

Summary

1. The Academy of Medical Sciences welcomes the opportunity to contribute to this inquiry into bridging the 'valley of death' and improving the commercialisation of research. One of the Academy's strategic priorities is to link academia and industry. Our elected Fellowship includes some of the UK's foremost experts in medical science who have contributed to this response and who would be happy to provide oral evidence to this inquiry. The Academy's response focuses on medical research as this reflects the expertise of our Fellows.
2. The Academy commends the Government's strong commitments 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, driving economic growth in the process.^{1,2,3,4} However, we believe that there is an opportunity for the Government to go even further in supporting the commercialisation of life sciences research.
3. The biomedical sector is one of the most significant and productive in the UK with great potential to increase jobs, enable sustainable economic growth and increase tax revenue. Medium-sized companies are a vital part of the life sciences industry due to their ability to perform early phase translational research efficiently with a portfolio of products and programmes, maximising the impact of experienced scientific and managerial staff, and enabling improved decision-making on commercial opportunities. However, there are currently too few medium life science biotechnology companies operating in the UK. A major barrier is a lack of funding from public markets that too often perceive investment in biotechnology as too long-term and too risky. Increasing the opportunities of small biotechnology companies to grow into medium-sized enterprises can fill this gap in the UK biomedical sector.
4. The delivery of increased commercial output from basic research and the growth of the biotechnology sector relies on the availability of financial investment in translational research, and importantly on the broader policy framework within which new innovations are researched and developed. Currently both these areas present opportunities for improvement if we are to match international competitors.

¹ Prime Minister David Cameron (2011). *Speech on life sciences and opening up the NHS*
<http://www.number10.gov.uk/news/pm-speech-on-life-sciences-and-opening-up-the-nhs/>

² 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>

³ Department for Business, Innovation and Skills (2011). *Innovation and Research Strategy for Growth*.
<http://www.bis.gov.uk/assets/biscore/innovation/docs/i/11-1387-innovation-and-research-strategy-for-growth.pdf>

⁴ 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

5. ***Proximate measures to strengthen translational research:***
 - Increase the financial support available to translational academic research and innovative businesses through initiatives such as the Biomedical Catalyst Fund and the Technology Strategy Board.
 - Create tax incentives to encourage venture capital investment in innovative businesses such as consortium tax relief or capital gains tax deductions.
 - Allow adaptive licensing in combination with stratified medicines, decreasing the time to revenue generation to promote investment in translational research.
 - Encourage universities to work together to provide a unified and efficient approach to technology transfer that will allow intellectual property to be appropriately valued to help commercialisation.

6. ***Improving the innovation ecosystem:***
 - Improve the valuation of innovation during early translational research, and during uptake by expanding National Institute for Health and Clinical Excellence (NICE) evaluations beyond quality-adjusted life years (QALYs) to include the wider economic and social impact of implementation.
 - Promote interdisciplinarity to support new areas of research at the forefront of idea generation.
 - Facilitate career mobility to allow the sharing and dissemination of knowledge and skills throughout academia, industry and the NHS.
 - Strengthen collaborations between the academia, industry and the NHS by continuing to support and grow Academic Health Science Networks and open innovation technology hubs.
 - Streamline research regulation to reduce costs and bring medicines to patients more quickly.

Building the life science industries

7. Recent Government initiatives such as the Life Science Strategy, NHS Innovation strategy and Innovation and Research Strategy give important support for the commercialisation of life sciences research.^{5,6,7,8} Measures include the creation of the Biomedical Catalyst Fund, for small but economically important biotechnology companies, and efforts to foster productive links between the NHS, industry and academia, through the setting up of a Cell Therapy Technology and Innovation Centre. The Academy welcomes these initiatives in addition to previous policies such as the protection of the medical and health research budgets in the recent comprehensive spending review, translational research partnerships, and the establishment of the Office for the Strategic Coordination of Health Research (OSCHR) and the National Institute of Health Research (NIHR).

⁵ 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>

⁶ 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

⁷ Department for Business, Innovation and Skills (2011). *Innovation and Research Strategy for Growth*. <http://www.bis.gov.uk/assets/biscore/innovation/docs/i/11-1387-innovation-and-research-strategy-for-growth.pdf>

⁸ Academy of Medical Sciences (2011). *Submission to the 2011 innovation and research strategy*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Contribu.pdf>

8. The biomedical sector is one of the most significant and productive sectors in the UK.^{9,10} The success of the biomedical sector in the UK is underpinned by world class academic researchers, innovative pharmaceutical and biotechnology companies, internationally renowned universities, uniquely strong medical research charities, and the NHS - one of the largest single healthcare systems in the world.
9. For academic research to be translated into commercial application new innovations must be developed and tested in a clinical setting. This has in the past often been performed by large pharmaceutical companies able to invest the considerable sums required, which can be upwards of £1 billion for each new drug.¹¹ The development of new medical innovations is a long-term enterprise that can take between 11 and 14 years, during which time there is a high attrition rate of new innovations due to failure in clinical trials.¹² In addition there are fewer new therapeutic agents in the pipeline and many current therapeutic agents due to come off patent. This has led many pharmaceutical companies to adopt a new model of open innovation. By forming partnerships with small biotechnology companies, the NHS and academia, a culture of innovation is being created that helps to build upon the UK's strengths in academic research, increasing commercial output.
10. In the US, medium-sized biotechnology companies, such as Amylin Pharmaceuticals and Gilead, form a vital part of this innovation ecosystem. By making more efficient use of experienced scientific and managerial staff with sufficient resources to support innovation, these companies efficiently perform early phase translational research with a portfolio of products and programmes and enable improved decision-making on commercial opportunities. This leads to sustainable economic growth, job creation and increased tax revenue.
11. Small biotechnology companies face many hurdles before they can grow into medium sized firms. At each stage of the lengthy drug development process more investment is required, diluting the value of previous investments. The process of acquiring venture capital investment is often difficult and many businesses fail at this stage, producing the so called 'valley of death'.
12. In the UK the difficulties in acquiring investment often leads to trade sales to large pharmaceutical companies, allowing continued development of innovations and investors to receive some financial return. While this route has many strengths, there should also be more opportunities for small firms to grow into independent medium-sized companies. These will promote better return on investments in small biotechnology companies, and encourage re-investment that will boost economic growth.
13. Without the opportunity to grow in the UK, companies and their ideas will move abroad for commercialisation. One example of this phenomenon is research performed at the University of Oxford during the late 1980s leading to the discovery of the hormone amylin. This was commercialised in San Diego, USA, by Amylin Pharmaceuticals where a synthetic form of amylin was developed and is now used in the treatment of diabetes.

⁹ Academy of Medical Sciences (2010). *Biomedical research: a platform for increasing health and wealth in the UK*. <http://www.acmedsci.ac.uk/download.php?file=/images/project/Biomedic.pdf>

¹⁰ 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-and-statistics/docs/10-541-bis-economics-paper-02>

¹¹ Paul S, et al. (2010). *How to improve R&D productivity: the pharmaceutical industry's grand challenge*. *Nature Reviews Drug Discovery* **9**, 203-214

¹² Ibid.

14. We recommend both proximate measures to increase the funding available to bridge the 'valley of death' as well as measures that address the broader aspects of the innovation ecosystem.

Proximate measures to strengthen translational research

15. Outlined below are four proximate measures to strengthen the commercialisation of research.

Incubate innovations in academia and support early translational research

16. Our universities are a unique strength and an important source of compounds and technologies that present commercial opportunities.¹³ To reach their full potential universities need substantial public programmes to allow them to incubate innovations for longer, and to help support innovative companies during early translation. This will allow new spin-out companies to have a more developed product for commercialisation, increasing the ability of those firms to attract investment and the likelihood that new innovations will reach the market. In the long-term such support will provide substantial returns through health benefits associated with the use of innovative therapeutic agents, increased tax revenues, jobs and sustainable economic growth. A number of schemes already exist to help achieve this goal. These include the Medical Research Council's (MRC) Developmental Pathway Funding Scheme, the newly announced Biomedical Catalyst Fund and initiatives by the Technology Strategy Board (TSB). However, there are significant opportunities to increase the magnitude of such schemes in line with the scale of investment in countries such as the USA. Moreover, 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.

Provide financial incentives for translation

17. 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.¹⁴ 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. For example, the establishment of a patent box is leading to substantial investment by pharmaceutical companies such as GSK and many in industry have found R&D tax credits to be beneficial.^{15,16}
18. One fiscal incentive is consortium relief that 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. Another option might be deductions on capital gains tax on investment in biotechnology companies.

¹³ Academy of Medical Sciences (2011). *Submission to the 2011 innovation and research strategy*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Contribu.pdf>

¹⁴ *Ibid.*

¹⁵ GlaxoSmithKline (2010). *Government patent box proposals 'transform' UK attractiveness for investment*. http://www.gsk.com/media/pressreleases/2010/2010_pressrelease_10124.htm

¹⁶ Department for Business Innovation and Skills (2006). *Applying for R&D tax credits - case studies of companies' experiences*. <http://www.bis.gov.uk/assets/biscore/corporate/migrateddd/publications/f/file36112.pdf>

Adaptive Licensing

19. The development of novel therapeutic agents is a long-term and expensive endeavour, particularly due to the high costs associated with late stage clinical trials, which can disincentivise investment in biotechnology companies. Adaptive licenses that allow new drugs in NHS priority areas to be made available to NHS patients following preliminary safety studies and proof of efficacy will generate much needed revenue for companies earlier and provide benefits for patients more quickly. This can then aid funding for continued development of these therapeutic agents for a wider population. Stratified (personalised) medicines also offer a particular opportunity for the application of adaptive licensing.¹⁷

Technology transfer

20. The transfer of intellectual property out of universities into industry is a vital step in the commercialisation of research.¹⁸ This can be achieved by collaborating with industry on research with intellectual property rights negotiated at the outset, in addition to forming intellectual property right agreements with companies on innovations that have already been developed by university based research. While technology transfer has significantly improved over the past decade, many opportunities still exist to increase university performance in this area.
21. To perform technology transfer effectively, expertise in licensing negotiation, spinout creation and market research is required, in addition to an understanding of the value of the intellectual property, and knowledge of the costs and risks involved in product development.¹⁹ By promoting an increase in the ability of universities to work together to form a unified framework of technology transfer, with investment to promote university capacity in these areas, the commercialisation of research will be improved.

Improving the innovation ecosystem

The valuation of innovation and the importance of procurement

22. The industrial model of drug development often pays too little attention to the way in which medicines might be used in the clinic or the community. Early evaluation of the clinical, economic and social value of potential therapeutic agents should occur during preclinical stages and will ensure that funding for translational research goes to those areas most likely to fulfil unmet need and produce sustainable economic returns.
23. Opportunities for improved valuation of innovation are also present at the latter stages of the bench to bedside research pathway.²⁰ NICE evaluation of new therapeutic agents for adoption by the NHS are vital for ensuring value for money, and these evaluations should support innovation. One way to achieve this goal could be to extend the scope of NICE evaluations beyond QALYs to include the wider economic and social impact of

¹⁷ Academy of Medical Sciences FORUM (2007). *Optimising stratified medicines R&D: addressing scientific and economic issues*. <http://www.acmedsci.ac.uk/download.php?file=/images/event/stratifi.pdf>

¹⁸ Lambert R (2003). *Lambert Review of Business-University Collaboration*. London, HMSO. http://www.hm-treasury.gov.uk/d/lambert_review_final_450.pdf

¹⁹ NESTA (2012). *After the Life Sciences strategy: managing science-based R&D collaborations*. http://www.nesta.org.uk/events/assets/events/after_the_life_sciences_strategy_managing_science-based_rd_collaborations

²⁰ Academy of Medical Sciences FORUM (2007). *Optimising stratified medicines R&D: addressing scientific and economic issues*. <http://www.acmedsci.ac.uk/download.php?file=/images/event/stratifi.pdf>

implementation. This will allow the substantial expenditure on procurement made by the NHS to reward commercial investment in research and development, and expand business innovation.

24. The cost of healthcare in the UK has increased since the early 1990's due to factors such as the ageing population, increasing patient expectations and rising rates of chronic disease.²¹ However, the expenditure on medicines has actually decreased since 1997 in proportion to the total NHS expenditure, and is now less than 10% of the total NHS budget.²² Analysis by the Milken Institute showed that the lost economic output caused by the presence of chronic diseases is considerably higher than the cost of treatment.²³ This suggests that increased spending on innovative technologies through procurement that help to reduce the disease burden on society can have substantial economic benefits. One of the challenges is that the costs of new products are added on top of those which they would replace, thereby providing economic disincentives to the purchase of new innovations.

Interdisciplinarity

25. There is growing recognition that the challenge of the commercialisation of research is only going to be solved with an interdisciplinary approach. Cross-fertilisation of traditional academic disciplines from a wider range of relevant research areas must be encouraged, as it is often at these intersections that innovative research is initiated. For example, interactions between social science, economics and drug development could allow models of human behaviour to be further developed that facilitate patient adherence to prescription regimes. Moreover, a deeper understanding of the human biology that underpins health and disease would help better identify which new medicines might be successful. By encouraging the training of scientists able to span disciplines, innovation will be advanced.

Career Mobility

26. Highly skilled individuals are UK medical science's most valuable resource and play a significant role in attracting commercial activity and investment.²⁴ We must nurture and develop a pool of talented bioscience professionals – across the healthcare, academic and private sectors – who are equipped with the full range of skills needed to advance understanding and develop novel interventions and diagnostics for major diseases. This will aid researchers in acquiring the necessary entrepreneurial and management skills required to be able to commercialise academic research, and facilitate the sharing and dissemination of knowledge in the innovation system. Opportunities for promoting flexible collaboration across sectors should be seized to develop a biomedical workforce with the skills to move between and bridge sectors, these include:²⁵
- Fostering interactions between academia, industry and the NHS such as short-term exchanges, secondments and mentoring across sectors.

²¹ Scarborough P, et al. (2011). *The economic burden of ill health due to diet, physical inactivity, smoking, alcohol and obesity in the UK: an update to 2006–07 NHS costs*. Journal of Public Health **33(4)**, 527-535.

²² ABPI (2011). *Did you know? Facts and figures about the pharmaceutical industry in the UK*. http://www.abpi.org.uk/layouts/download.aspx?SourceUrl=http://www.abpi.org.uk/our-work/library/industry/Documents/Did%20you%20know_Jan11.pdf

²³ The Milken Institute (2007). *An Unhealthy America: The Economic Burden of Chronic Disease*. <http://www.milkeninstitute.org/healthreform/PDF/AnUnhealthyAmericaExecSumm.pdf>

²⁴ Academy of Medical Sciences (2011). *Submission to the 2011 innovation and research strategy*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Contribu.pdf>

²⁵ Academy of Medical Sciences (2007). *Careers for biomedical scientists and clinicians in industry*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Careersi.pdf>

- Promoting flexibility in career options, such as mutually agreed 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.

Collaboration

27. In the UK's world class universities, hospitals and companies we have the individual building blocks for a flourishing 'life science ecosystem'.²⁶ The future of this sector lies in putting these elements together and collaborating to share expertise, skills and resources. One major opportunity to increase collaboration, set out in the NHS Innovation Strategy, are Academic Health Science Networks that bridge academia and the NHS.²⁷ Supporting and growing these Networks will help them act not only as a hub for innovation, but as a framework for applied health research, diffusion of evidence and research-informed education.

28. 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 and skills across the academic and industry sectors and a supportive legal, financial and capital infrastructure. One important way to support the development of hubs is by increasing the funding available to set up open innovation centres, such as the Stevenage Bioscience Catalyst campus funded by TSB and GlaxoSmithKline. This new facility provides the infrastructure for small and medium enterprises to form a base that will facilitate partnerships with larger pharmaceutical companies allowing resources and skills to be shared.

Regulation

29. An overly complex regulatory and governance environment can undermine the innovation ecosystem, delay the time to revenue generation, increase costs and deter commercial investment. The Academy welcomes the creation of the Health Regulatory Authority (HRA) that aims to create a unified approval process and to promote proportionate standards for compliance and inspection as recommended in the Academy's 2011 report 'A new pathway for regulation and governance of health research'. However, to fully realise the opportunities offered by streamlined regulation it will be important to:^{28,29}

²⁶ Academy of Medical Sciences (2011). *Submission to the 2011 innovation and research strategy*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Contribu.pdf>

²⁷ 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

²⁸ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. <http://www.acmedsci.ac.uk/download.php?file=/images/project/130734957423.pdf>

²⁹ Academy of Medical Sciences (2011). *Submission to the 2011 innovation and research strategy*. <http://www.acmedsci.ac.uk/download.php?file=/images/publication/Contribu.pdf>

- Provide a clear and comprehensive vision of the functions of the 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 a way as to achieve the required efficiency gains and ensure a single, consistent, efficient process for the NHS as a whole.
 - 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 closely monitoring the impact of new metrics for R&D permissions for NIHR funding and NIHR Research Support Services.
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We are grateful to the Fellows of the Academy of Medical Sciences and experts for contributing to this response, which was approved by Professor Sir John Tooke PMedSci on behalf of the Academy of Medical Sciences' Council.

Declaration of interests

Many of the Academy's Fellows and experts who contributed to this response are involved directly or indirectly with academia, life sciences industries and the NHS. Further details are available upon request.

The Academy of Medical Sciences

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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