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### General comments on Horizon Europe proposal

- The EU is the prime source for funding of successful collaborative cross border multidisciplinary translational research. Continued transnational funding is needed to foster knowledge transfer, entrepreneurship and partnerships between academia and industry, and to maintain Europe competitiveness.
- The ERC, since its creation, has demonstrated outstanding results, and contributed to the visibility of EU research. It has established a gold standard for excellence within and beyond the scientific community.
- Health research is an area with immediate societal relevance and visibility to the European population.
- Biomedical research has increased its competitive visibility over the last decades as obvious from the increased attendance and quality of the European biomedical conferences and increased impact of the European biomedical journals.
- The proposed budgets do not make full use of the respective potentials and requirements. Horizon Europe includes € 7.7 billion for health research and the ERC has approximately the same budget share it had in Horizon 2020. We strongly believe that the proposed budget is insufficient. We advocate increasing the total Horizon Europe budget to at least €120-125 billion and dedicating 25-30% of the Horizon Europe budget to biomedical and health-related research<sup>1</sup>.

### Strategies for the Horizon Europe proposal

Irrespective of the overall budget, structural elements of European biomedical research funding should be developed with a priority over funding of individual thematic areas and topics. Sustainable research structures will foster European competitiveness (as evident from the ERC example), will increase enduring transnational collaboration and establish a European perspective. They are needed to tackle relevant biomedical needs on a basis of value oriented research. It is important in these structural initiatives that the research and innovation driven components are closely coupled with responses to societal needs, represented by patient groups. Such structural components are suggested by the European BioMed Alliance.

### **European Council for Health Research**

will provide a science-led vision and long-term strategy for health research, which involves citizens, patients, health professionals and researchers.

Europe must build on its existing achievements by a bold and comprehensive policy for health research. A sound mechanism for implementing pan-European research projects, using funds from Horizon Europe and EU structural funds complementing national funding instruments and industry support is a must. 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, other

<sup>&</sup>lt;sup>1</sup><u>https://www.biomedeurope.org/images/eu-policy/Recommendations of the BioMed Alliance for the FP9.pdf</u>



relevant sectors of research and industry and, relevantly, patient representatives. The European Council for Health Research would be best-placed to ensure a sustainable approach and balanced funding for basic, translational and clinical research. It would spark a European spirit in the scientific community and support the development of future-proof regulation for biomedical research.

### ✓ Added value:

- <u>For the health research community</u>: provide **sustainability** in funding strategies and mechanisms allowing for long-term projects and ambitious missions, ensure fruitful transnational research collaborations that **maximize the European potential** and translate results into health systems, increase the use of multidisciplinary research between disease areas where commonalities exist and thereby decrease duplication and isolated research.

- <u>For the political leadership in Europe</u>: if health research is a top priority, then provide a sound mechanism for health research, increase **visibility of Horizon Europe** and its **benefit for EU citizens**, address the partially fragmented responsibilities for science and research within the EU governing bodies, streamline the existing funding mechanisms.

- *For patients and society*: foster *citizens' participation* and engagement in bottom-up decision making process, provide *value oriented health research,* better health solutions and reduce inequalities

A concept for the European Council for health Research<sup>2</sup> has been developed by the <u>Scientific Panel for</u> <u>Health</u> and has been endorsed by the biomedical research community and the European BioMed Alliance.

### ✓ Actions to be implemented under Horizon Europe:

The implementation of such a body will require a **dedicated road map** based on cooperation between the EC and member states, and should involve the society at large from the beginning. Given the breadth of the proposal, transition scenarios must be considered. These could build on existing multilateral cooperation or on initiatives in specific domains that may at the basis of missions. Another alternative is to build on the SAPEA advice mechanisms, taking it to a policy building level for health research.

The Scientific Panel for Health ends its life with Horizon 2020. As an expert panel within the EC, the SPH was able to build a stakeholders community that engaged in workshops and conferences, resulting in briefs and recommendations, such as the current proposal. However, towards the future health research needs a stronger position that links between different DGs (current Health Panel in DG SANTE) and other mechanisms within the EC (SAPEA) and outside the EC. This could be part of a transition scenario towards a European Council for Health Research or to a future European Health Research Institute. The transition scenarios will be needed as a blueprint to steer coordination and cooperation and to identify possible missions to tackle societal needs.

<sup>&</sup>lt;sup>2</sup> https://www.biomedeurope.org/images/eu-policy/Building\_the\_future\_of\_health\_research\_SPH\_22052018\_final.pdf



## The European Reference Networks (ERNs)

is a EU successful project with a clear and direct benefit for EU citizens, potential for high European visibility and with high acceptance in the scientific community albeit with insecure and insufficient funding.

ERNs have great potential for diagnosis, treatment and for health research, and are a crucial example for areas, which can only be addressed by European funding. They are cross-border networks of healthcare providers seen as crucial for bringing together the scarce and scattered expertise needed to diagnose and treat patients with rare, low-prevalence and complex diseases. By building patient registries, collecting clinical data and identifying gaps in education and research, the ERNs could provide a significant boost to both fundamental and clinical research into rare diseases and beyond.

- ✓ Added value:
- For the health research community: *improve diagnosis, treatment, education and research in the field of rare and complex disease.*
- For the political leadership in Europe: example for the need for EU funding which adds value for EU citizens and promotes the value of cross border health research, diagnosis and treatment in Europe.
- For patients: increased *access across Europe* to advanced diagnosis and treatment

### ✓ Actions to be implemented under Horizon Europe :

- Increased, sustained and long-term funding for the ERNs.

For the ERNs to achieve their goals – both the primary goal of improving patient access to diagnosis and treatment across Europe, as well as the complementary research-supporting and educational objectives – more and sustained funding is essential.

Since the added value of ERNs is in their cross-border nature, EU funding must be prioritised over Member State funding. Relying on Member State contributions seems overly optimistic, causes uncertainty and risks increasing the concentration of expertise in certain centres and countries rather than spreading it more evenly across Europe. The EU should grasp the chance to develop a very promising initiative into a visible success.

- Ensure the quality, continuity and coherence of the ERNs.

The ERNs are a good example of successful EU-funded initiatives that would benefit from the establishment of a scientific council which can guide implementation, prioritize funding allocation and provide strategic direction, coherence and long-term planning. By ensuring the continuity and quality of projects with a clear and direct benefit for EU citizens, such as the ERNs, a European Council for Health Research as described above could be instrumental in getting more value for EU money.



# Pan-European infrastructure to support the use of patient data for health research.

Moving forward from drug-centred to patient-centred basic and clinical research

The drive towards precision medicine is leading to new patient-focused clinical outcome measures, novel approaches to clinical trial design and the establishment of new systems and infrastructures to enable the collection of healthcare data. The gap that currently exists between market approval and real-life clinical practice requires a new infrastructure for applied clinical research. There is an absolute need to foster an integrated pan-European infrastructure to support the use of patient data for health research. The existence of such infrastructure would allow not only optimal selection of patients in clinical trials, but also enable long-term follow-up of all patients as well as benchmarking of clinical research in real life with no loss to follow-up.

### ✓ Added value:

- For the health research community: enface *collaborative, cross and inter-disciplinary approaches* to clinical and health research across the EU

- For patients: **benefit from the latest scientific discoveries**, access to the highest level of clinical evidence and involvement in trial design and the choice of primary outcomes

- For the political leadership in Europe: quick *identification of effective treatments and successful drugs*, better control of the reimbursement systems, promote the practice of "intelligent" and sustainable health care.

### ✓ Actions to be implemented under Horizon Europe:

- Include academic clinical research in the "Areas of intervention" proposed for the Health Cluster (Annexes, pag.3)
- Building a European-wide infrastructure that allows patient identification and affordable long-term follow up
- A European Council for Health Research would be a logic mechanism to implement and coordinate such a European-wide infrastructure