

Recommendations of the Alliance for Biomedical Research in Europe (BioMed Alliance)

for the EU's ninth Framework Programme for Research and Innovation (FP9)

The European Union's Framework Programmes play a significant role in fostering a coherent, internationally competitive European research landscape. The added value and the potential of EU funding are most evident in health research, which is of enormous significance for the well-being of Europe's population and for the economy. However, health research is often too complex to be effectively supported and managed at the national level. The BioMed Alliance therefore calls for more robust EU support for health research, through increased funding under FP9 and the development of a long-term vision and strategy involving the creation of a European Council for Health Research.

1. Increased funding for health research under FP9

Only 10.5% of Horizon 2020's initial budget of &80 billion was earmarked for biomedical and healthrelated research.¹ This amounts to an investment of approximately &2-3 per EU resident per annum. The predecessors of Horizon 2020 did not perform much better, with less than 15% of their budgets dedicated to medical research.²

The meagre funding of health research in Europe does not reflect the high return on investment associated with biomedical research. Benefits come in many dimensions.³

- Biomedical research has «advanced medical diagnostics, therapeutics and technology in many fields, with major impact on both life expectancy, and healthy life years»⁴.
- A healthier, longer-living population, in itself, generates an important economic benefit.
- Innovation in biomedical and health research gives rise to new companies and employment. Increases in public expenditure on biomedical and health research significantly boost private sector Research & Development investments.⁵
- Over 50% of the cumulated research output in Europe, measured by the number of journal papers and citations, can be traced back to biomedical and clinical research.⁶

¹ Bouillon et al. 2015. Public investment in biomedical research in Europe. *Lancet* 386: 1335. ² Ibidem.

³ European Medical Research Councils. Why we need a new strategy for health research in Europe.

Science/Business. 22 November 2012 - link

⁴ Scientific Panel for Health. 2016. Better research for better health. A vision for health and biomedical research from the Scientific Panel for Health. P8. - <u>link</u>

⁵ Sussex et al. 2016. Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom. *BMC Medicine* 14(32): 1-23.



The Lamy report⁷ suggests the EU should be committed to maximizing the return on investment of future Research & Innovation programmes. It is imperative that the budget for health research under FP9 is increased. This has also been advocated by the European Parliament's research committee⁸.

Another argument for increasing the health research budget is provided by the most recent Eurobarometer survey⁹, which suggests that 70% of Europeans want the EU to do more for health. By providing an ambitious budget for health research, FP9 would clearly demonstrate its intention of being responsive to citizens' needs and wishes.

We also strongly support the Lamy report's recommendation to double the overall budget of the next Framework Programme.¹⁰ We advocate dedicating 25-30% of the FP9 budget to biomedical and health-related research.¹¹

The BioMed Alliance considers increased, structural and balanced EU funding for basic, clinical and translational research a must. These three are intertwined and equally essential to achieving the full potential of health research in Europe.

1a. Basic research

An increase in the budget for biomedical research under FP9 should be coupled with a much stronger commitment towards basic research. The latter should represent a significant area of investment, for several reasons. First, basic research is the ultimate source of innovation. Truly innovative ideas are more likely to originate from blue-sky, frontier research than from pre-determined approaches. Second, there is little incentive within the private sector to invest in blue-sky research as the latter is considered high-risk without immediate economic impact, despite its significant long-term potential. Thus, it is imperative for the public sector to fill this funding gap created by the private sector.¹²

1b. Clinical research

High-quality, industry-independent, academic clinical research is key in the pursuit of outcomes that provide clear added short-term value for patients. At a time of molecular breakthroughs, the importance of precision medicine-based, patient-centred solutions and the involvement of health professionals should be reflected in the design of clinical trials.

⁶ See footnote 3.

⁷ Independent High-Level Group. 2017. LAB-FAB-APP. Investing in the European future we want. Report of the independent high-level group on maximising the impact of EU Research & Innovation Programmes. - <u>link</u>

⁸ Opinion of the Committee on Industry, Research and Energy for the Committee on Budgets

on the next MFF: Preparing Parliament's position on the MFF post-2020 (2017/2052(INI)). 15 January 2018. - link

⁹ Eurobarometer of the European Parliament 87.1 - <u>link</u>

¹⁰ See footnote 7.

¹¹ See footnote 3.

¹² EU-LIFE. 2017. Towards better research value in Europe. Translating knowledge to innovation. - <u>link</u>



EU funding is particularly needed for clinical research that is unlikely to get support from industry: research that is patient- and disease-centred rather than drug-oriented, with emphasis on treatment modalities such as surgery and radiotherapy or focusing on high-need areas such as risk factors (preventive medicine) and rare diseases.

Clinical research at present tends to focus on the minimum requirements for market authorization – with regulators, in accordance with their mandate, assessing efficacy rather than effectiveness¹³. The emphasis should shift to outcomes research, health economic assessment and real added value for patients. The rising costs of healthcare, often without clear added value to society, point towards an urgent need for academically assessing the value of innovative treatments.

1c. Collaborative multidisciplinary translational research

Support for translational research helps ensure that European patients and society at large gain maximum benefit from the latest innovations in health research. Considering the increasingly interactive, multidisciplinary and circular nature of 21st century science, there is an urgent need for a better integration of complex processes, from basic research to clinical practice and back again. This is not sufficiently acknowledged or encouraged under Horizon 2020, with its fragmented funding structure.¹⁴

There is a strong imperative to invest in special training programmes for the next generation of research-oriented clinicians and clinically-oriented researchers under FP9. This is required due to the ongoing internationalisation of health research and the divergence in training requirements across the EU.

The BioMed Alliance encourages EU authorities to incentivise translational components in FP9 applications, by rewarding the inclusion of a concrete and realistic plan for the translational followup to each fundamental or clinical research project. This would help strengthen a translational mindset in research planning and decision making.

Continued funding of multidisciplinary collaborations in translational research – whether initiated bottom-up or top-down – is needed to foster knowledge transfer, entrepreneurship and partnerships between academia and industry. As the prime source for funding of successful collaborative multidisciplinary translational research¹⁵, EU support is indispensable.

¹³ Efficacy vs effectiveness: performance of a medical intervention in a (controlled/idealised) clinical trial setting vs in the real world.

¹⁴ Joint position paper FEAM – BioMed Alliance. 2017. Strengthening biomedical research for the benefit of European citizens - <u>link</u>

¹⁵ Scientific Panel for Health. The value of collaborative research in Europe, presentation by Karin Sipido at the European Parliament, 29 November 2016 - <u>link</u>



2. The creation of a European Council for Health Research, that will support biomedical and clinical research in Europe

Biomedical research in Europe requires investment and prioritisation in order to make substantial leaps in advancing the health of European citizens in the coming decades and transform health systems. This, in turn, requires a long-term vision and strategic approach. While successful research in this area already takes place in Europe, it is often scattered and operates in silos. The EU's Research Framework Programmes have been a step in the right direction and helped overcome this separation through implementing collaborative EU-funded research. However, the above-mentioned lack of prioritisation for basic, translational and clinical research and appropriate funding shows that there is still a need for long-term strategic planning to strengthen biomedical and clinical research in Europe.

The BioMed Alliance therefore calls on the European Commission to create a European Council for Health Research. Other key stakeholders and expert groups¹⁶ ¹⁷have endorsed this proposal. In concrete terms, the council's mandate should be the development and funding of a science-led vision and long-term strategy for health research, which involves citizens, patients and health professionals.

A bottom-up scientific council made up of leading biomedical scientists should develop this longterm strategy for biomedical research and innovation, in close interaction with policy makers and other relevant sectors of research and industry. The European Council for Health Research would be best-placed to ensure a balanced approach and funding for basic, translational and clinical research.

It should provide a sound mechanism for implementing pan-European research projects, using funds from FP9, EU structural funds, national funding instruments and industry support. Centralising and streamlining functions spread out under Horizon 2020 should significantly simplify existing procedures and thus make European funding mechanisms in this area much more attractive and acceptable to the scientific community. In addition, it would support the development of future-proof regulation for biomedical research.

The European Council for Health Research has the potential to foster European health research while creating societal benefits and long-term positive economic impact, through the job-creating potential of health research and increases in healthy life years.

It would provide continuity in funding long-term projects and setting ambitious missions, such as finding cures for the most burdensome diseases affecting European citizens. This would ensure fruitful research collaborations that can maximize their potential and translate results into health systems. In addition, it would increase the use of multidisciplinary research between disease areas where commonalities exist and thereby decrease duplication and isolated research.

¹⁶ Scientific Panel for Health. 2016. Better Research for Better Health. A vision for health and biomedical research from the Scientific Panel for Health - <u>link</u>

¹⁷ See footnote 11



Furthermore, its creation would demonstrate commitment to biomedical research in Europe and promote the EU as a global hub for health research innovation, attracting today's top researchers as well as the next generation of research talents.

The full concept paper for the European Council for Health Research can be found under the following <u>link</u>.

Supporting recommendations: design, continuity and regulatory context

To ensure that the next Framework Programme builds on the successes of Horizon 2020 and can be even more effective and impactful, the BioMed Alliance considers the following aspects of utmost importance:

- Design & implementation of FP9 (lessons from H2020): Improving the low success rate of applications through balance of targeted and broader calls, as well as a rigorous selection at 1st stage and improved feedback. Time spent by researchers on grant applications with minimal chances of success is time not spent on research and innovation.¹⁸
- **Building on successes:** Continuity in funding for successful networks established in previous Framework programmes is crucial.¹⁹
- **Regulation**: Streamlining, simplifying and harmonising the regulatory framework is essential. With directives and regulations on clinical trials, data protection, in-vitro diagnostics, biomarkers, medical devices, advanced therapies etc., fragmentation of the regulatory framework is considered a major bottleneck by the biomedical research community.²⁰

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 28 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.

¹⁸. BioMed Alliance Board of Directors Ulrich Jaeger. Learn from Horizon 2020 to address unmet medical need in Europe. *Science/Business*. 4 January 2018 - <u>link</u>

¹⁹ See footnote 12.

²⁰ Negrouk, A. Lacombe, D., Meunier, F. Journal of Cancer Policy (2017) - <u>link</u>