NHS European Office

NHS European Office response to the Science and Technology Committee (Commons) inquiry: ‘Leaving the EU: implications and opportunities for science and research’

1. Medical science and clinical research are essential components of our healthcare system and collaboration at EU level in these areas has helped the NHS to develop new treatments, adopt innovation more quickly, and improve the quality of care we provide to patients.

2. In this paper we highlight some important areas of EU collaboration in scientific research and innovation from an NHS perspective.

3. **European Reference Networks for rare and complex diseases**

3.1 As part of the implementation of the EU Directive on patients’ rights in cross-border healthcare, the European Commission is required to support Member States in the development of European Reference Networks for rare and complex diseases between healthcare providers and centres of expertise.

3.2 The intention of European Reference Networks is to facilitate improvements in access to diagnosis, treatment and provision of high-quality, accessible and cost-effective healthcare for patients who have a medical condition requiring a particular concentration of expertise or resources.

3.3 There has been significant NHS interest in this initiative, with a quarter of all applicant networks expected to be led by NHS trusts, in particular covering:
   - rare auto-immune and auto inflammatory diseases;
   - rare hepatic diseases;
   - rare neuromuscular diseases;
   - rare malformation and developmental anomalies and rare intellectual disabilities;
   - rare and complex urogenital conditions;
   - rare epilepsies.

3.4 Furthermore, all proposed networks feature one or more NHS trusts in their membership, making the UK the most represented country in this initiative.

3.5 As only healthcare providers from EU or EEA countries can be members of these networks, uncertainty has now emerged around the possibility for continued involvement of NHS organisations as leaders or members of European Reference Networks.

3.6 When the European Commission started shaping plans for the development of European Reference Networks, from the very outset, many specialised NHS providers wanted to take a leading role. This new form of EU collaboration between hospitals was indeed seen as strategically very important to progress medical science and improve patient treatment in clinical areas where expertise is rare, and where collaboration at EU level brings significant added value.

3.7 The plan for these networks is to link up leading specialised providers from across Europe, so they can pool knowledge and expertise. This is intended to lead to more evidence-based treatments and increase the speed and scale at which innovation in medical science and health technologies is incorporated into healthcare provision. Participating clinicians will collaborate on
a wide range of activities, from improving clinical guidelines and patient pathways, to sharing medical information on clinical cases and agreeing on treatment options, to conducting clinical research and improving medical education and training.

3.8 While collaboration has long been a common feature in the international medical world, what is new with European Reference Networks is that this collaboration will be put on a more formal footing and structured around a defined programme of work. Importantly, participants will benefit from EU support, including a joint IT platform, which will support the secure and confidential exchange of patient information across borders.

3.9 Another important innovation is that these networks will function as an accreditation system, with participating healthcare providers being awarded a protected logo which certifies them as centres of clinical excellence in a particular clinical domain.

4. EU Health Programme

4.1 EU membership allows for joint learning and the exchange of scientific expertise, technical input and knowledge sharing on policy development on public health related issues through the EU’s Health Programme. Joint Actions in particular are designed to encourage governments, academics and other non-profit organisations, to join forces across Europe to tackle problems shared by many EU Member States. NHS organisations have been involved in the Joint Actions, which include partner organisations from many different Member States and jointly develop targeted solutions to common challenges.

4.2 The European Commission provides co-funding (usually up to 60% of costs) towards these collaborations. Of the 30 Joint Actions funded from 2008 to 2013, 25 (over 80%) had involvement from UK organisations. These collaborations included a wide variety of themes, including, Alzheimers, health technology assessment, rare diseases, patient safety, organ donation, chronic diseases, health inequalities and health security.

4.3 Of the 5 Joint Actions which have been launched in 2016, there are UK agencies nominated to be involved in all actions. This includes one Joint Action on antimicrobial resistance and healthcare associated infections, in which the UK (and most recently the O’Neill Review) has played a leading role globally.

4.4 Involvement in the EU Health Programme has allowed the NHS to develop standards and expertise with European colleagues which has helped us to work together to meet mutual challenges and needs.

4.5 To participate in the EU Health Programme, it is necessary to be an organisation from an EU Member State or the EEA, or have an agreement/ MoU to be a participating country.
5. Horizon 2020

5.1 The EU’s Research and Innovation Programme, called Horizon 2020, has an overall budget of over €70 billion, with €7.5 billion specifically dedicated to health research and innovation from 2014 to 2020. It offers significant opportunities to NHS organisations to source funding for the use of innovation therapies and tools for better patient outcomes. The UK was the Member State that benefited most from health projects in the predecessor to H2020, FP7.

5.2 We welcome the clarification given by HMT that the UK Government will underwrite payments under Horizon 2020, even when projects continue beyond the UK’s departure from the EU. This guarantee will help reassure partner institutions in other EU countries who have raised concerns about whether to continue to collaborate with UK institutions on EU funding bids.

Example 1: There are several examples of NHS involvement in H2020 and previous Framework Programme projects. Some examples of successful FP 7 projects led by NHS organisations are included as case studies in our briefing on Horizon 2020.

Several projects have also been funded more recently by Horizon 2020 which involve NHS partners. Two interesting examples from Horizon 2020 are:

Example 2: NEPHSTROM
The European Commission through its research programmes endeavours to fund collaborative clinical trials on common challenges, in particular where there gaps in the research pipeline. This example project is led by the University of Galway, Ireland and involves three UK NHS organisations, NHS Blood and Transplant, University Hospital Birmingham NHS Foundation Trust (Queen Elizabeth Medical Centre) and Belfast Health and Social Care Trust. This project is conducting a phase 3 clinical trial on a novel therapy (Stromal Cell Therapy) to combat Diabetic Kidney Disease. Type 2 Diabetes will affect more than 500 million adults by 2040. As well as the human cost, its secondary complications will generate enormous socioeconomic costs. This includes diabetic kidney disease (DKD), which is already the most common cause of chronic kidney disease. The results of this project could have a significant impact on the NHS. Type 2 diabetes treatment currently accounts for just under nine per cent of the annual NHS budget. This is around £8.8 billion a year.

Example 3: SMART4MDD
This project, led by the Anglia Ruskin University, including South Essex Partnership University NHS Foundation Trust as a partner is developing an mHealth tool specifically targeted to patients with mild dementia. The tool will help patients to adhere to their treatment and share data with their carers and doctors. The pilot project aims to increase patients’ adherence to treatment, while improving the quality of life of carers and patients. It also aims to bring considerable savings to healthcare providers. In England it is estimated that around 676,000 people have dementia. In the whole of the UK, the number of people with dementia is estimated at 850,000. There is a considerable economic cost associated with the disease estimated at £23 billion a year. This project fits well with the 2015 Challenge on Dementia 2020, sets an aim that by 2020 the UK is the best country in the world for dementia care and support for individuals with dementia, their carers and families to live and the best place in the world to undertake research into dementia and other neurodegenerative diseases.
6. **Multi-national clinical trials**

6.1 A new EU Clinical Trials Regulation is due for full implementation in 2018 to improve rules in this area. In particular, it seeks to streamline the procedures to assess and authorise new clinical studies, removing duplications and reducing delays for launching clinical trials.

6.2 Importantly, these new EU rules will introduce a number of flexibilities and simplifications which will make it easier for NHS trusts to participate in multinational clinical trials, as outlined in our briefing *The new EU Clinical Trials Regulation: how NHS research and patients will benefit.*

6.3 As an example of the practical impact of these positive changes, it would in the future be possible to launch a clinical trial with patients in several different countries through the submission of a single application dossier, instead of having to apply separately in each of the countries involved. This is a significant change and will certainly speed up the time for launching multi-country clinical trials, such as those looking into treatments for rare diseases which, by their very nature, require the participation of patients from several different countries.

6.4 Consideration should be given to how to ensure that these positive changes will be maintained in the future.

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**Example: Clinical Trials on Medicines for Children**

Many paediatric illnesses have a high public health impact but are uncommon. Multinational collaboration is the most effective way to develop treatments for many conditions affecting children.

The current European landscape for paediatric research infrastructure includes the European Network of Paediatric Research at the European Medicines Agency (EnprEMA) and the chair of the network is a senior NHS clinician from the UK.

EnprEMA is mandated under Article 44 of the Paediatric Regulation (1901/2006) to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population. EnprEMA does not receive any funding to support paediatric trials and/or their organisation/management. The UK leads an initiative to set up a European joint infrastructure on paediatric clinical trial infrastructure, building on the globally recognised strengths of the NIHR CRN, and has ensured that this paediatric work is included on the Road Map of the European Strategic Forum of Research Infrastructure. As a result of the Leave vote, there is uncertainty about whether the UK can to continue to lead, or even to be involved with, EnprEMA or the Research Infrastructure that is informed by UK experience.

EU funding for Paediatric research has been somewhat fragmented, but is significant and has filled gaps where other funding has been insufficient. This includes projects such as TEDDY, GRIP with major UK involvement and leadership. FP7 funded 20 research projects about off-patent medicines that are widely used despite the lack of an evidence base. The UK was involved in more of these projects than any other country. The UK had the largest number of participants in these projects including SMEs, NHS Trusts and HEIs.
7. **European Innovation Partnership on Active and Healthy Ageing**

7.1 The European Innovation Partnership on Active and Healthy Ageing (the Partnership) was initiated in October 2010 to tackle the common challenge of an ageing population in Europe. It brings together public and private stakeholders to develop new innovations which can improve the quality of life of older people, whilst simultaneously creating market opportunities for businesses. The Partnership aims at improving the conditions for uptake of innovation, leveraging financing and investments in innovation and improve coordination and coherence between funding for research and innovation at European, national and regional level in Europe.

7.2 This year five English regions (all with NHS partners) and Scotland, Northern Ireland and Wales have been successfully recognised as European Reference Sites in Active and Healthy Ageing, celebrating their proven track record in developing, adopting and scaling up innovative digital solutions for their populations. Greater Manchester, North West Coast and North East England have been successful for the first time, while it’s second time success for Liverpool and Yorkshire and the Humber, Wales, Northern Ireland and Scotland.

7.3 While this is not EU funded, these networks facilitate expertise and knowledge sharing at pan European level. They also provide a platform for economies of scale and larger potential markets for industry as they develop innovation which meets the needs of a wide stakeholder group. Also they have helped raise the profile of the excellent innovation in the NHS across the UK – which in turn encourages interest from innovative industries and researchers. The partnership is accessed through EU membership.

8. **Conclusions**

8.1 In view forthcoming negotiations with the EU, consideration should be given to how to ensure that:

- the NHS can continue to play a leading role in medical science internationally going forward;
- there will be no risk to slow down the speed at which innovation is taken up and translated into medical practice in the NHS;
- patients’ ability to take part in multi-national clinical trials will not be constrained.

**About us**

Hosted by the NHS Confederation, the NHS European Office is the representative body for the range of NHS organisations in England on EU affairs. Our work includes monitoring and influencing EU policy and legislation in the interest of the NHS, facilitating access to EU funds for NHS bodies and their partner organisations and supporting pan-European collaborations and sharing successful EU practices.