European Commission: ERA Framework Public Consultation: Areas of untapped potential for the development of the European Research Area

Response by the Wellcome Trust
November 2011

KEY POINTS

1. The Wellcome Trust is the largest independent charity in the UK, committing over €792 million in 2009/10 to support the brightest minds in biomedical research in the UK and internationally. The Wellcome Trust supports the European Research Area (ERA) and makes the following points to enhance the further development of the ERA:

- The ERA framework must balance measures to promote harmonisation with flexibility for Member States to adapt to local circumstances. This will help to reduce bureaucracy, maximise national strengths and increase European competitiveness.

- Europe must commit to the long term sustainability of research infrastructures, as set out in the European Strategy Forum on Research Infrastructures (ESFRI) Roadmap. Support for e-infrastructures will be particularly important to maximise the value of the growing amounts of data produced by European research.

- Measures which nurture and support high quality researchers at all stages of their career are essential for sustaining research excellence in the ERA. Initiatives that encourage researcher mobility (such as the Scientific Visa Package) and flexibility in the career pathway are needed, but any changes must be taken with a long-term view.

INTRODUCTION

2. Research and innovation are central to the Europe 2020 agenda and the Wellcome Trust supports measures to promote these goals as part of the ERA in 2012. We have provided input to the Commission’s previous consultations on the subject, and would now like to highlight some high-level issues as the ERA is developed further.

Researchers
(consultation document section 2.1; questionnaire section 4 and 9.11-9.14)

3. The Wellcome Trust agrees that there are barriers that hamper the attraction and retention of the best researchers. Employment conditions may be insufficiently attractive and there are often difficulties in inter-sector and cross-border mobility. We are strongly supportive of the Scientific Visa Package and would like to see the UK adopt a similar approach.

4. Wellcome Trust funding schemes support cross-border research in Europe. We fund the brightest minds to conduct ground breaking research in excellent environments wherever they are found worldwide, and our grants allow researchers to move within Europe. The International Senior Research Fellowships scheme supports outstanding researchers who wish to establish independent research careers in an academic institution in
selected European countries: Croatia, Czech Republic, Estonia, Hungary, Poland, Slovakian Republic and Slovenia.

5. The consultation questionnaire notes that progress towards achieving a gender balance in research is slow. Recently, a UK ‘Principal Investigators and Research Leaders Survey’ indicated that, although the majority of research leaders believed their institutions are committed to equality and diversity, many senior female researchers still felt a lack of fairness in terms of promotion, reward and participation in decision making\(^1\). These findings show there is still work to be done.

6. As a research funder, we do our utmost to provide flexible and fair funding that allows excellent applicants, whether male or female, to be successful. We are active in debates surrounding gender in science, recently responding to the European Commission’s consultation on the EU gender summit\(^2\). While the proportion of men and women applicants is similar for our early career awards (PhDs, early career fellowships), we do see a drop in the number of applications from women as the awards increase in seniority. However, award rates remain similar to proportion of applications. We have developed a longitudinal study - the “Wellcome Trust Career Tracker” – to help gain a better understanding of career progression over time; this will help to inform the Trust’s provision of research and career support.

7. Initiatives such as the UK Concordat and European Charter for Researchers support the career development of researchers\(^3\), and promote diversity and equality in all aspects of career management. We are a signatory to the Concordat and expect all organisations which we fund to abide by its principles. We hope that the forthcoming review of the Concordat’s implementation, will demonstrate significant progress in the sector. Other Member States may be able to learn from this exercise.

**Cross-border operation of research actors**
*(consultation document section 2.2; questionnaire section 5)*

8. There is considerable evidence that international collaboration is beneficial for research and produces papers with greater impact\(^4\). We therefore support measures to promote collaboration between countries, but it is important that standardisation does not unintentionally impede research.

   Question 5.6: Describe which specific factors (can) hamper the cross-border operation of research programmes implemented by funding agencies, research-performing organisations including universities etc.

9. Measures for harmonisation must not override best practices at a national level. This problem is evident in current proposals to standardise the treatment of Value-Added Tax (VAT) for public bodies across Europe. UK charities are currently eligible for a number of VAT reliefs, consistent with the social benefits they provide – if a European standardised ‘full taxation’ model is introduced, the loss of the reliefs may remove incentives for UK foundations to invest in research.

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\(^1\) [http://www.vitae.ac.uk/policy-practice/1393-449461/Principal-Investigators-and-Research-Leaders-Survey.html](http://www.vitae.ac.uk/policy-practice/1393-449461/Principal-Investigators-and-Research-Leaders-Survey.html)

\(^2\) [http://www.wellcome.ac.uk/About-us/Policy/Consultation-responses/](http://www.wellcome.ac.uk/About-us/Policy/Consultation-responses/)

\(^3\) [http://www.researchconcordat.ac.uk/](http://www.researchconcordat.ac.uk/)

Research infrastructure  
*(consultation document section 2.3; questionnaire section 6)*

10. The European Strategy Forum on Research Infrastructures (ESFRI) has been a valuable process to encourage planning and coordination for research infrastructures across Europe, based on current and future needs. The Wellcome Trust provides support for a number of the biomedical infrastructures identified through the Roadmap including INFRAFRONTIER to establish robust systems to phenotype, archive and share embryos and mice throughout Europe. As the initiatives within ESFRI reach maturity, they must receive sufficient funding from the Commission to fulfil their goals. It is absolutely crucial that the Commission not only provides capital support but also the operational funding required for long-term sustainability.

11. Managing the exponential growth of research data in a sustainable way is one of the key challenges facing the research community. We are pleased that the Commission recognises the importance of e-infrastructures and the interoperability of data systems in order to maximise the long-term value of research data.

6.3: *How could, in your opinion, national, regional and pan-European research infrastructures best contribute to raising the research base across the ERA?*

12. It is vital that the Commission ensures sustained funding for the EMBL European Bioinformatics Institute (EBI), which provides the data resources that underpin European life sciences research. The EBI is coordinating the development of the European Life-Science Infrastructure for Biological information (ELIXIR), which aims to build an integrated platform for biological data from genomics through to systems biology. We believe that it is vital that the European Commission provides sufficient on-going funding to ELIXIR to ensure its success – recognising that these resources are absolutely critical to the success of the broader European Research Area. ELIXIR offers a model to put the EBI and other European data centres on a sustainable footing.

Knowledge circulation  
*(consultation document section 2.4; questionnaire section 7)*

Knowledge transfer

13. Current intellectual property legislation hampers product development: the need to patent in multiple member states is inefficient and introduces substantial financial and administrative burdens. Implementation of the Code of Practice (2008) on intellectual property policies has differed between Member States and a coordinated approach is lacking. A harmonised system across member states could be more efficient but this must meet the highest common standards and not impede existing best practice.

14. We agree that the public research organisations should be encouraged to develop and implement knowledge transfer strategies; the Wellcome Trust actively supports knowledge transfer through its technology transfer division5. When developing ERA policies, the Commission should consider evidence from national systems that seek to promote translation. The UK is currently developing the Research Excellence Framework (REF) to assess the quality of research at UK higher education institutions and inform future funding allocations. For the first time, the REF will include a range of

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5 [http://www.wellcome.ac.uk/Funding/Technology-transfer/index.htm](http://www.wellcome.ac.uk/Funding/Technology-transfer/index.htm)
measures that assess knowledge transfer in an attempt to encourage behaviours that facilitate translation and the uptake of research, both within the UK and internationally.

Open access to publications and data

15. The Wellcome Trust strongly supports efforts to encourage the sharing of scientific knowledge, recognising that free online access to scientific publications and data can enhance the research process. We agree with the factors identified in the consultation questionnaire that act as barriers to knowledge circulation in Europe. Moreover, we argue that the inability of potential users to access many of the research outputs generated by public funding – whether data or publications – is an unacceptable hindrance to research and limits the value of public funding.

Question 7.12: Given the ensemble of issues addressed in this section ‘open access’, which action, other than funding, is needed at EU level to remedy some of these issues?

16. We support the Commission’s commitment, as a funder, to strengthen open access and data sharing, by making it a requirement of EU research funding. As noted (paragraphs 10-12), we also believe strongly that pan-European e-infrastructure for scientific data and publications should receive sustained EU funding via the ELIXIR initiative.

17. UK PubMed Central (UKPMC) is a key repository enabling open access to biomedical research literature. UKPMC is currently supported by 18 partner funders – including a range of public and charitable funders in the UK, the Austrian Science Fund (FWF) and Telethon in Italy. A major strategic objective of UKPMC is to work with biomedical research funders across Europe to transform UKPMC into a single, Europe-wide, life-sciences’s repository – Europe PMC – which ultimately will act as a “literature node” within the ELIXIR framework. The UKPMC partners are in active discussions with both OpenAire and the European Medical Research Councils (EMRC) to progress this vision, and would welcome dialogue with the European Commission and any other European funders interested in joining the new Europe PMC.

International dimension
(consultation document section 2.5; questionnaire section 8)

18. We agree with the Commission’s appraisal that Europe is facing increasing competition from emerging global economies, such as China, India, Singapore, Korea and Brazil. Although we share concerns that Europe may be losing out as an international research partner, the evidence suggests that this is not due to fragmentation but rather because some European legislation has decreased Europe’s competitiveness. The Academy of Medical Sciences report A new pathway for the regulation and governance of health research identified the Clinical Trials Directive as a damaging barrier to research because burdensome regulatory requirements delay the onset of trials.6

Managing and monitoring the ERA partnership, cross-cutting issues and next steps (consultation document section 2.6; questionnaire section 9)

Question 9.1: How can ERA best contribute to reducing the current research and innovation gap within Europe and the large disparities between research systems at national and regional level?

6 http://www.acmedsci.ac.uk/index.php?pid=99&puid=209
19. We support measures to promote a European area of knowledge exchange to promote innovation and research. This vision must be based on a flexible overarching framework. Although harmonisation of practice is desirable in certain areas, it must be balanced with the need to take into account national strengths and priorities. A framework should remain overarching and adaptable to allow details to be suited to local circumstances. We support moves towards reducing bureaucracy and believe that this will increase Europe’s international competitiveness as well as increase productivity and accelerate translation.

*Question 9.5: What would have been the potential gains resulting from a higher level of involvement of stakeholders?*

20. As discussed above (paragraph 18), the European Clinical Trials Directive is a recent example where legislation and its implementation has had negative consequences. While the Directive has had some benefits, for example in establishing processes for single country-wide ethics opinion in Member States, it has not achieved its aims of greater harmonisation, nor appreciably changed patient safety. Instead the Directive has increased the bureaucratic burden for getting approval, delaying the onset of trials and increasing costs. We hope that the revision of the Clinical Trials Directive will address these problems and the inconsistencies in its interpretation to harmonise practices in Europe. The revised Directive must stimulate international trials without hindering the progress of single country trials.

21. The EU should consult widely to ensure that all appropriate stakeholders are identified early in the drafting of European legislation. This should mitigate the chance that European legislation will have unforeseen implications in the research sphere. An example of this is the Physical Agents Directive 2002/40/EC which set minimum requirements to protect workers from risks posed by electromagnetic fields. The Directive seriously threatened the use of magnetic resonance imaging (MRI) in research and clinical practice, but these concerns were not addressed until after the Directive had been published, resulting in the need to delay implementation from 2008 to April 2012. The European Parliament and Council are currently discussing the proposed revision of the Directive, including an exemption for MRI, following extensive consultation with the research community.

22. It is essential that the current revision of the Data Protection Directive makes suitable provisions to facilitate the use of personal data in research. In the current Directive there is a lack of clarity on the use of data for research purposes, for example, greater clarification is needed on when the research exemptions can be applied and whether pseudonymised data falls within the scope of the legislation.

*Question 9.15: There should be a common European Approach and practices to research ethics and scientific integrity (Agree or Disagree)*

23. The European Science Foundation has recently produced an excellent Code of Conduct for Research Integrity. We suggest non-binding approaches such as this are the best way to promote best practice across Europe.⁷ In the UK, we are also working with Universities UK and the Research and Funding Councils to develop a Research Integrity Concordat setting out the responsibilities of researchers, their employers and funders. However, it is crucial that any ethical framework is able to take into account local issues and sensitivities and we therefore do not think mandated policies are an appropriate way to enforce research ethics across Europe.

⁷ http://www.esf.org/activities/mo-fora/research-integrity.html
The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.