (EC) Green Paper 'From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation Funding' – COM(2011)48¹.

Biomedical research clearly meets the targets identified in the 'Europe 2020 strategy for smart, sustainable and inclusive growth' [COM(2010) 2020]. It represents an outstanding example of research-driven innovation which, through the development of medicinal products and the improvement of medical treatments, may boost scientific excellence and knowledge as drivers of future growth. In addition, it has a crucial role in tackling those societal challenges, such as an ageing population, which weigh heavily on the EU competitiveness and on its citizens well-being.

In order to develop the full potential of biomedical research, the BioMed Alliance welcomes the vision of a single comprehensive strategic framework for funding, which it sees as a major opportunity. It supports the EC objectives of making participation easier, increase scientific and economic impact and provide better value for money.

* The Alliance for BioMedical Research in Europe (BioMed Alliance) was founded in December 2010 by the European Association for the Study of Diabetes (EASD), the European Society of Cardiology (ESC), the European CanCer Organisation (ECCO), and the European Respiratory Society (ERS). The founding members drafted the position paper presented. In 2011, four additional societies joined the Alliance: the European Society of Human Reproduction and Embryology (ESHRE), the European Hematology Association (EHA), the European Association for the Study of the Liver (EASL) and the European College of Neuropsychopharmacology (ECNP). Overall, the BioMed Alliance represents over 150,000 health professionals in Europe. The Alliance intends through its actions to promote excellence in biomedical research, and thereby improve the health and wellbeing of all citizens in Europe.

¹ http://ec.europa.eu/research/csfr/pdf/com_2011_0048_csf_green_paper_en.pdf



To this end, it invites the EC to reflect and take action on the main obstacles identified in biomedical research regarding:

1. **RESOURCES:** Overall research funding in Europe (1.8% of GDP average investment) is too limited and far below that available in the US (2.6%) and Japan (3.3%).² Of particular concern is the investment in biomedical research. EU funding for health research represents a mere 10% of the overall EU research funding budget (€6.1 billion out of €53.2 billion), which is largely **insufficient to address the challenges in health** and to remain competitive in biomedical research.
2. **PARTICIPATION OF RESEARCHERS:** The configuration of EU research funding does not allow for the rightful involvement of researchers in the conception, development and evaluation of innovative research. In particular, in biomedical research, funding strategy and **priorities must be defined by the biomedical community**. Only if experts are involved from the beginning of the strategic setting of research funds can it truly address the challenges faced by science and society in its entirety.
3. **STRATEGIC COORDINATION:** Fragmentation is a particular concern in biomedical research. To increase efficient use of resources and gather strength through focus, **a single dedicated agency for biomedical research** with strong input from the biomedical community is needed.
4. **INNOVATION CHAIN:** Funding must be comprehensive, covering all domains from basic science to outcome research. However, not all steps from basic research to innovation should be covered in single projects. In biomedical research further support for translational research is necessary. To support risk-taking and ground-breaking research with potential high gain, there must be a **balance between bottom-up initiatives and top-down strategically defined programmes**.
5. **SIMPLIFICATION:** Funding is not easily accessible and is unattractive due to the administrative complexity of applications. Surveys among researchers in the biomedical field indicate that **participation of researchers will be boosted by a further simplification of EU research funding procedures**.

The BioMed Alliance hopes that its views and recommendations will prove of value for the definition of future EU research and innovation (R&I) funding instruments and wishes to express its eagerness in taking part in the EC reflections. The direct involvement of active scientists and research-oriented societies through the BioMed Alliance will greatly benefit the development of successful European research policies and strategies.

² "Science, Technology and Competitiveness (ST&C) key figures report 2008/2009", http://ec.europa.eu/research/era/pdf/keyfigures-report2008-2009_en.pdf



RECOMMENDATIONS FOR A COMMON STRATEGIC FRAMEWORK FOR RESEARCH AND INNOVATION (R&I) FUNDING

WORKING TOGETHER TO DELIVER ON EUROPE 2020

1. Simpler and more transparent R&I landscape

Due to the high cost of application procedures and an average success rate of only 21.7% (17.6% for the Cooperation programme), applying to an FP project is currently considered a high risk investment.³ In order to support the scientific community to produce cutting-edge research, the EC should deploy easy-to-use, effective and flexible mechanisms to reduce the administrative burden of application procedures.

Suggestions from the BioMed Alliance include:

- > the preparation of clearer and more accessible guidance documents and consistency in the follow-up and management of programmes at the EC;
- > more legal certainty by refraining from applying a stricter definition of the rules for participation retroactively and by refraining from asking recipients to recalculate financial statements already approved by EC services;
- > more precise, consistent and transparent rules of procedure for audits;
- > two stage-application processes for all projects, without overlaps between the two stages;
- > a longer submission time, but a shorter time preceding the calls and a shorter time from evaluation to contract. Such an improvement would also address the current unofficial circulation of draft EC documents which does not give all potential applicants equal opportunities to succeed;
- > the simplification of accounting rules, with a specific focus on maternity leave as current rules do not necessarily encourage the employment of women;
- > the consideration of VAT as an eligible cost to simplify the calculation of costs;

³ Accompanying document to the "COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS On the progress made under the Seventh European Framework Programme for Research", European Commission, 2009, p.11



- > the consideration of the difference in personnel costs existing between Member States. Such difference is susceptible of engendering inequalities as countries where personnel costs are higher than average will be less inclined to participate in projects;
- > the acceptance of usual (national) accounting practices for the eligible costs;
- > the EC should address the issue of equipment funding. Currently, equipment funding is based exclusively on the pay-off amount (i.e. amortization from purchase to the date of project closure). This makes purchase of equipment possible only at the beginning of the project and on condition that another funding source is available to cover a significant part of its cost. This reduces the possibility of technological innovation under EU funding. Purchase of equipment during the project, motivated by unpredicted technical requirements or by breakdown, is also not possible under the current regulations. This is a significant limitation to project implementation and policymakers should thus consider complete coverage of justifiable equipment expenses more suitable;
- > abolishment of the legal requirement for an opinion by committees of Member State representatives on selection decisions on individual projects: decisions should be taken by experts.

2. Against fragmentation of research programmes

The EU research and innovation funding landscape is currently exceedingly fragmented. Research projects are addressed by too many different initiatives – FPs, Competitiveness and Innovation Framework Programme (CIP), European Institute of Innovation Technology (EIT), Cohesion policy. Additional complexity arises from the fact that, within the same funding instrument, EC administrative responsibility for a single research area may fall under different EC directorates and/or directorates general (DGs), and even EU Agencies.

This is the case for biomedical research, which falls under the remit of different directorates within DG RTD, but also of other DGs (SANCO and INFSO). This results in overlaps as well as gaps in the needs for support of funding.

The BioMed Alliance suggests addressing this apparent paradox by creating a dedicated administration for biomedical research, equivalent to a European Health Institute. Given that health represents a large part of the great societal challenges identified by the EU, it is imperative to make sure that resources are made available and used optimally including overcoming the fragmentation resulting from the complex procedure to obtain grant extensions for successful projects.



3. Setting of Priorities

In biomedical research, two major concepts drive priorities of scientists and of funding bodies: curiosity/opportunity for novel discoveries and societal needs. The free, explorative, approach will yield innovative insights and concepts, but the impact on health care may be remote in time. For prioritizing funding within this approach, excellence of applicants and projects are the only selection criteria. On the other hand, in biomedical research, challenges in health care call for focusing research in certain areas, and this with the expectation of more direct applicable result. In this more directed funding approach, excellence still remains the selection criterion, but applications are restricted to the defined areas. However, setting such priorities based on needs in health care itself poses important challenges. The BioMed Alliance is convinced that this is a cornerstone for the future FP, and would thus like to see the following elements taken into account:

- > Coherent priority setting: allocation of funding resources based on public health needs to be defined thanks to the analysis of:
 - comparable health data
 - burden of disease for EU society
 - cost of disease for EU society
- > Systematic consultation with stakeholders for definition of priorities, in particular with professional medical societies, clinicians, researchers and industry. In addition, the potential of the EU joint initiatives such as the Innovative Medicines Initiative should be further explored.
- > Funding of projects that examine priorities for research in important research and public health areas (roadmaps).

This implies more direct involvement of the biomedical community in the development of funding strategies and the process of priority setting.

4. The need for a comprehensive strategy for BioMedical research

A dedicated institute for health and biomedical research could be much closer to the field and have the capacity to identify the needs and opportunities for increasing knowledge, enhance innovation and deliver better health care. The full innovation cycle could be developed in a single dedicated strategy, with a specific research programme for biomedical research at EU level. This does not imply that one funding



instrument should cover the full cycle. In biomedical research in particular the cycle is long, typically spanning up to 10 years and different actors may take part in successive as well as iterative steps.

Such steps include:

- > developing ideas into novel concepts starting from clinical findings as well as basic research;
- > translating novel concepts into clinical practice;
- > taking findings to the market;
- > evaluating treatment strategies by monitoring outcomes.

These various stages should be interactive, but can not be bundled into a single project. As collaboration will be a key component in each approach, collaborative projects must remain the cornerstone of the programme. There is no predefined 'right size' in terms of number of partners for projects, so the composition and size of consortia should depend on the nature of the project.

The different actors are academia and industry, both SME and large companies. These actors should be partners of the policy makers in developing these strategies.

Part of the strategy should be to secure the necessary funding for the continued and enhanced support of translational research. This should span from project funding, to education and training of researchers and medical doctors, to implementation into clinical practice and evaluation.

5. Resources for R&I funding

In the specific field of health research, despite the impact that R&I in this sector may have on the wellbeing of EU citizens and notably in anticipation of major societal challenges, such as the ageing population, EU funding for health research remains rather low. EU funding for health research represents a mere 10% of the overall EU research funding budget (€6.1 billion out of €53.2 billion). To compare, in the US, the NIH invests on average 3.5 times more (\$31.2 billion = €21.5billion) than the EU (€6.1 billion) in health research.



In particular, noncommunicable diseases – a group of conditions that includes cardiovascular diseases, cancer, mental health problems, diabetes mellitus, chronic respiratory disease and musculoskeletal conditions⁴ – do not obtain the appropriate attention, even though:

- > They are the cause of 86% of deaths and 77% of the disease burden in the WHO European Region;⁵
- > They are largely preventable and are linked by common risk factors, underlying determinants and opportunities for intervention through research advancements and research-informed policies;
- > EU Member States have formally invited the EC to integrate chronic diseases as a priority in European research and action programmes.⁶

For comparison, CVD research alone was granted € 123 million for the first 4 years of FP7, while in the US the NIH dedicated €550 million (\$797 million) in 2010 only⁷. Similar discrepancies are present for the other major public health problems and non-communicable diseases.

To overcome such obstacles, the BioMed Alliance strongly requests credible funding level by increasing the overall research funding budget.

Even more importantly, the budget share for biomedical research funding should be dramatically increased. This can not be referred to the member states. While the EU has developed instruments to leverage on national funding and enhance cooperation, substantial investment at the European level remains essential for high performance and competitiveness in biomedical research.

Indeed, cross-boundary research is the key for successful and innovative biomedical research. Only the European research area can provide the necessary complementarities and critical mass for the comprehensive and multidisciplinary approach that is needed in biomedical sciences. Networking, knowledge exchange and a greater focus on translational research require EU support. For clinical research, the total of the European population must be considered when gathering data and designing new therapies and treatments. These essential features of biomedical research can only be addressed in a truly European research program.

⁴ <http://www.euro.who.int/en/what-we-do/health-topics/disease-prevention/what-are-noncommunicable-diseases>

⁵ <http://www.euro.who.int/en/what-we-do/health-topics/disease-prevention/what-are-noncommunicable-diseases>

⁶ Council conclusions « Innovative approaches for chronic diseases in public health and healthcare systems », 7 December 2010

⁷ www.nih.gov



A single vision and single budget decision will further enhance cohesion and chances for success. It will improve the capacity to attract private sector investment in order to complement national and EU funding for research.

6. Evaluating success requires a long term vision

The impact of biomedical research eventually is measured in terms of improved health for European citizens. Economic benefit comes from both the increased contributions of a healthy population and by the economy generated in health care itself. Short-term vision and demands for fast translation into economic output - such as new products on the market - do not take into account that success in biomedical research is a long-term investment.

For all projects, evaluation of success should be based on measures of the quality of the research that has been performed in addressing the initial goals. There must be strong incentives for risk-taking and the value of negative results must be recognized.

The EU should ensure sustainable and long-term investments in excellent research platforms for enhanced competitiveness/research infrastructures. It is unacceptable and, in fact, a dissipation of European research money that there is no real instrument in place to ensure extended funding of projects which have accomplished unique results and which need to be preserved and/or further developed into real success and exploitation. Sustainability of research networks and infrastructure needs to be made available in order to ensure consistency and preserve excellence.

TACKLING SOCIETAL CHALLENGES

The severe burden of an ageing society represents an obvious call for the discovery and deployment of innovative solutions, including medicinal products and medical treatments, which have the potential to provide high-quality and safe healthcare while increasing the efficiency and sustainability of care systems in the EU. The current economic climate naturally increases the financial pressures but research and budgets should not, and cannot be, under threat due to this as the societal challenges to be faced will reap benefits when investment is made in science. Biomedical research moreover specifically and directly addresses societal challenges, i.e. the health of European citizens. Bridging the gap between the health and research agenda should be encouraged, particular at EU level where DG SANCO and DG RTD need to collaborate better. At national level, health and research ministries must also work hand-in-hand to address the challenges Europe is facing.



In its research agenda, the EU traditionally has set priorities and has funded projects within predefined areas. To base these on societal challenges is appropriate and fitting, and the BioMed Alliance strongly supports further investment in health and biomedical research from this point of view. However, within the choices for biomedical research there must be a balance between top down and bottom up approaches. A program driven predominantly by identifying specific challenges and setting up funding can be hampered by the time lag in the process.

Suggestions to improve the current framework include:

- > setting a research program that is driven by societal challenges in a broad framework. Within that framework a balance must be found between program-based funding and free initiatives from the research actors. Indeed, discovery research, following up ideas and opportunities, may provide answers to yet unidentified challenges independently and timely. A record of excellence in past results and achievements should be the credentials and passport for funding investigator-driven programs. Setting up a correct balance between these top-down and bottom-up initiatives again calls for a much closer involvement of the research community, including academia and industry, in defining funding strategy and priorities.

In addition, science and research must be supported by society. Therefore it is suggested to:

- > make science attractive by using innovative communication and new media tools to gauge the interest of the public. This will allow for civil society backing to advance research for the benefit of all. Inspiring the next generation to become more involved in science and recognizing the importance of placing it on top of the political agenda will ensure a better future for all. Clear and straightforward communication to promote science is vital to ensure it plays a central role in society and in order to encourage the attractiveness of research careers in Europe.
- > better relations between science and media should be encouraged - media-savvy scientists and researchers should be promoted to bridge the gap between science and journalism.

STRENGTHENING COMPETITIVENESS

There is a still unmet need for interdisciplinary and multidisciplinary collaborative research. In biomedicine in Europe, there is a lack of interdisciplinary centres of excellence for translational research. Multidisciplinary refers to scientific expertise across fields within life sciences but even more so, to interaction of life sciences with research in science and technology. This process is already initiated within



academia and actively encouraged for instance in programmes on eHealth and medical technology. Again, this calls for integration and coordination of funding strategies within the EU.

Especially in biomedical research, new partnerships are being built between academia, biotechnology SMEs and industry. They strengthen translation of research, innovation and economic benefits. Yet the process is not always easy and requires a change of mentality. SMEs should be supported at EU level for their participation in developing translational research. In order to harmonize European, national and regional schemes it is important to set up a data bank of SMEs with their track records, which, in turn, can be utilized by researchers in the preparation of their grant applications.

Further elaboration of IP rules is a point of concern. Sufficient freedom must be retained for all partners. Medical technological developments require close cooperation of academic researchers and clinicians with industry. The pharmaceutical industry as well performs exploratory research that precedes more targeted drug development, in collaboration with academia and SMEs. Yet such collaborations must respect the independence of the different actors and ensure a balanced benefit.

Rules and regulations hampering research need to be addressed. Of specific concern are the regulations around clinical trials that should balance protection of patients and physicians, but also avoid excessive costs which may discourage and even prevent necessary research activities.

In biomedical research, partnership with NIH will also increase competitiveness in the global science activity. Collaborations in clinical and basic research have been successful before but currently lack a strong framework.

STRENGTHENING EUROPE'S SCIENCE BASE AND THE EUROPEAN RESEARCH AREA

Excellence remains the foundation of European research. The ERC approach provides examples for pure excellence-based and bottom-up research. As argued above, in biomedical research, a balance must be defined in a comprehensive strategy between this approach and more topic-defined project funding. Typically for biomedical research there is a need for collaborative, European-wide programs. The recent discussion on an ERC plus program for a small group of scientists, rather than a single investigator, is a first step in providing access to this bottom-up channel with a research team. The BioMed Alliance welcomes more possibilities for collaborative research in an ERC-type funding of research driven by excellence, which should be recognized in translational research as well as in hypothesis-based, curiosity-driven research.

ALLIANCE FOR BIOMEDICAL RESEARCH IN EUROPE



To have excellence in research requires the training of excellent researchers. The Alliance is particularly concerned about the future of young researchers. Europe needs a strong new generation of medical researchers, who are trained to tackle the different aspects from basic research to translational and clinical research, and who can support the needed chain of innovation. Critical in this training program is cross-disciplinary and international mobility. The BioMed Alliance strongly supports further expanding the Marie Curie Actions and asks for special attention to the needs of medical doctors in training.

Many opportunities are wasted due to obstacles in the movement of ideas and challenges. Addressing professional mobility in Europe as well as knowledge exchange between biomedical research institutions and bodies should be a key objective for the EC and the future EU research framework and agenda.

Related to mobility of researchers and knowledge, Europe needs to also look further afield: collaboration with non-EU countries must also be considered. International cooperation with research groups outside the EU is suboptimal: building educational opportunities and exchange amongst our young researchers is an important step to address this issue.