Strengthening biomedical research for the benefit of European citizens

Background

The need to address current gaps in the support of biomedical research in Europe has to be a key priority for the next EU Framework Programme for Research and Innovation (FP9).

The Alliance for Biomedical Research in Europe (BioMed Alliance) and the Federation of European Academies of Medicine (FEAM) have united to respond to this challenge.

Europe is facing a number of major healthcare challenges, particularly as a result of an ageing population more than 100 million European citizens are suffering from chronic disease. For instance the prevalence of chronic disease (including cancer and mental disorders) and associated disabilities, affects more than 14% of Europe's working population.[1] It has been estimated that more than 7% of GDP may be lost in some European countries through the impact of non-communicable diseases alone, which does not take into account the care provided by family members. In 2013 the WHO report on priority medicines was updated to support the planning of the Horizon 2020 research programme. Four years on, the findings of that report [2] are still relevant, in its identification of Europe's unmet medical needs.

We call upon European Institutions and EU Member States to take advantage of this timely opportunity to strengthen the environment for clinical and health research in Europe, in view of the upcoming Framework Programme.

1 http://www.alliancechronicdiseases.org/fileadmin/user_upload/policy_papers/ECDA_White_Paper_on_Chronic_Disease.pdf

2 http://www.who.int/medicines/areas/priority_medicines/en/

Overview

In order to overcome the current fragmentation in the funding of clinical and health research across the European Union, the BioMed Alliance and FEAM recommend a strong focus on:

1. **more support for collaborative multidisciplinary translational biomedical research**
2. **continuity in funding for successful networks established in previous Framework programmes**
3. **recognising the importance of precision medicine-based, patient-centred solutions in designing clinical trials**
4. **special training programmes for the next generation of research-oriented clinicians and clinically-oriented researchers**
5. **the creation of a European Council for Health Research, that will support biomedical and clinical research in Europe**

BioMed Alliance - the Alliance for Biomedical Research in Europe (www.biomedeurope.org)

The Alliance for Biomedical Research in Europe (BioMed Alliance) is a non-profit organization representing 26 leading European research and medical societies uniting more than 400,000 researchers and health professionals. The BioMed Alliance is committed to promoting excellence in European biomedical research and innovation with the goal of improving the health and well-being of all European citizens.

FEAM- the Federation of European Academies of Medicine (www.feam.eu.com)

FEAM's mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide them with a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

1) Need for more support for collaborative multidisciplinary translational biomedical research

To ensure that European citizens and patients can gain maximum benefit from recent developments in biomedical research we propose that the FP9 focuses more strongly the support of multidisciplinary translational research.

There is a need for new approaches to be taken to help overcome the existing bottlenecks in the EU in the translation of basic research into real clinical benefit. Funding for clinical and health-related research to address these unmet medical needs is fragmented within the European Union, across Member States and in the current research programmes managed by the European Commission (via DG RTD, DG SANTE and DG Connect).

Further, possibilities for the establishment of interdisciplinary collaborative networks of various sizes as in previous Framework programmes (bottom-up topics) should be implemented to support novel research and/or explore newly emerging research topics.

2) Continuity in funding for successful networks established in previous Framework programmes

The existing model of collaborative network projects being funded within Framework Programmes has made important contributions to science. However, its limitations have 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. One should implement instruments within FP9 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. With this one avoids a major loss of knowledge and maintains, in its transfer, potential opportunities for innovation and for its implementation into the health system.

3) Recognising the importance of precision medicine–based, patient-centred solutions in designing clinical trials

Many advances are taking place in the development of innovative and novel clinical trial designs. The drive towards precision medicine is leading to new patient-focused clinical outcome measures, novel approaches to clinical trial design (particularly in the assessment of benefit/risk in stratified patient populations) and the establishment of new systems and infrastructures to enable the collection of healthcare data.

In view of the increasingly multidisciplinary character of clinical research and the rapid advance in the development of innovative medicines, devices and diagnostics, there is a growing need for independent academic investigator-driven "not-for-profit" clinical studies.

Whilst the role of commercially-focused late phase clinical studies is acknowledged , there is a crucial need for obtaining follow-up data from independent longer-term studies. Adequate infrastructure funding for groups carrying out such studies is essential.

Many of the emerging technologies and new agents are currently being developed in silos and cannot be sufficiently benchmarked to understand the biology. More needs to be done to support collaborative, cross and inter-disciplinary approaches to clinical and health research across the EU.

The move towards a greater implementation of novel clinical trial design will also require the increased involvement of patients and clinicians operating in a real-life setting, e.g. through the use of patient registry-based research. This would improve the prognosis and the quick identification of effective treatments and successful drugs, and enable a better understanding of the triggers of disease.

There is a growing need for more methodologically-sound comparative effectiveness solutions to support optimal implementation of such new interventions. At the same time, recognising the importance of precisionmedicine- based, patient-centred solutions, more must be done within the EU to help ensure that genetically-characterised patients are given access to the best available treatments, either in a clinical research environment or in subsequent routine clinical care. It is imperative that we reach the critical mass required both for research efficiency and the establishment of patient cohorts and for making optimal use of novel 'big data' approaches.

At present, a lack of sufficient funding and focus prevents the EU from taking full advantage of new healthcare (related) cost effective technologies and interventions under development, and from ensuring compliance with regulatory guidelines. A better integration of direct patient input would provide the necessary translational impact in the real-world setting.

4) Special training programmes for the next generation of research-oriented clinicians and clinically-oriented researchers

There is an urgent need for a better integration of complex processes, from basic research to clinical practice and back again. It is important that clinical researchers are knowledgeable in basic research while basic researchers need to appreciate clinical challenges.

This will require a major investment in training the next generation of research-oriented clinicians and clinically-oriented researchers, with a greater degree of coordination and harmonization of training programmes across Europe to do justice to the increasingly international nature of research and clinical practice. The current lack of investment in training programmes is a major bottleneck as there is a divergence of training requirements across the continent.

In Horizon 2020 a translational, interactive and circular process of science is not encouraged, with basic science (funded through the European Research Council - ERC) divorced from the societal challenges and health research pillar. There is a real opportunity for this fragmentation to be addressed under FP9.

Cross-border training programmes and bottom-up initiatives developed by stakeholders will help basic researchers and clinical scientists understand the innovation cycle and business

principles. These programmes and initiatives will definitely contribute to enhancing scientific careers and making Europe an attractive centre for creative thinking in biomedical research.

5) The creation of a European Council for Health that will support biomedical and clinical research in Europe

We acknowledge and endorse the advice put forward by the EC's Scientific Panel for Health (SPH) in its May 2016 vision paper "Better Research for Better Health" 3 calling for the EU and Member States to further investigate the concept of a science-led European Council for Health Research.

The European Council for Health Research [4] can act as catalyst for reform, as proper funding mechanism and as a scientific advice platform. Its goals would be to implement long-term, sustainable research programmes and to exploit in full the benefits of coordination and cooperation across Europe in the hope of avoiding fragmentation.

As stated in the concept paper developed by the BioMed Alliance[5], the European Council for Health Research should focus on accelerating excellent biomedical research in Europe and promote Europe as a hub for health research innovation.

The European Council for Health Research should promote deeper and longer-term collaborative initiatives that address the current gaps in the 'innovation cycle' and strengthen cross-fertilisation and collaboration across all relevant disciplines. It should provide strategic advice on the steering of European health research to policymakers, and address the partially fragmented responsibilities for science and research within the EU governing bodies.

In its setting-up, attention must be given to the establishment of an appropriate and effective evalutation system.

The European Council for Health Research should incorporate all relevant stakeholders, not only biomedical scientists but also patient representatives, Health Technology Assessment bodies and leading investigators, in order to boost creativity and innovation in this sector and promote a healthier Europe.

3 https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/SPH_VisionPaper-02062016.pdf

4 The concept was introduced and discussed during the Scientific Panel for Health Forum 'Health Research in a Connected and Participative Society'

5 http://www.biomedeurope.org/images/pdf/developments/Concept_Paper_EuCHR_Biomed_Alliance_FINAL.PDF