Position paper on the European Commission Green Paper

From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation funding

Approved by the VPH Institute Board of Directors on May 19th, 2011

Rationale

The present document summarises the position of the VPH Institute on the European Commission Green Paper - *From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation funding,* which introduces major changes to the EU support to research and innovation.

The VPH Institute welcomes this document, as it aims at making participation easier, increasing scientific and economic impact and providing "better value for money".

The VPH Institute fully supports the Green Paper's emphasis on the link between the health of European citizens and the economic prospects of the European Union. We are convinced that EU funding mechanisms should work towards the promotion of excellence and a more integrative approach to research and development in order to fully respond to societal challenges.

Preamble

The Board of Directors of the VPH Institute decided to take part in this consultation by elaborating a position statement summarising the Institute's position with respect to the future EU framework for funding research in general, and with respect to the specific positioning of VPH-related research in it.

General recommendations for the next framework program

The recommendations the VPH Institute makes in this section are in part based, and thus resonate, those made by the European Alliance of Medical and Biological Engineering and Science (EAMBES).
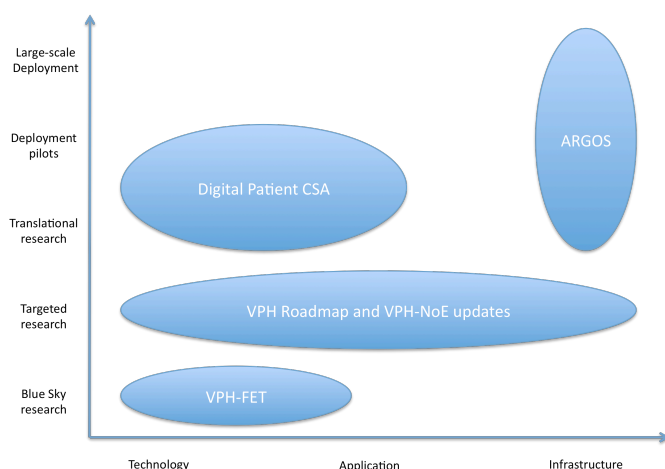
1. Organise the administrative and reviewing procedures in line with the principles expressed in the "**Trust Researchers**" declaration, which the VPH Institute endorses: http://www.trust-researchers.eu.

2. Modulate procedures so that the effort required to apply for and manage a grant is proportional to the size of the grant.

3. Reward researchers, institutions, and consortia achieving excellence by introducing appropriate grant renewal mechanisms. Reward the ability to achieve and deliver results, not the ability of making promises.

4. Create renewal mechanisms to enable a) a progressive selection and concentration of clouds of small projects into a sustainable international consortium, which would have the critical mass required to address grand societal and medical challenges, and b) an appropriate support to research consortia along the entire innovation chain.

5. Develop and implement improved measures for identifying and contacting potential partners, in order to set-up a consortium fitting the requirements of a given call.

6. Ensure that panels evaluating grant applications in this multidisciplinary area consist of experts with relevant background and experience, familiar with both health care *and* technology.

7. Recognise that an important way to address societal challenges, which are often based on health and care issues, is to invest in health & care technology research.

8. Support the entire cycle of innovation in healthcare technology from basic technological research to large-scale deployment. Promote the understanding that not all research results will turn into deployable innovation, and that this is not a failure, but rather is the nature of the process.

9. EU funding should cover the full innovation cycle and focus on the "missing mile", the gap between the completion of a research project and the provision of sufficient evidence to attract private investments. Specific actions must be designed to address this gap – including targeting pre-clinical validation and early clinical evaluation of new technologies.

10. Create mechanisms supporting start-ups and academic spin-offs, support Seed Investment for start-up ventures. Most of the European Commission's strategies revolve around the idea of transferring research results to existing enterprises for exploitation. However, the translation of research results into socio-economic value most frequently happens through the creation of start-ups – usually spin-offs of academic institutions.

11. The VPH Institute is favourable to an appropriate level of concentration on national and regional funding programs - especially on grand challenges such as active and healthy ageing. However, this should not involve additional layers of bureaucracy. It seems more appropriate to earmark a portion of the regional development funds to target R&D and Innovation on specific grand challenges defined at European level, leaving at the local level the actual management of the resources.

VPH-related research in the next framework program

Five years after its publication, the development and deployment strategy drafted by the VPH research community in the *VPH Research Roadmap* remains largely valid, as it has been considerably complemented by a number of additional documents.

The *VPH Network of Excellence*[1] has promoted a consensus process that produced in 2009 and 2010 two vision documents extending and updating the original roadmap. The **Argos transatlantic observatory on eHealth**[2] is elaborating a policy brief on the long-term sustainability of a global research *info-structure* for VPH research. The **VPH-FET support action**[3] is elaborating another research roadmap

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[1] http://www.vph-noe.eu/

[2] http://argos.eurorec.org/

[3] http://www.biomedtown.org/VPHFET/reception/

targeting mostly the curiosity-driven research (also known as technological "blue sky" research). **Discipulus**, another support action being negotiated, is expected to map the territory of the so-called "**Digital Patient**", a new term that indicates the translation and deployment of VPH technologies into instruments that can be used directly by medical professionals.

The adjacent graph shows how all these documents chart the territory that goes from curiosity-driven research to large-scale deployment, with respect to the development of technologies, of applications, and of the support infrastructures.

The elaboration of this project has involved hundreds of experts worldwide, from academia, industry and the clinical world – including mathematicians, physicists, computer scientists, engineers, physiologists, biochemists and biologists, clinical researchers, social scientists and experts in legal, ethical and gender issues. The vision that emerged from this preparatory process has been repeatedly discussed with representatives of patients, consumers, and citizens' organisations, trade organisations, standardisation and regulatory bodies and healthcare and welfare authorities.

The work that emerges from this intense and detailed road-mapping work makes possible a gap analysis, on which we based the following recommendations for the further development of the VPH vision in the next framework program:

a) In such a complex domain, road-mapping activities are unquestionably useful for both the research and innovation communities, and for the policy-makers. In FP7 we covered most of the ground, with two notable gaps that should be addressed in the next framework program:

   I. In the ICT program we recommend a support action or a **network of excellence** that **monitors all deployment pilots**, their outcomes and work with clinical and industrial experts to develop strategies for large-scale deployment of VPH-related technologies.

   II. In the Health program, we recommend a **support action** to roadmap the role that **integrative modelling** can have **in fundamental biomedical research**. This roadmap should involve both the VPH and the systems biology communities and should be positioned at the end of FP7 or at the beginning of FP8, so as to provide useful elements for the design of the latter.

b) In the ICT program we recommend identifying, as one of the priorities linked to the *Active and Healthy Ageing* European Innovation Partnership, the development of the next-generation personal welfare ICT services (code-named **Personal Health Forecasters)**. What we propose is to develop personalised VPH models (integrative predictive models) that constantly elaborate all the data transmitted by personal health systems, wearable sensors, ambient assisted living technologies, mobility monitors, etc. and predict how specific aspects of our health will evolve in a near or not-so-near future. Such models should account for chronic diseases, recurrent prescriptions, or specific disabilities and could be further personalised with clinical data such as medical imaging, biomedical instrumentation, biomarkers, etc.

c) In the ICT program we recommend identifying, as one of the priorities for the next framework program, the **development of the Digital Patient.** The projects is intended to be a framework of information technologies that enable a more integrative, predictive, personalised, and patient-centric medicine, following the indications that will emerge from the specific research roadmap the *Discipulus* support action is expected to produce. By its nature the Digital Patient program should begin from targeted research, followed by innovation and deployment pilots as the framework develops.

d) In the ICT program, we recommend a parallel program that in the next framework should be limited to targeted research, entitled ***in silico* clinical trials**, which targets the use of ICT to simulate how

large cohorts would react to new drugs, medical devices, biotech and tissue engineered products. If proved effective these new technologies could be positioned before real animal and clinical trials, in order to increase the efficacy of their design, reduce the size of the cohorts, the risks for the patients (or the invasiveness for the animals), and the costs for the biomedical industry (which could turn into a reduction of costs for these products). It could also open an entirely new market, for *In Silico Clinical Research Organisations*, a new type of CRO that would conduct these simulated clinical trials on the next-generation computing cloud.

e) In the ICT program, we recommend that some **Future and Emerging Technologies (FET) Proactive calls** explicitly targeting the technological blue-sky research challenges that are being identified by the VPH-FET action.

f) In the Health Research program we recommend specific calls for **Health Technology projects** where VPH technologies developed in FP7 are combined with other technological means to form healthcare solutions that are evaluated for accuracy, safety and efficacy in pre-clinical and clinical trials.

g) In the Health Research program we recommend that the **Systems Medicine** program is designed to explicitly target the integration **from the molecule to the organism**, and that there is an explicit requirement for proposals to leverage on the results obtained in VPH technological research projects.

h) In the research infrastructures, starting from the Argos VPH policy brief, we recommend establishing a global meta-infrastructure called the **VPH Infostructure** that connects and integrates all research infrastructures that collect and share data, information, and knowledge about the human body. The VPH Institute plans to work for the inclusion of such a proposal in the next ESFRI roadmap.

About the VPH Institute

In spite of the human desire to reduce to parts in order to understand life, in reality life is the result of an intricate systemic interaction between very many processes occurring at radically different spatial and temporal scales. Every day worldwide biomedical research and clinical practice produce a huge amount of information on such processes. But this information is highly fragmented, and its integration is largely left to the human actors, who find this more and more difficult as the breath and depth of information available increases exponentially. We need to develop a new approach, which makes possible the integration of information, and simplifies its transformation into integrated knowledge. *The Virtual Physiological Human (VPH) is a framework of methods and technologies that once fully established will make possible the investigation of the human body as a whole*.

The VPH Institute is an international no-profit organisation that represents academic, clinical, and industrial stakeholders involved with the development of the VPH. The mission of the VPH Institute is to ensure that the Virtual Physiological Human is fully realised, universally adopted, and effectively used both in research as well as in industrial, clinical, and social applications.

The 2011 Board of Directors includes representatives from the University of Auckland (NZ), the Universitat Pompeu Fabra (ES), University of Sheffield (UK), Università di Roma 4 (IT), KU Leuven (BE), Universidad de Zaragoza (ES), INRIA (FR), Entelos Inc. (USA), Ospedale Pediatrico Bambino Gesù (SCV), and Istituto Ortopedico Rizzoli (IT).