



Summary on Horizon 2020 & Medical Imaging

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Introduction

Last calls from FP7 are launched and the European research and innovation community has been contributing for the last 2 years to the preparation of the programme HORIZON 2020. At the summit of the heads of states or government held on Nov. 22, no agreement could be reached on the 2014-2020 EU budget. However, disproportionate cuts for research in the new proposal which was discussed at the summit are disturbing: almost 6% cuts on the total EU budget compared to the Commission's proposal, but 12% cuts on the research, innovation and education budget.

At its Nov 28/29 Meeting, the Industry, Research and Energy Committee of the European Parliament adopted its negotiating mandate on the Horizon 2020 Package asking for an increase of the budget for Horizon 2020 from €80bn to €100 bn. "This programme is an opportunity for Europe to invest in its future and to help us get out of the crisis ", said the industry committee chair, Amalia Sartori (EPP, IT), warning against possible budget cuts in research and innovation.

The ESR would like to call upon the research community to take a moment to sign the petition and help secure the full Horizon 2020 research budget. Here is the link for the petition to the European Union <http://www.no-cuts-on-research.eu>

It is also time to share ESR's view regarding the future of EU scientific research towards maintaining and promoting "excellency" in research, developing "competitive industries" and, even most importantly, towards building a "better society" as the three pillars of Horizon 2020 sum up its strategy.

Therefore, as member of both medical and scientific community, we would like to welcome such initiatives but also express our opinion towards where should we focus our efforts and how these programs should help achieve these objectives towards better economic growth and most importantly for better health of European citizens.

Medical Imaging & Horizon 2020

Medical Imaging is crucial not only as a final tool to improve diagnosis but should also be seen as an intermediate means that can provide a large set of information essential for developing early prediction, personalised medicine, quantitative biomarkers and cellular-molecular imaging.

Investing in and developing medical imaging can have tremendous impact for patients in the future and transform medicine towards a tailored oriented approach for the benefit of the patient as well as reducing the cost for National Health Systems.

To achieve this, clinicians, basic researchers and engineers should work closer together. This can be favoured if we have programmes promoting crosscutting and multidisciplinary themes.

Beyond the reinforcement of cooperation between the medical and academic world, SMEs also form an important element in the innovation chain so that gaps are narrowed between public and private sector in a way it benefits to all.

Basic research serves industry by providing them with the elementary and most important part of added value knowledge while industries provide the financial means.

However, for ambitious projects, financial risk is high and this is where the European Union through its research and innovation programme can intervene.

Horizon 2020 with its pillars seems to respond to these needs by strengthening already successful programs and by introducing new elements to address challenges for the next seven years.

The first pillar focuses on Excellency (i.e. ERC), Technologies (FET), Research infrastructures (RI), and investing in the human factor (Marie Curie). All of them are elements on which medical imaging relies.

The Second pillar "Competitive Industries" can also fill the weak point that the public sector cannot provide and also help our economy to develop within the EU and try to avoid brain drain outside the EU.

The third pillar towards a "Better Society" is at the heart of our interest as after all the main concern is to improve the life of our citizens by providing them with new tools to prevent disease and to allow better evaluation of early treatment effects.

Why *optimising biomarkers* is important to address societal challenges in Europe?

Ageing population and what it implies in terms of health problems is a major concern for Europe today. Research towards biomarkers leading to surrogates for early diagnosis and therapy prediction would be crucial for reducing morbidity and preventing undesirable effects in an ageing population, as well as reducing assistance cost.

Health research in particular in the area of biomarkers has proved the last few years to be very promising towards fighting neurodegenerative diseases, cardiovascular diseases and early prediction of cancers just to mention few of them.

To go a step further, one of the objectives would be to focus on finding biomarkers and probes that are *sensitive enough* to diagnose and follow up the disease and *strong enough* to be used in clinical trials.

This type of research can only be done if there are good interactions and cooperation between different actors in the field that comprise both public and private sector. In this context, we encourage initiatives such as the Joint Technology Initiative (JTI)¹ within the wider Innovative Medicines Initiative (IMI). PPP (Public and Private Partnerships) with medical device manufacturers can also lead to the creation of research platforms where state-of-the-art research can reach medical practice more effectively. New biomarker-based analysis involves a feasible business model that can be implemented on top of existing healthcare budgets without a deep impact on the routine tests made to patients.

We hope that the next IMI topic on "Developing an aetiological based taxonomy of human disease"² will be fully taken into account.

Imaging has a very important part in the establishment of the relationship between molecular and cellular pathogenesis, disease classification and grading, as well as with the simulation of physiology, like in the Virtual Physiological Human initiative.

Medical technologies: the case of *medical devices*

The last few months have witnessed an increased interest in medical devices as the proposal for the new Medical Device Regulation shows and which is currently being discussed at the European Parliament and Council.

As EAMBES (European Alliance of Medical and Biological Engineering and Science) highlights, *"the new Medical Device legislation will directly affect research with medical devices. The efforts required to conduct clinical research on medical device technology and introduce results from biomedical research in medical product for patient care are expected to significantly increase once the new Medical Device legislation is adopted by the European Parliament and the Council of Ministers"*.³

We will pay close attention to the coming discussions early 2013 regarding this new legislation.

Besides that, we particularly approve what CONNECT-EU Medical Technologies Group has presented in their *"Strategic R&D lines for the Catalan sector of Medical Technologies"*. Their main areas of interest cover Medical Devices & Implants, Computational Medicine and e-Health.

Although our high concern is in medical devices covering research lines in Image Diagnosis, Image Guided Therapy, Quantitative Imaging Biomarkers and Image Devices, we also are attentive to the two other areas.

As CONNECT EU explains *"The priorities of Horizon 2020 related to Health will be focused on addressing the needs of the health cycle and value chain. The idea is to help to understand the interdependences that exist between the phases of the disease that are provided by*

¹ http://ec.europa.eu/research/horizon2020/index_en.cfm?lg=en&pg=faq&sub=details&idfaq=42185

² See pdf in attachment on "IMI indicative Call topic"

³ <http://www.eambes.org/news/medical-device-regulation-now-published>

different healthcare professionals in order to show better cost effectiveness in the access and the quality of the assistance”.

This aspect goes in the same direction of what we believe and defend through the developing of Image-Based Research Strategies. The active participation of the medical device sector will even further establish its position as a leading industry sector in Europe as most important companies are based in Europe.

Personalised Medicine: Develop P4

Personalised Medicine based on the P4 (personal, predictive, preventive and participatory), still faces reluctance from national healthcare systems and patients.

Personal Medicine requires great efforts from healthcare systems to adapt from a one-fit-to-all approach to an individual one, while patients need to be reassured that the access to their data is restricted to authorised people and treated in a secure way.

During the first EuroBioForum meeting that took place on 18th April 2012 in Brussels, Dr. Ruxandra Draghia-Akli, Director for Health Research, DG for Research and Innovation at the European Commission highlighted the importance and potential of Personalised Medicine: *“The time is now for this rapidly emerging area, which will have a large impact on both the economy and the patient.”* Draghia drew attention to Vision for Europe 2020 and the next framework programme Horizon 2020, in which Personalised Medicine has an important place. According to her, these initiatives have the potential to bring solutions to a variety of societal issues in Europe, including demographic developments”.

On the scientific level, Draghia added: *“one of the main challenges is, for instance, to link molecular data to the discovery of new biomarkers, to clinical practices. Clinical trials need to be adapted so that smaller, stratified populations are sufficient for the introduction of new medicines, a must for Personalised Medicine”.*

The conclusions of the EuroBioForum addressed two main points that seem crucial to go further in Personalised Medicine: raise awareness among the public and lead small-scale pilot projects to demonstrate the advantage of it.

It would be good to directly mention the importance of developing non-invasive imaging methods, intelligent contrast agents, molecular imaging probes and theranostics. Industry is currently not pushing this field sufficiently and EU funding will be essential to move new imaging tools to the clinics.

In brief, these are all positive signs that Personalised Medicine (P4) is at the heart of priorities and will be dealt with in the future framework programme. Quantitative and integral imaging has a quite important role in this proactive and health-oriented initiative.

Recommendations for biomedical research under Horizon 2020

Better coordination between health, research and IT programs

Within the EU programs, biomedical projects can fall under different DGs: RTD (Research and Innovation), Sanco (Health & Consumers) or CONNECT (Communications Networks, Content and Technology). For example, we are experiencing that DG Energy is leading the research on Radiation Protection, without any apparent interactions with DG CONNECT. This

can sometimes lead to duplication of work and/or confusion among participants involved in such projects. We would like to draw the attention on this issue so that biomedical projects are less fragmented among the different DGs and to avoid that EC administrative responsibility for one and the same project falls under different DGs⁴.

Promote and strengthen translational research: from bench to bedside

As mentioned previously, medical imaging mainly relies on the interaction between academia, medical staff and high-tech SMEs. The latter should be better involved in the translational process through, for instance, creating a database containing their records.

This can facilitate the work of participants towards finding adequate SME partners while responding to a grant.

On 1st October 2012, Máire Geoghegan-Quinn, European Commissioner responsible for Research, Innovation and Science, has declared during the 2nd convention on "The Horizon 2020 programme: what's in it for SMEs" that: *"The excessive cost of patenting across the EU is a burden that falls disproportionately on SMEs. The European Commission's proposal for unitary patent protection will reduce the costs by up to 80%."*⁵

Such declaration is a very good incentive to encourage SME to take part in biomarking projects that involve patents.

Towards an open data policy

The European Commission has shown a strong will towards encouraging the sharing of data and declared that open access to research results will boost Europe's innovation capacity.⁶ The availability of open, high-quality and large imaging biobanks and processing facilities in terms of data, services and resources will radically simplify access to knowledge, improve interoperability and standardisation and will even help on consolidating more at European level the medical imaging research community.

In the future, biomedical imaging will become one of the major data producers, and people working in this area have to face the burden of data management and analysis within imaging biobanks. Thus, we encourage the following:

1. Standardize imaging data storage and anonymization, and ensure full interoperability with other biobanks.
2. Develop platforms for long-term storage and image organisation.
3. Sharing best practice and image data between researchers from all over Europe.
4. Open access of image data to the concerned community and training of research infrastructure users.
5. Better use of health data to approach system based initiatives.
6. Re-use of existing data to tackle new issues by saving time, energy and money.

ERC grants: boost for bio-imaging researchers

Bio-imaging researchers who tackle complementary research appreciate ERC grants, which despite its high competitiveness are an excellent way to boost research, both at

⁴ See written response to the Green Paper (20 May 2011) of Alliance for BioMedical Research in Europe (BioMed Alliance)

⁵ See http://europa.eu/rapid/press-release_SPEECH-12-663_en.htm

⁶ See press release on 17th July 2012 http://europa.eu/rapid/press-release_IP-12-790_en.htm

experimental and clinical areas, where it demonstrates the added value of joint research at its best.

Last example on it is the call launched on 10th October 2012 titled «Synergy Grants».

We, therefore, would like to encourage this «success story programme called ERC» towards more crosscutting themes and express our concern regarding the percentage of budget that will be dedicated to ERC in Horizon 2020.⁷ Even more, «Health and Well-being» programmes will promote multidisciplinary research.

Researchers' mobility and international cooperation: crucial for success

Researchers' mobility is essential to gain expertise abroad and exchange ideas and share experience. Special attention should be paid to programme such Marie Curie Actions, which have demonstrated to be successful. We highly welcome actions towards avoiding brain drain of our best elements and make EU research area attractive for foreign researchers in biomedical imaging.

We also hope that international cooperation will not only focus on US and emerging economies but also towards neighbouring countries (South Mediterranean Partners) as we both need this cooperation especially that we share same challenges (such as ageing population, developing common types of diseases, etc.).

Administrative and financial aspects: how can we improve?

The main two comments regarding the procedure and budget issue are:

1. The procedure to respond to a call should be proportional to the size of the grant, which would imply a simplification of most procedures.
2. Rethinking the way of calculating direct and indirect cost and to make the VAT eligible.

Conclusion:

We mostly approve Horizon 2020 initiatives but would appreciate that biomedical research is better recognised as a theme on its own and not only a subcategory under Health. We also hope that through the next framework programme, more barriers will break between the research academia and the medical world as the synergy between the two is a precondition to advance studies on biomarkers and bioimaging towards early prediction and better diagnosis.

This statement is endorsed by the European Institute for Biomedical Imaging Research (EIBIR), www.eibir.org

⁷ see www.no-cuts-on-research.eu/