

From the President
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29 November 2012

Rt Hon David Cameron MP
Prime Minister
10 Downing Street
London
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Dear Prime Minister,

I am writing in light of the forthcoming anniversary of your speech that launched the *Strategy for UK Life Sciences* and *Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS*.

The Academy of Medical Sciences continues to support your vision to position the UK as the best place in the world to translate scientific discovery into clinical use and bring medical innovation to patients more quickly. Our Fellows and established partnerships enable us to add value at the intersection of medical science, healthcare and policymaking, and we are committed to maximising this unique position to support the delivery of the Life Sciences Strategy. Whilst we acknowledge that the Strategy is a long term vision, the anniversary of its launch provides a timely opportunity to reflect on the initiatives that have been announced. The views in this letter reflect discussions that the Academy has had with representatives of the public, private and charitable funders of life science research. I enclose a short document summarising the Academy's work that supports the delivery of the Life Sciences Strategy and the aims of the Innovation Health and Wealth report. We would be pleased to provide further information on this, or any of the issues highlighted in this letter.

We welcome the funding provided under the Strategy for specific areas of research, such as **stratified medicine** and **regenerative medicine**. Our recent international symposium on stratified medicine explored solutions to the regulatory, economic and infrastructure barriers to the development and adoption of this approach to therapy in the UK with a view to maximising the effectiveness of the Government's investment in this area. More broadly, we consider research to be a fundamental part of a modern industrial strategy. In particular, it is crucial that there is **long-term, sustained, ring-fenced public funding for basic through to translational science** to fuel the development pipeline in the UK and to address the Government's priorities including realising the full potential of genomics, 'big data' and dementia. The replacement, reduction and refinement of the use of animals in research remain guiding principles for research involving animals but Government support for, and effective regulation of, their appropriate use for biomedical research purposes remains crucial.

Continued efforts to **breakdown cultural barriers and encourage collaboration and mobility between academia, industry and the NHS** are essential to realise the benefits of public funding, and is a key objective of the Academy's five-year strategy. The high quality of UK's centres of excellence, often underpinned by effective collaboration between these sectors, attract investments from both the UK and abroad. We value the development of increasingly co-ordinated strategies between the Department for Business, Innovation & Skills, Department of Health and Treasury in recent years, which are essential in ensuring policies that support a vibrant life sciences ecosystem.

We note that the **Patent Box** and amendments to the **R&D tax credit** have been welcomed by industry. Ongoing innovation in this area will enable the Government to build on this early success and incentivise more business investment. The **Biomedical Catalyst Fund** is another scheme that has been welcomed by the sector and has leveraged significant private finance. To capitalise further, the Government may wish to consider expanding the scheme to include small and medium pharmaceutical companies, and 'evergreening' the Fund with longer term support, for instance, over ten years.

Embedding a culture of research and innovation across the NHS is a crucial component of developing a thriving UK life sciences sector. The National Institute for Health Research (NIHR) has done much to create a stable and sustainable base for research within the NHS. Our work to identify and reduce barriers to clinical trials and other health research will help to reverse their decline in the NHS and we welcome the efforts of the Health Research Authority, supported by the community, to **develop a more streamlined and proportionate approach to regulation**.

Adoption and diffusion of innovation in the NHS, for instance in the use of genomic technology, remains a challenge and could undermine Government measures to increase UK competitiveness and investment in this area. We welcome the proposed establishment of **Academic Health Science Networks (AHSNs)**, which aim to address some of these issues. Awareness and understanding of the purpose, role and modes of engagement with these networks, however, remain low in some parts of the life sciences sector. More work is required to ensure that this initiative leads to a step change in the anticipated collaboration between the different stakeholders, including industry. Consideration should also be given to how AHSNs map onto and maximise (rather than diminish) the strength of existing geographic and subject-specific clusters.


AHSNs, particularly those with well developed and integrated clinical trials expertise, could lead on novel approaches such as **adaptive licensing** which, provided there is timely adoption by the NHS, will offer faster access for patients to innovative medicines and earlier revenue for the medicine developer. We see cross-sector debate on the development of these adaptive approaches, including the identification of appropriate pilots, as a priority. The current negotiation on **value based pricing** of medicines is another area that requires close attention. It is vital that the agreed system allows flexible pricing - both up and down - based on evidence of the medicine's effectiveness post-launch to ensure ongoing industry investment, for example in the area of stratified medicine.

Another vital component that underpins the delivery of the Life Sciences Strategy is a robust **health informatics** system. The Academy is a strong advocate for the use of patient data for research with appropriate safeguards and we welcome the different Government initiatives in this area, including the launch of the Clinical Practice Research Datalink (CPRD) and the proposed amendments to the NHS Constitution. Ongoing funding for infrastructure and technological development, as well as operational resources, to underpin the use of patient data will be essential if the UK is to realise its full capability in this area and retain a competitive edge over other countries.

In **summary**, the Biomedical Catalyst Fund, the Patent Box and the amended R&D tax credits are widely seen as successes. The work to improve the regulation and governance of health research and the aims of AHSNs are seen as positive, although it is too early to be certain how successful these will be. The challenges of adoption and diffusion within the NHS remain a concern. There is a desire to see more progress in developing an approach to adaptive forms of licensing and to ensure that flexibility is built into value based pricing. Finally, there is unanimous agreement that continued government investment in a strong science base and a robust informatics system is essential to underpin these more specific actions, along with ongoing efforts to promote effective collaboration between academia, industry and the NHS.

We look forward to continue working with the Government to strengthen the UK's position as a global hub of biomedical innovation and investment.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'John Tooke', with a long horizontal stroke extending to the right.

cc Rt Hon David Willetts MP
Lord Howe
Sir John Beddington FRS
Dame Sally Davies FMedSci

Overview

This document highlights the work of the Academy with direct relevance to the actions contained in the *Strategy for UK Life Sciences*¹ and *Innovation, Health and Wealth*². Our activities are primarily summarised against the five key themes outlined in the Life Sciences Strategy Update from the Department for Business Innovation & Skills in August 2012 but the document also includes sections on cross-cutting issues and on adoption of innovation in the NHS.

The work of our individual Fellows, the leading researchers in academia, industry and the NHS, is vital in delivering the Government's vision for UK Life Sciences. The Academy as an institution is also helping to maximise the health and wealth benefits of the UK's Life Sciences sector through its policy activities.

Cross-cutting

- The Academy hosted an international symposium on **stratified medicine** in October 2012. The meeting focused on the ongoing regulatory, economic, and infrastructure requirements for the adoption of stratified medicine approaches in the UK and will help maximise the value of Government's investment in this area. The report, expected in spring 2013, will have recommendations that cut across the Life Sciences Strategy and require collaborative working from multiple stakeholders including academia, industry, the NHS and regulators.
- We are generating and collecting evidence about the **impacts of publicly funded research** and its ability to leverage private and charitable funding. Work by the Academy, Wellcome Trust and the Medical Research Council (MRC) has clearly demonstrated the economic returns of public investment in medical research in the areas of cardiovascular diseases and mental health (£0.39 and £0.37 for every £1 invested, in perpetuity)³. In collaboration with Cancer Research UK, the Wellcome Trust and the Department of Health, we are commissioning similar research on the impact of cancer research funding that will be published in 2013. We are also collecting evidence of research impact in the form of case studies from our Fellows.

¹ Department for Business, Innovation and Skills (2011). *Strategy for UK Life Sciences*.

<http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences.pdf>

² Department of Health (2011). *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131784.pdf

³ Health Economics Research Group at Brunel University, Office of Health Economics and RAND Europe (2008). *Medical research: what's it worth?* <http://www.acmedsci.ac.uk/index.php?pid=99&puid=137>

1. Research clusters and collaborations

- In November, the Academy launched the report of its roundtable on '**team science**' which is part of its ongoing work to identify attributes for successful collaborations, partnership and networks⁴.
- We are actively engaged in debates around maximising the value of the new Academic Health Science Networks and establishing productive partnerships between industry, academia and the NHS.

2. Data

The Academy is a strong advocate for the use of **patient data in research**, with appropriate safeguards.

- We co-hosted a meeting in Parliament this summer on the value of patient data with the All-Party Parliamentary Group on Medical Research and key medical research funders.
- We co-signed a letter to the Times welcoming plans to update the **NHS Constitution** and an associated consultation that will clarify how patients can expect their data to be used to improve healthcare and to offer them opportunities to take part in trials of new drugs and treatments.

3. Improving the environment, including for SMEs

Proportionate regulation and governance

- The Academy is committed to following its report, ***A new pathway for the regulation and governance of health research***⁵, including the development of the **Health Research Authority (HRA)** (where we are represented on the Collaboration and Development group). We publicly welcomed the recent announcement that HRA will explore whether it can provide the study-wide checks relating to health research that are currently carried out by each NHS Trust. This would reflect one of the most significant recommendations of our report.
- The Academy is actively engaged in ensuring that the revisions to European legislation do not adversely affect medical research.
 - We have published a joint statement on the **Clinical Trials Regulation**⁶, will brief MEPs and will participate in a reference group convened by the Medicines and Healthcare products Regulatory Agency (MHRA) to inform the UK's position.
 - We have taken a leading role in preparing a pan-European statement on the European Commission proposals for a new **Data Protection Regulation** in collaboration with the Federation of European Academies of Medicine (FEAM) and the Wellcome Trust⁷. We are now engaging with

⁴ Academy of Medical Sciences (2012). *Team Science Discussion Paper*. <http://www.acmedsci.ac.uk/index.php?pid=47&prid=117>

⁵ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. <http://www.acmedsci.ac.uk/p47prid88.html>

⁶ For further information see <http://www.acmedsci.ac.uk/p47prid118.html>

⁷ For further information see <http://www.acmedsci.ac.uk/p47prid107.html>

policymakers at the UK and European level to ensure that this regulation facilitates medical research.

- **The use of animals** is an essential component of biomedical research and an active policy area for the Academy. We have liaised extensively with the Home Office throughout the process of transposition of the European Directive 2010/63/EU on the protection of animals used for scientific purposes, both independently, and as a member of the UK Bioscience Sector Coalition⁸. We are a key partner in the development of a concordat on openness in the use of animals in research.
- Working with other stakeholders, the Academy seeks to identify areas of regulatory uncertainties arising from scientific developments and ensure that any changes in regulation are sufficiently future-proofed.
 - We held a joint forum with the Association of the British Pharmaceutical Industry (ABPI), Economic and Social Research Council (ESRC), MRC and MHRA on the **regulation of regenerative medicine** (October 2012). Along with our work on stratified medicine, this will support the most effective use of additional funding announced by Government.
 - We will hold a joint workshop to explore new ways to establish **medical device safety and efficacy** with the Royal Academy of Engineering (January 2012).

4. Global marketing of UK

- The Academy, and its Fellows, engage with senior international figures in medical science and champion the UK's strength in this area. This year we have arranged high level roundtable with Dr Tom Frieden; Director of the US Centers for Disease Control; hosted Professor Harvey Fineberg, President of the US Institute of Medicine; and supported the staff of the UK's Science and Innovation Network.
- Through our press and communications activities we promote positive changes in the UK Life Sciences environment, such as improvements in regulation and governance, to an international audience, including industry.

5. Skills, talent & workforce

- The Academy is an authoritative voice on the development of academic training and careers across the clinical and biomedical spectrum. Currently we are engaging with the review of the structure of postgraduate medical education and training to ensure that it supports academic trainees and delivers a workforce that meets future health needs.
- We are a leader in the development and mentoring of the UK clinical academic workforce with funding and support to nurture the next the generation of medical researchers.
- The looming fiscal cliff in the US presents major opportunity for UK science to recruit some of the world's greatest scientific talent. We have been seeking to ensure that immigration policy facilitates the mobility of researchers. The

⁸ For further information see <http://www.acmedsci.ac.uk/p47prid76.html>

Academy also provides immigration advice (via the Royal Society) regarding 'exceptionally talented' clinical academics.

- We are working with a group of Learned Societies to explore how to ensure the ongoing supply of skilled researchers to support UK drug development.

Adoption of innovation in the NHS

The Academy is a strong advocate of the NHS acting as a driver and adopter of research and innovation and supports the actions contained in *Innovation, Health and Wealth; Accelerating Adoption and Diffusion in the NHS*, as well as the Life Sciences Strategy. We will continue to highlight the importance of embedding a culture of research and innovation across the NHS. Some of our recent activities in this area are listed below.

- We responded to the Department of Health's consultation on the draft **Mandate for the new NHS Commissioning Board**⁹ and welcomed the inclusion to promote and support participation by NHS organisations and patients in research, as one of the Boards' objectives in the new Mandate.
- The Academy co-hosted a series of regional meetings with National Institute for Health Research and the NHS Confederation to mobilise NHS R&D Directors and related staff to drive work on achieving faster, easier clinical research locally.
- The Academy is one of the Board members of the **NICE Implementation Collaborative (NIC)**, to support consistent and prompt uptake of NICE guidance.

⁹ Academy of Medical Sciences (2012). *Response to 'Developing our NHS care objectives: A consultation on the draft mandate to the NHS Commissioning Board'*. <http://www.acmedsci.ac.uk/p100puid252.html>