The Academy of Medical Sciences

Submission to the 2011 innovation and research strategy

Summary

Innovation in the medical sciences offers Government an engine for renewed economic growth that could help to reduce public debt, create jobs, cut the deficit, rebalance the economy and allow the UK to better compete internationally. To harness the power of medical research, Government should commit to long-term support for a broad, diverse national science base. This will give companies, researchers and charities the confidence and support that they need to translate scientific advances into benefits for patients and society. Outlined below are a number of opportunities under the four areas Government identified in developing its strategy:

Driving innovation across the economy

- Ensure that funds available for the translational research should support the best activities whether they involve the private sector, public sector or cross-sector collaboration.
- Consider how assets from across academia, large pharmaceutical companies and small biotechnology firms could potentially be combined to facilitate the growth of medium sized biotechnology companies.
- Create fiscal incentives such as consortium tax relief to encourage investment by large, established companies in small and innovative businesses.
- Support areas of medical science that are on the cusp of translation into benefits for patients and society, such as stratified medicines, diagnostics, medical devices and regenerative medicines.
- Develop immigration policies that attract and retain the best medical research talent in the UK.

Strengthening the sharing and dissemination of knowledge in the innovation system

- Implement measures to encourage the mobility of medical researchers between academia, industry and the NHS.
- Enhance the performance of UK geographical clusters and establish better shared programmes and facilities between the commercial and academic sectors.

Creating a more coherent and integrated innovation infrastructure

- Encourage the development of safe and secure systems and governance arrangements at the local or national level, which enable researchers to access both anonymous and identifiable patient information for important research, while protecting patients and researchers.

Ensuring that the public sector is a major driver of innovation

- Implement the recommendations of the Academy's recent report '*A new pathway for regulation and governance of health research*'.

- Consider expanding the role of the Biomedical Research Units and Centres (BRUs/BRCs) and Academic Health Science Centres (AHSCs) in driving innovation and the evaluation of new interventions in the NHS.
- Drive cultural change in the NHS to ensure health research and the uptake of innovation is formally embedded within NHS leadership and governance processes by: ensuring appropriate responsibility for innovation across new NHS structures; raising the profile of the NHS as a centre for innovation; and linking the performance of NHS Trusts and Clinical Commissioning Groups to the adoption and diffusion of innovation.
- Foster innovation in the NHS through: procurement; consistent and swift local and national decision making; and replacing older less effective technologies with superior new ones rather than retaining both.
- Implementing measures to streamline decision-making regarding the value of new medicines, removing national and local level duplication and re-interpretation, and introducing strict deadlines for local commissioning decisions.
- Harness the Research Excellence Framework (REF) to encourage academics to participate in entrepreneurial and translational science, as well as maintaining the system of Clinical Excellence and Distinction Awards to help incentivise clinical academics.

With the right policy choices, Government can make the UK the best location in the world for medical research across the public and private sectors, attracting vibrant medical science industries and skilled researchers.[1]

Introduction

The Academy of Medical Sciences welcomes the opportunity to provide input into the forthcoming innovation and research strategy. We support the inclusion of 'research' alongside 'innovation' in the strategy, as both are integral components of the knowledge economy of the 21st century.

To ensure that the innovation and research strategy has maximum impact it should be joined up with the Office of Life Science's Review and NHS Innovation Strategy, to which the Academy has also contributed.[2,3] As a priority, Government should ensure that any new initiatives to emerge from the strategy compliment existing arrangements and do not divert vital resources from successful programmes. The Health and Social Care Bill offers a particularly timely opportunity to embed innovation and research in the NHS; further details of how this might be achieved can be found in the Association of Medical Research Charities (AMRC) briefing paper '*Building research into the health system'*.[4] Many of the messages in this submission echo those in the recent Cancer Research UK (CRUK) report '*Building the ideal environment for medical research in the UK*'.[5]

---

[1] Academy of Medical Sciences (2010). *Biomedical research: a platform for increasing health and wealth in the UK*. http://www.acmedsci.ac.uk/p48prid84.html
[2] Academy of Medical Sciences (In press). *Response to the Office of Life Sciences Review*.
[3] Academy of Medical Sciences (In press). *Response to the NHS Chief Executive's Innovation Review.*
[4] Association of Medical Research Charities (2011). *Building research into the health system.* http://www.amrc.org.uk/news-policy--debate_policies-positions-and-guidance_briefing-papers
[5] Cancer Research UK (2011). *Building the ideal research environment for the UK*. http://info.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_076936.pdf

Medical science and innovation are engines of economic growth

Groundbreaking advances in medical science over the last 30 years offer the UK unprecedented opportunities to improve health, generate economic growth, create jobs and rebalance the economy. For instance, every £1.00 invested in public or charitable research into cardiovascular diseases in the UK between 1975 and 1992 produced a stream of health and economic benefits equivalent to earning £0.39 per year in perpetuity.[6] Public investment leverages private investment: a recent study showed that every £1 increase in public funding stimulates up to £5 investment into research by the pharmaceutical industry.[7] With private spending on health-related goods and services in the major emerging markets of China and India expected to reach 13-14% of household consumption by 2025, the medical sciences offer a major driver for future growth. [8]

The UK's world class medical science and innovation

Medical science is one of the most significant and productive sectors in the UK, and comes near to financial services in terms of economic importance.[9] The UK has a vibrant pharmaceutical and biotechnology sector that is the largest in Europe and second in size only to the USA. With only 1% of the world's population we generate 12.7% of the world's clinical science citations and 13.8% of the world's health science citations.[10]

Despite an unprecedented phase of scientific discovery that has generated opportunities to develop novel medicines, the commercial medical sector faces difficult issues in its R&D pipeline. [11] The number of new molecules approved for clinical use continues to fall despite increasing commercial expenditure on R&D. The impending expiration of patents on many older medicines will also lead to loss of profits in the pharmaceutical sector. Recent figures demonstrate a sharp decline in commercial clinical research being undertaken in the UK: in 2002, 46% of EU products in clinical trials were being developed in the UK but by 2007 this had fallen to 24%.[12]

To address these challenges and boost innovation and productivity, much of the pharmaceutical industry has adopted a new business model. Companies are now investing in flexible partnerships with

---

[6] 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

[7] Alzheimer's Research Society (2009). *Forward together. Complementarity of public and charitable research with respect to private spending*. http://www.ohe.org/publications/recent-publications/list-by-date-20/detail/date////forward-together-complementarity-of-public-and-charitable-research-with-respect-to-private-research.html

[8] Department of Business, Innovation and Skills (2010). *Life science in the UK – economic analysis and evidence from 'Life Sciences 2010: Delivering the Blueprint'*. http://www.bis.gov.uk/assets/biscore/economics-andstatistics/docs/10-541-bis-economics-paper-02

[9] Academy of Medical Sciences (2010). *Biomedical research: a platform for increasing health and wealth in the UK*. http://www.acmedsci.ac.uk/p48prid84.html

[10] Department for Innovation, Universities and Skills (2009). *International comparative performance of the UK research base.* http://webarchive.nationalarchives.gov.uk/tna/+/http://www.dius.gov.uk/publications/IntComparativePerformanceUKResearch.pdf/

[11] Bioscience Innovation Growth Team (2009). *The review and refresh of bioscience 2015*. http://www.bis.gov.uk/files/file49805.pdf

[12] Bioscience Innovation Growth Team (2009). *The review and refresh of bioscience 2015*. http://www.bis.gov.uk/files/file49805.pdf

biotechnology firms and universities to access specialist expertise and share skills and resources. No other country is as well placed as the UK to benefit from the opportunities of this new model and the rearrangement of assets, people and investment. Bold leadership is needed now to make the UK a prime location for medical research in both the private and public sectors. This will attract medical science industries and skilled researchers who will translate world-class medical science into health and wealth benefits.

A long term commitment to science

Medical science is a long-term endeavour, and areas of research that are terminated before they can deliver represent wasted investment.[13] The resulting loss of staff and expertise mean that projects and research areas cannot easily be resumed if funding subsequently becomes available. Without a clear long-term commitment to science from Government, companies are less likely to make the sustained investments in the UK that lead to jobs and economic growth. What is more, our brightest and best researchers may take their considerable talents abroad where support is more secure.

We welcome the Government's decision in the recent spending review to protect the medical and health research budgets. However, the UK's international competitors, in both the more developed and developing world, are realising the economic value of science by rolling out long-term investments over and above short-term economic stimulus packages.[14] In 2008, the UK spend on R&D was equivalent to 1.8% of GDP, below the OECD average of 2.34% and behind Israel, Finland, Sweden, Japan and Korea.[15]

We repeat our call for Government to make a long-term commitment to the UK's science base.[16] A new framework relevant to all areas of science should:

- Prioritise excellence, particularly excellent people.
- Safeguard our world-class universities, research institutes and university departments by concentrating funding on excellence.
- Protect the autonomy of universities and Research Councils, allowing them to respond flexibly and rapidly to a changing international research environment.
- Provide as much stability and certainty as possible by indicating upfront the overall level of future changes to funding.
- Focus on reversibility, allowing the UK to maintain capability to regenerate key areas when future funding becomes available.
- Maintain and grow the essential partnerships between public, private and charity sector funders, which leverage significant private and philanthropic investment and promote rapid translation of medical research into health and wealth outcomes.

---

[13] Academy of Medical Sciences (2010). *Academy submission to the spending review consultation.* http://www.acmedsci.ac.uk/p100puid198.html
[14] Academy of Medical Sciences (2010). *Biomedical research - a platform for increasing health and wealth in the UK*. http://www.acmedsci.ac.uk/p48prid84.html
[15] Campaign for Science and Engineering (2011). *Public funding of UK science and engineering: putting Government rhetoric to the test*. http://sciencecampaign.org.uk/?p=7144
[16] Academy of Medical Sciences (2010). *Academy submission to the spending review consultation.* http://www.acmedsci.ac.uk/p100puid198.html

- Ensure limited funds are spent most effectively by promoting co-ordination amongst funders and reducing unnecessary bureaucracy in areas such as medical research regulation.
- Foster a policy environment that facilitates research through proportionate and streamlined regulations and tackles novel areas of science such as Animals Containing Human Materials.[17,18]
- Monitor the impact of changes to higher education funding on the uptake of Science, Technology, Engineering and Medicine (STEM) courses to ensure a supply of future scientists.

Interdisciplinary opportunities

Given the Academy's constituency, we have focused primarily on medical science in our submission.[19] However, many of the immediate challenges facing society today, such as ageing or obesity, require expertise from across the full range of medical, natural, engineering, humanities and social science disciplines. For example understanding the genetic basis of disease is increasingly reliant on mathematics and computing and the insights provided by the social sciences are essential in translating the findings of medical research into public health benefits. In short, support is required across the research base to safeguard the valuable advances that benefit patients and society.

Driving innovation across the economy

Fueling the pipeline

Our universities are a unique strength and an important source of compounds and technologies that have commercial potential. Universities need more support in thinking strategically and incubating a portfolio of products for longer to increase the potential for investment from venture capital and the pharmaceutical industry. Strong and coherent public programmes to support early phase innovation in universities will leverage further inward investment in the UK and bridge the gap between idea generation and commercial financing. A number of schemes already exist to facilitate technology transfer and to fund the space between academia and industry, including the MRC's Developmental Pathway Funding Scheme.[20] However, there are significant opportunities for enhancement of such schemes, and funds available for translation should be used to support the best translational activities, regardless of whether they involve the private sector, public sector, or cross-sector collaboration.

Supporting a vibrant small company sector

Reducing the time that innovations require private risk capital investment, and allowing hubs for biotechnology and innovation to evolve in areas of world leading academic and commercial activity, will have a significant impact on the small company sector. A strong UK biotechnology sector is increasingly important, both in the creation of clusters and to attract a significant share of international investment to the UK.

---

[17] Academy of Medical Sciences (2011). *A new pathway for regulation and governance in health research*. http://www.acmedsci.ac.uk/p47prid88.html
[18] Academy of Medical Sciences (2011). *Animals containing human material* http://www.acmedsci.ac.uk/p47prid77.html
[19] Academy of Medical Sciences (2010). *Academy submission to the spending review consultation.* http://www.acmedsci.ac.uk/p100puid198.html
[20] Further details are available from: http://www.mrc.ac.uk/Fundingopportunities/Grants/DPFS/index.htm

The UK currently lacks medium sized life science companies that can function efficiently with a portfolio of products and programmes, realising the full potential of experienced scientific and managerial staff, and enabling improved decision making on commercial opportunities. Consideration should be given to how assets from across academia, large pharmaceutical companies and small biotechnology firms could potentially be combined to facilitate the growth of medium sized companies, following the examples of Gilead, Amylin or Cephalon, which currently operate largely outside of the UK.

Fiscal incentives

In a global market, it is vital that fiscal incentives are in place to support UK biotechnology firms and ensure they attract a significant share of pharmaceutical and risk capital investment. Consortium relief is an important way of encouraging investment by large, established companies in small and innovative businesses, as it allows a consortium of corporate investors to offset the losses of the small business against their taxable profits. Consortium relief in the UK would encourage earlier interactions between biotechnology and pharmaceutical companies and would provide a significant fiscal incentive to encourage this sector to thrive. Measures that promote investment from 'high-value' individuals and the corporate venture funds of 'big pharma' are crucial and would increase risk capital flow into this vital sector of the economy.

Immediate opportunities for innovation in the medical sciences

Many recent UK scientific advances are now on the cusp of translation into benefits for patients and society. Important opportunities that might quickly contribute to health and wealth include:[21]

- Delivering more effective treatments to the right groups of patients through stratified (personalised) medicines.
- Molecular diagnostic tools to improve the diagnosis of disease and detect markers of its severity, and genome-wide association studies to offer novel insights into the genetics of common diseases, such as type II diabetes and depression.
- Medical devices for unmet needs, such as robotic surgery, medical implants and prostheses.
- Regenerative medicines such as alternatives to blood, cell-based therapies and interventions to restore vision and motor function.

Attracting the best international talent

To maintain our role as a leading scientific nation in the face of substantial investment in science in other countries the UK must continue to attract world-class research talent. While Government has gone some way to reduce the impact of recent changes to immigration policy on medical research, concerns still remain, including:

- Recent changes to immigration policy risk sending a message to researchers abroad that the UK is not 'open for business' so they may not consider applying to work here. Considerable efforts are needed to ensure that there is an understanding among medical scientists internationally that the UK welcomes their talents.

[21] Academy of Medical Sciences (2010). *Reaping the rewards: a vision for UK medical science*. http://www.acmedsci.ac.uk/p48prid78.html

Strengthening the sharing and dissemination of knowledge in the innovation system

Mobility between academia, industry and the NHS

A key ingredient for successful sharing and dissemination of knowledge in the innovation system is the ability of researchers to move easily across academia, industry and the NHS. Improvements could be made in researchers' awareness and understanding of career opportunities across the sectors, particularly among academics who might consider careers in industry.[22,23] Areas for action include:

- Fostering interactions between academia, industry and the NHS such as short-term exchanges, secondments and mentoring across sectors.
- Promoting flexibility in career options, such as indicators of individual success that are shared across academia, industry and the NHS and mechanisms for clinicians to maintain clinical registration while in industry.
- Raising awareness such as 'industry days' at universities and the extended provision of open days at companies.
- Gaining a greater understanding of the UK biomedical research workforce profile by collecting and disseminating more data on workforce numbers to allow a more strategic appraisal of mobility between sectors.

Supporting a 'life science ecosystem'.

In the UK's world class universities, hospitals and companies we have the individual building blocks for a flourishing 'life science ecosystem'. The future of this sector lies in putting these elements together and collaborating to share expertise, skills and resources. In other countries, hubs for biotechnology and innovation have developed largely in clusters where a critical mass of academic scientists and institutions fuel a small company sector that ultimately supports the large pharmaceutical companies. The best international examples include the Bay Area in California, the San Diego cluster and the cluster around Boston. Successful clusters are characterised by a critical mass of academic and commercial scientific activity, a high percentage of the local population being degree-qualified, an exchange of personnel across the academic and industry sectors and a supportive legal, financial and capital infrastructure.

In the UK, a Scottish cluster based around four major universities has delivered commercial collaborations with a number of large pharmaceutical companies and resulted in the growth of a number of biotechnology prospects. The biotechnology sectors around Oxford (Thames Valley) and Cambridge are the largest in the UK and present opportunities to develop internationally competitive clusters. In short, enhancing the performance of UK geographical clusters and establishing better shared programmes and facilities between the commercial and academic sectors must be a priority for economic growth.

In addition to geographical clusters, networks that join expertise in specific disease areas, and bring together enabling technologies and cohorts of well characterised patients are powerful hubs for commercial interaction and inward investment. Translational Research Partnerships in the areas of

[22] Academy of Medical Sciences (2005). *The freedom to succeed*. http://www.acmedsci.ac.uk/p48prid31.html
[23] Academy of Medical Sciences (2007). *Careers for biomedical scientists and clinicians in industry*. http://www.acmedsci.ac.uk/p48prid56.html

'joint and related inflammatory diseases' and 'inflammatory respiratory disease' are the first attempt to do this in the UK.[24]

Creating a more coherent and integrated innovation infrastructure

Patient data for public good

The information contained in NHS patient records is a rich resource for medical research.[25] Patient data are essential for the delivery of healthcare services and for the recruitment of patients to clinical trials, research to understand disease, and the development of new treatments. A clear framework that enables the safe use of this information for research, while protecting both patients and researchers is vital. As part of efforts to create a more coherent and integrated innovation infrastructure, Government must encourage the development of safe and secure systems and governance arrangements at the local or national level, which enable researchers to access both anonymous and identifiable patient information for important research, while protecting patients and researchers.

Ensuring that the public sector is a major driver of innovation

A new pathway for the regulation and governance of health research

Despite the UK strengths in medical science, there is evidence that our health research activities are being seriously undermined by an overly complex regulatory and governance environment.[26] For example, a recent analysis from CR-UK showed that after funding for a study has been agreed, it now takes an average of 621 days to recruit the first patient.[27]

The Academy's recent report 'A new pathway for regulation and governance of health research' recommended the creation of a single health research regulator and the linking of funding and metrics for efficient sign-off of research approvals by NHS Trusts. We are pleased that Government has supported the thrust of our report in the 2011 Budget and associated Plan for Growth. However, to fully realise the opportunities offered by streamlined regulation we urge Government to:

- Provide a clear and comprehensive vision of the functions of the Health Regulatory Authority (HRA), its role in managing a coordinated regulatory and governance pathway, and how it will work alongside other relevant bodies. Ensure the HRA works closely with the Medicines and Healthcare Regulatory Authority (MHRA) to improve standards of compliance and inspection.
- Provide clarification on how the process by which NHS Trusts approve research studies will be streamlined in such as way as to achieve the required efficiency gains and ensure a single, consistent, efficient process for the NHS as a whole.

---

[24] Further details are available from:
http://www.nihr.ac.uk/industry/Pages/translational_research_partnerships.aspx
[25] Association of Medical Research Charities (2011) *Building research into the health system.*
http://www.amrc.org.uk/news-policy--debate_policies-positions-and-guidance_briefing-papers
[26] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.*
http://www.acmedsci.ac.uk/p47prid88.html
[27] The 621 days is the time from decision to support the study to first patient entered at the first site. This is the average time from 25 studies approved by Cancer Research UK's Clinical Trials Awards and Advisory Committee during the period of November 2006 to July 2007.

- Provide the HRA with powers to monitor the impact of changes to the regulatory pathway on approval times and ensure the UK becomes a more attractive location for academic and commercial research. This should include losely monitoring the impact of new metrics for R&D permissions for National Institute of Health Research (NIHR) funding and NIHR Research Support Services.

Engaging the NHS

NIHR has led the way in creating effective clinical and academic partnerships, including the NIHR BRCs and BRUs and AHSCs.[28] The BRCs/BRUs and AHSCs provide a locus for world-class translational research within the health service and have the potential to position the UK as a preferred site for clinical development by the pharmaceutical and biotechnology industries. As well as providing an engine for research, consideration could be given to expanding the role of the BRUs/BRCs and AHSCs in driving innovation and the evaluation of new interventions in the NHS. This could include embarking on joint development programmes with industry – particularly in diagnostics and devices – which share both risk and reward, and optimise the use of data for clinical studies and healthcare applications.

Efforts should also be made to ensure the wider health care system supports and recognises the importance of research and innovation to improved patient care. The Academy has long championed the opportunities for health research available through the NHS, and there are now important examples of what can be achieved when the right framework and culture are put in place, for example the Northwest Exemplar programme.[29] However, cultural change is required to ensure health research and the uptake of innovation is formally embedded within NHS leadership and governance processes.

Innovation: the uptake and adoption of new interventions

Our strengths in basic and translational research have resulted in the UK creating a quarter of the world's top 100 medicines.[30] However, this expertise in advancing knowledge and developing new treatments has not been routinely matched by an ability to quickly deliver the benefits to patients.

A national health system that supports and adopts innovation is a crucial component in fostering an environment where companies look to invest in the UK. However, a number of obstacles exist that currently hinder innovation in the NHS including: a tendency for the cost of new innovations to be loaded on top of existing technologies, adding to total cost rather than achieving an appropriate balance between cost and benefit; an approach that fails to utilise procurement as a mechanism to resource innovative technologies; and variation and delay in national and local level commissioning.

The NHS Chief Executive's ongoing review of innovation provides an important opportunity to address these obstacles and put in place a set of national and local incentives to accelerate the adoption and diffusion of innovations in the health service. The cultural obstacles to innovation must be removed by ensuring appropriate responsibility for innovation across new NHS structures, raising the profile of the NHS as a centre for innovation, and linking the performance of NHS Trusts and Clinical Commissioning Groups to the adoption and diffusion of innovation. Measures are needed to streamline decision-

[28] Further details are available from: http://www.nihr.ac.uk/infrastructure/Pages/default.aspx
[29] http://www.research.northwest.nhs.uk/programmes_of_work/exemplar_program
[30] Association of the British Pharmaceutical Industry (2004). *Innovating for a healthy tomorrow.* http://www.abpi.org.uk/publications/pdfs/annual_report_05.pdf

making regarding the value of new medicines, removing national and local level duplication and re-interpretation, and introducing strict deadlines for local commissioning decisions.

Incentivising researchers in academia and the NHS

Early phase translational studies of novel therapeutics represent one of the greatest challenges of biomedical research. Engaging the university sector more effectively in these activities, either in collaboration with industry or alone, will be crucial to enhancing the environment for biomedicine in the UK. Academics must be supported in undertaking early stage clinical studies, and incentive mechanisms such as the Research Excellence Framework should recognise the value of entrepreneurial and translational science activities. The UK should also maintain a system of Clinical Excellence and Distinction Awards, for which outstanding contributions to research, medical education and clinical leadership are key criteria.[31]

For further details about this submission please contact Laurie Smith on +44 (0)20 3176 2167 or laurie.smith@acmedsci.ac.uk

The Academy of Medical Sciences is the independent body in the UK representing the whole spectrum of medical science. Our mission is to ensure better healthcare through the rapid application of research to the practice of medicine.

The Academy of Medical Sciences
41 Portland Place
London W1B 1QH
Tel: 020 3176 2150
E-mail: **info@acmedsci.ac.uk**

Registered Charity No. 1070618
Registered Company No. 3520281

[31] Academy of Medical Sciences (2010). *Response to the consultation for the review of compensation levels, incentives and the Clinical Excellence and Distinction Award schemes for NHS consultants.* http://www.acmedsci.ac.uk/p100puid205.html