



EU support for Global Health R&D

10 RECOMMENDATIONS FOR THE HORIZON 2020 MTR AND THE FUTURE FP9



**IMPROVED HEALTH AND WELLBEING OF THE
PEOPLE IS THE ULTIMATE GOAL OF RESEARCH**
THE EUROPEAN COMMISSION'S (EC) SCIENTIFIC
PANEL FOR HEALTH (SPH)¹



1. Maintain the overall budget and the grant-nature of research funds

- Reverse the budget cuts to Horizon 2020 (H2020) caused by the introduction of the European Fund for Strategic Investment.
- Safeguard the grant-nature of research funding under FP9 and prevent diverting any funds to debt-based financing mechanisms. Not all R&D areas are economically viable (in the short term) despite the huge socio-economic impact they may have (in the long term), and many research entities are not allowed to take out loans².
- Commit to a budget of at least 100 billion euros for the future FP9. H2020 is a highly successful programme, but it suffers from strong demand and historically low success rates³. A significantly increased budget is needed if all high quality proposals are to be funded.⁴



2. Mainstream sustainable development

- FP9 should address sustainable development as a cross-cutting issue and set targets similar to H2020 (60% of the budget to sustainability-related research).
- FP9 needs a robust system in place to ensure this commitment is met, given that it was found that H2020 lacks sustainability-related research agendas and a corresponding, effective monitoring system⁵.



3. Strengthen international cooperation

- **Take measures to increase international cooperation, in particular with low- and middle-income countries (LMIC),** to counter the “sharp decline in the participation of international partner countries”⁶ in H2020 compared to FP7.
- **Support local innovators** in LMIC through new partnerships, technical assistance, and regulatory strengthening with the goal of building capacities to translate ideas through the innovation value chain, ensuring a more sustainable innovation ecosystem.
- **In the area of health research, “a more proactive policy and international commitment by Europe is urgent”⁷**
 - **Particularly in the area of Global Health (SDG 3),** “the emerging global European research community of practice may be well-positioned to foster research collaboration towards addressing some of the major global challenges in an effective manner”⁸.
 - **Relaxing restrictions on geographic locations of applicants** for EU R&D funding (whether through EDCTP, H2020/FP9 work programmes, or IMI), in disease areas where there is no clear profit incentive to invest in research, can be an effective way to ensure the involvement of suitable product development organisations that may not meet current geographic criteria.
 - **Develop innovative partnerships,** for example with product development partnerships (PDPs), and the Medicines Patent Pool, to help track and ensure patient focused, needs-driven and access-enabling investments.



4. Develop a comprehensive vision and action plan for health research and product development

- **“to coordinate European programs with the national priorities** of national governments in Europe to make a real difference at the global scale”⁹. Member States and the EU should set out “a strategy through consultation with all stakeholders”¹⁰.
- **Which ensures that EU health research priority-setting is global health needs-driven,** as foreseen by the EC Communication on the EU Role in Global Health¹¹. The 2013 update of the WHO Report on ‘Priority Medicines for Europe and the World’¹², was commissioned by the EC to be used as a resource in planning H2020. Societal Challenge 1 on Health, Demographic Change and Wellbeing, however, makes no reference to unmet global health needs as drivers for public investment.
- **Which introduces a greater focus on disease areas where industry interest is absent** due to limited market incentives, and where R&D relies on public funding to support candidates beyond the early-stage of research, through to late-stage clinical trials. This is particularly the case for poverty-related and neglected diseases (PRNDs) and conditions included in goal 3 of the SDGs.
- **That includes a pillar on PRND R&D** which:
 - Makes a commitment to achieving the **funding target of 0.01% of GDP** for PRND R&D as recommended by the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG)¹³.
 - Adopts a **product portfolio approach,** to allow successful projects and products to progress through the development pipeline to patients. We strongly advocate for the EU to create a **funding mechanism that allows (possibly conditionally approved) follow-up funding** for successful projects based on the attainment of pre-identified scientific criteria.
 - Includes an approach to improving **coordination between the European and global research communities,** as stressed by the Council of the EU in its conclusions on lessons learned for public health from the Ebola outbreak in West Africa¹⁴. The Council also highlighted the importance of strengthening **preparedness research,** notably with regard to diagnostic methods, vaccines and therapeutic products development.
- **Which includes a focus on fighting antimicrobial resistance (AMR),** in line with the upcoming renewed EU action plan on AMR and its second strategic pillar “Boosting research, development and innovation against AMR”¹⁵



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5. Ensure accessibility and affordability

- The EC should explore alternative biomedical innovation and financing models that do not rely on high prices for its financing, i.e. models that provide transparency to the cost of R&D while understanding a sustainable price of the product with clear access, suitability and affordability conditions. For example: innovation prizes, PDPs, open and collaborative models of innovation with open access to data and results. These models should be employed as a suite of mechanisms to incentivize innovation and to de-link the costs of R&D from product prices when possible.



6. Ensure greater transparency of publicly funded medical R&D

- Fully disclosing and **tracking public funding** for pharmaceutical R&D
- Attaching **transparency provisions** to EU-funded medical R&D to ensure the costs of R&D are disclosed
- Promoting **open access to research data** to make sure research is not being duplicated.



7. Ensure appropriate metrics to measure impact

- **Assess the share of funding to signed grants that contribute to advancing global health** in addition to the tracking of sustainability-, climate-, and biodiversity-related expenditure (as required by the H2020 regulation), in annual monitoring reports of H2020 and the future FP9.
- Currently, the outcomes of the PRND R&D conducted under H2020 are measured using the same metrics as other research¹⁶, which are often a poor proxy for actual global health impact. This issue also affects other research areas which are key enablers of sustainable development.¹⁷ **Research impact should be additionally measured, for example, on the degree to which scientific excellence is translated into national, regional and international policies.**
- **The EU should invest in M&E tools and partnerships with the WHO** and other international organisations to ensure that grants in health innovations fit with globally agreed priorities and portfolios that are monitored for progress.



8. Strengthen support for bottom-up research

- “**Flexibility and openness, balance between strategic agendas and bottom-up initiatives**”¹⁸ is required in health research due to the lack of predictability of ‘new’ or re-emerging infectious diseases.
- **FP9 should include a pillar similar to the current ERC with an increased budget that allows for bottom-up research initiatives.**



9. Strengthen the European and Developing Countries Clinical Trials Partnership (EDCTP2)

- EDCTP is a successful partnership delivering both, in terms of global health impact and economic benefits for Europe.¹⁹ EDCTP, however, suffers from very high demand and low success rates²⁰.
- Make sure that the committed budget ceiling of 683 million for the second phase of EDCTP is met, or exceeded, with clear commitments from the European Participating States.
- Ensure that the partnership is continued in a third phase with a more ambitious budget adequately reflecting the widened scope of the instrument.
- Maximum funding under EDCTP calls for proposals cannot be limited to 10 or 15 million euros to allow for phase III clinical trials of promising future candidates to be funded.



10. Refocus the Innovative Medicines Initiative (IMI)

- IMI has not played an important role in channelling EU funding for GH R&D²¹, and was recently found to not have a systematic approach to assessing potential socio-economic impacts of its funding²².
- IMI's focus should be further widened towards global health R&D and disease areas with limited market incentives, making use of IMI's potential to bring together industry, academia and possibly civil society.
- IMI should also put a more effective system in place to monitor the corresponding impact, both in Europe and globally.

FOOTNOTES

- 1 Cf. SPH vision paper "Better Research for Better Health", May 2016, p. 3, available at: [research" https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/SPH_VisionPaper_02062016.pdf](https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/SPH_VisionPaper_02062016.pdf)
- 2 Cf. The European University Association "One year of EFSI - What's in it for Universities", p. 4, available at: <http://www.eua.be/Libraries/publications-homepage-list/one-year-of-efsi-whats-in-it-for-universities-an-eua-review>
- 3 Cf. Horizon 2020 Monitoring Report 2015, p.11, available at: http://ec.europa.eu/research/evaluations/pdf/archive/h2020_monitoring_reports/second_h2020_annual_monitoring_report.pdf
- 4 Ibid, p.11.
- 5 Cf. ExPost Evaluation of the 7th EU Framework Programme (2007-2013), November 2015, p. 75, available at: https://ec.europa.eu/research/evaluations/pdf/fp7_final_evaluation_expert_group_report.pdf#view=fit&pagemode=none
- 6 Ibid, p.79.
- 7 Cf. SPH vision paper "Better Research for Better Health", May 2016, p. 26.
- 8 Cf. "A study into the contribution and complementarity of EU international research and innovation cooperation with developing countries in FP7 (2007-2013)", October 2016, p. 41, available at: http://ec.europa.eu/research/iscp/pdf/publications/ki0116693enn_final_report.pdf#view=fit&pagemode=none
- 9 Ibid., p.4.
- 10 Ibid, p. 4.
- 11 Available at: https://ec.europa.eu/europeaid/sites/devco/files/communication-eu-role-in-global-health-com2010128-20100331_en.pdf
- 12 Available at: www.who.int/medicines/areas/priority_medicines/en/
- 13 Cf. Report of the CEWG, April 2012, available at: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1
- 14 Available at: [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52015XG1217\(02\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52015XG1217(02))
- 15 Cf. Roadmap for an EC Communication on a One-Health Action Plan to support Member States in the fight against Antimicrobial Resistance (AMR), October 2016, available at: http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_176_action_plan_against_amr_en.pdf
- 16 E.g. key performance indicators such as the number of peer-reviewed journal articles or of joint public-private publications
- 17 A recent independent evaluation report confirmed that "the knowledge and evidence on impacts of FP7 and HORIZON 2020 on society in general and on SDGs in particular is still very limited" (Cf. ExPost Evaluation of the 7th EU Framework Programme (2007-2013), November 2015, p.759)
- 18 Cf. "Better Research for Better Health - A vision for health and biomedical research", May 2016, p. 17, available at: http://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/SPH_Vision_Paper_27052016.pdf
- 19 Cf. "Saving Lives - Making the case for European investment in poverty-related and neglected disease R&D", pp. 30, 35, available at: http://www.dsw.org/en/wp-content/uploads/2016/11/DSW_SavingLives_making-the-case-for-EU-investment-in-GH-RD.pdf
- 20 Cf. Horizon 2020 Monitoring Report 2015, p. 234, available at: http://ec.europa.eu/research/evaluations/pdf/archive/h2020_monitoring_reports/second_h2020_annual_monitoring_report.pdf
- 21 Cf. "Saving Lives - Making the case for European investment in poverty-related and neglected disease R&D", p. 16, available at: http://www.dsw.org/en/wp-content/uploads/2016/11/DSW_SavingLives_making-the-case-for-EU-investment-in-GH-RD.pdf
- 22 Cf. IMI Socio-economic Impact Assessment Expert Group – Final Report, May 2016, p72, available at: http://www.imi.europa.eu/sites/default/files/uploads/documents/Publications/SocioeconomicImpactAssessment_FINALMay2016.pdf

