The Academy of Medical Sciences | FORUM

# Biotechnology innovation: opportunities and challenges

Meeting report, April 2009

The Academy of Medical Sciences

**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.

**The Academy's FORUM with industry**

The Academy's FORUM is an active network of scientists from industry and academia, with representation spanning the pharmaceutical, biotechnology and other health product sectors, as well as trade associations, Research Councils and other major charitable research funders. Through promoting interaction between these groups, the FORUM aims to take forward national discussions on scientific opportunities, technology trends and the associated strategic choices for healthcare and other life-science sectors.

The FORUM builds on what is already distinctive about the Academy: its impartiality and independence, its focus on research excellence across the spectrum of clinical and basic sciences and its commitment to interdisciplinary working.

This report provides a summary of the discussion at the FORUM roundtable on 'Biotechnology innovation: opportunities and challenges' held in March 2009. For further information please contact Dr Robert Frost, Manager, FORUM robert.frost@acmedsci.ac.uk.

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# Summary

In March 2009, the Academy of Medical Sciences' FORUM with industry convened a high-level roundtable meeting on 'Biotechnology innovation – opportunities and challenges'. The meeting was chaired by the Academy's President Sir John Bell FRS PMedSci and was attended by Lord Drayson, Minister of State for Science & Innovation. Delegates spanned senior figures in Government, the UK pharmaceutical and biotechnology sectors (and associated trade associations), academia and venture capital.

The purpose of the meeting was to: **explore the challenges currently facing the UK biotechnology sector, and discuss the steps needed to stimulate and sustain a vibrant, world-class biomedical sector.**

Participants stated that the key challenge facing the biotechnology industry is difficulty in attracting finance. Investors have become increasingly reluctant to invest in biotechnology citing: the long development times involved in drug development; the perceived conservatism of regulatory authorities; and increasing risk aversion in the community-at-large. As a result, it was suggested that many UK biotech firms have only 6 months of funding left. In the face of international competition, it is important that the UK utilises its competitive advantages to attract investment. New funding initiatives that involve venture capital, 'big pharma' and Government were identified as crucial to raising confidence in the sector.

Participants at the roundtable meeting agreed that an amalgamation of measures is needed to reinvigorate the UK life science sector. The roundtable discussion covered four key themes: innovation; finance; collaboration; and skills and the wider environment. Consensus was reached on a number of proposals:

- New capital funding for the UK bioscience sector; including initiatives that promote investment from Government, venture capital and 'large pharma'.
- Additional seed and proof-of-concept funding to enable bioscience companies to progress innovations.
- Creating incentives for international pharmaceutical companies to invest in UK biotechnology by:
    - Applying tax credits.
    - Allowing the losses of the SME to be off-set against taxable income.
    - Introducing tax-incentives for companies to exploit intellectual property in the UK.
- Encouraging pharmaceutical companies to collaborate in areas of UK strength e.g. in 'experimental medicine' and 'proof of concept' research, and stratified medicines and the molecular basis of disease.
- Encouraging universities to manage and incubate a portfolio of ideas to a later stage at which they can be picked up by industry.
- Promoting university-industry collaboration to share risk and reward in R&D.
- And in the longer term, addressing some of the cultural barriers to greater industry-government-academia collaborations.

Attention was drawn to the important role of the new Office for Life Sciences (OLS).[1] Led by Lord Drayson, the OLS has been created with a remit to address key issues affecting the bioscience sector and has been tasked, by the end of July 2009, with taking action to improve the operating environment for life sciences companies and build the UK's life sciences industry.

[1] www.dius.gov.uk/news_and_speeches/press_releases/office_life_sciences.aspx

# Background

The FORUM 'Biotechnology Innovation' roundtable meeting brought together international and national experts from a range of sectors to share perspectives on the current state of the UK biotechnology industry. The meeting was timely, and took place against a background of Government plans to ensure the UK maintains and realises its leadership position in life sciences. These plans, including the formation of the Office for Life Sciences, were outlined in Lord Drayson's 2009 FORUM Annual Lecture, which followed the roundtable meeting and was entitled 'UK life sciences – ensuring a healthy future'. Lord Drayson urged the roundtable meeting attendees to focus on the practical measures that would help UK biotechnology firms and make an immediate, material difference to the sector.

Following an introduction from Sir John Bell FRS PMedSci, Sir David Cooksey FMedSci provided an overview of the recently published report 'Bioscience 2015: review and refresh'. To initiate the discussion, perspectives on the challenges currently facing the life science industry were given by:

- Ms Aisling Burnand, Chief Executive Officer, BioIndustry Association
- Professor Patrick Vallance FMedSci, Senior Vice President, Drug Discovery, GlaxoSmithKline
- Dr Stephen Reeders, Partner, MVM Life Sciences
- Dr Helmut Schühsler, Managing Partner, TVM Capital & former Chairman of the European Private Equity and Venture Capital Association (EVCA)

The meeting agenda and full participant list are annexed.

# Introduction

No other country enjoys the outstanding opportunities for health research represented by the National Heath Service (NHS), which together with the world-class status of our researchers, universities and research funders, offers an unparalleled competitive advantage for the UK. The UK health research sector has:

- A historical record of international excellence in medical science – UK researchers punch above their weight in publications, citations and international prizes.
- First class universities, with four universities currently in the global top ten.
- World-renowned research funders, including the Medical Research Council (MRC), Wellcome Trust, Cancer Research UK and others.
- Impressive examples of industry-academic collaborations and commercialisation of academic research.
- The unique strategic advantages of the NHS, including the enormous potential of 'Connecting for Health' to support research and innovation.
- Public support, as evidenced through the strength of support for UK medical research charities.

A strong pharmaceutical and biotechnology sector is crucial to the UK's ability to turn scientific discoveries into new treatments and interventions. The UK has historically been the home of a strong pharmaceutical and biotechnology presence, with an industrial base second only to the US. In 2003, the Bioscience Innovation and Growth Team (BIGT), led by Sir David Cooksey, set out a vision to ensure the UK's medical bioscience industry maintained a leading place on the global stage. The vision, articulated in the report 'Bioscience 2015',[2] aimed to provide a roadmap to drive forward the innovation agenda.

The BIGT report coincided with the publication of the Academy's report 'Strengthening clinical research'.[3] Together, these reports catalysed a number of significant developments to invigorate UK bioscience and its translation into health and wealth benefits, including:

- The formation of a single, ring-fenced budget for health research, overseen by the Office for the Strategic Co-ordination of Health Research (OSCHR).
- The formation of NIHR, following 'Best Research for Best Health',[4] as well as the UK Clinical Research Collaboration (UKCRC) and UK Clinical Research Networks (UKCRN).
- The vision for innovation in the NHS set out in Lord Darzi's 'NHS next stage review'.[5]

[2] Bioscience Innovation and Growth Team (2003). *Bioscience 2015.* http://www.bioindustry.org/bigtreport/downloads.htmlhttp://www.bioindustry.org/bigtreport/downloads/exec_summary.pdf
[3] Academy of Medical Sciences (2003). *Strengthening clinical research*. http://www.acmedsci.ac.uk/p48prid18.html
[4] Department of Health (2006). *Best research for best health: A new national health research strategy.* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127127
[5] Darzi A (2008). *High quality care for all: NHS next stage review.* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

In January 2008, the Government, in partnership with the BioIndustry Association (BIA), announced an independent review of Bioscience 2015 to consider progress against the original aims and objectives. 'BIGT Review and Refresh' (BIGTR2)[6] identified a number of successes: progress has been made in the animal rights debate; the UK's bioprocessing capability has grown; and there have been some improvements in training people with the full range of entrepreneurial and research skills to lead successful bioscience companies.

However, BIGTR2 also highlighted that, five years on from the original report, the UK biotechnology sector has declined in strength relative to its competitors. Underlying problems present in 2003 have been exacerbated by the financial downturn, which has left investors reluctant to invest in emerging companies. The purpose of the FORUM roundtable meeting was to build on the recommendations in BIGTR2, explore the challenges currently facing the UK biotechnology sector, and to discuss the steps needed to stimulate and sustain a vibrant, world-class biomedical sector.

The discussion broadly covered four main areas: innovation, finance, collaboration, and skills and the wider environment.

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

# Innovation

There is now widespread recognition that, despite increasing expenditure on research and development (R&D), the number of new molecules approved for clinical use continues to fall. Challenges around the development of new medicines are compounded by the impending expiration of patents on many older medicines, leading to loss of profits and increased generic competition. As a result, the pharmaceutical industry is looking for new ways of working to boost innovation and productivity.

This period of uncertainty occurs during a highly productive phase in basic research: advances in biological research over the past decades have generated profound insights into the pathophysiology of disease. There are now many opportunities involving different therapeutic targets and in areas of significant unmet medical need. To capitalise on these opportunities and to facilitate progress across a broad range of targets, there is an increasing trend for pharmaceutical companies to externalise R&D. A shift by pharmaceutical companies to increasingly invest outside their own 'four-walls' presents openings for small and medium size enterprises (SMEs) and for the academic community. However, in a global market, how do we attract a share of this investment to the UK?

Participants agreed that opportunities to attract and leverage investment in UK research must be seized in the near and longer term by: maximising on the unique opportunities presented by the NHS; and building on the UK's excellence in basic and translational science.

The NHS, and its potential to become a unique resource for translational medicine and clinical trials, remains a selling point for the UK in attracting R&D activity of global companies. Progress to create the necessary infrastructure to deliver high quality clinical trials has been made through the establishment of the UK Clinical Research Network (UKCRN). It will take time for other strategies such as the 'NHS Connecting for Health' to mature, but these have a key role in creating a major competitive asset for research in the UK.

Participants highlighted the legacy of strong medical research in the UK. Existing strengths in basic and translational science need to be celebrated and marketed to global pharmaceutical companies; there is a need to foster an environment where global companies look to invest in the UK. Participants identified the potential to attract investment in: 'experimental medicine' (clinical investigation directed at establishing disease causation and 'proof of concept' research to test the validity and importance of potential treatments); stratified medicines; and research into the molecular basis of disease.

Participants agreed that while the UK excels in basic science and retains a strong presence from large pharmaceutical firms, a gap is emerging in relation to the biotechnology industry. If the UK life sciences are to benefit from the increasing externalisation of 'big pharma' R&D, it is important to redress this situation and prevent the UK sector declining in strength relative to continental European competitors.

## Finance

Participants stated that the key challenge facing the biotechnology industry is difficulty in attracting finance. Investors have become increasingly reluctant to invest in biotechnology citing: the long development times involved in drug development; the perceived conservatism of regulatory authorities; and increasing risk aversion in the community-at-large. As a result it was suggested that many UK biotech firms have only 6 months of funding left. The situation is not unique to the UK: recent estimates suggest that around one in five European biotech companies could go bust by the end of 2009 if new funding is not made available.[7]

New funding initiatives that involve both venture capital and Government were considered to be crucial to raising confidence in the sector. One suggestion made in BIGTR2 - and supported at the roundtable meeting - was the creation of a UK investment fund that would match venture capital investment in start up biotechnology companies. It was proposed by one participant that Government funding could be triggered by investment from an accredited investor and in turn would serve to encourage 'big pharma' to invest.

It was agreed that the Government, in partnership with others, had a key role in facilitating the availability of new finance. Participants cited two developments that have already created opportunities for Government and industry to co-invest in this sector:

- The creation of the Technology Strategy Board (TSB), with competition for collaborative R&D in the bioscience sector.
- New Enterprise Capital Funds (ECFs), where Government funding is used alongside private sector finance to establish funds to fill the 'equity gap' for early stage companies.

The creation of Cyclofluidic was cited as a positive example of Government and industry working together. Drug companies UCB and Pfizer jointly own Cyclofluidic, however, the TSB helped facilitate this innovative arrangement and will continue to support Cyclofluidic by co-funding its R&D.

A number of proposals were put forward to address major shortcomings in the financing of the biotechnology sector including:

- The need for seed funding and proof-of-concept funding to enable bioscience companies to progress ideas to a stage at which they are increasingly attractive to venture capital.
- A focus on improving the terms of Venture Capital Trusts.
- Encouraging 'big pharma' to invest in UK bioscience companies by:
    - Applying tax credits.
    - Allowing the losses of the SME to be off-set against taxable income.
    - Introducing a tax-incentive for companies to exploit IP in the UK.

[7] European Biopharmaceutical Enterprises (2009). *Assessment of the global crisis impact on small biopharmaceutical companies in europe.* http://www.ebe-biopharma.org/index.php?option=com_news&task=view&id=165&Itemid=28

## Collaboration

Participants emphasised that improving the translation of medical research into economic and health benefits requires collaboration across sectors. Industry, venture capital, the NHS, the academic research base and Government need to be pulling in the same direction to translate UK excellence in basic science. The new Office for Life Sciences, with representation from across the sectors, is tasked with taking action by the end of July 2009 to make a real difference to the operating environment for life sciences companies. Working across Government departments, the virtual Office will co-ordinate national policy, undertaking work to build a sustainable and integrated life sciences industry in the future.

Participants highlighted the important role for universities in both knowledge generation and technology transfer. A number of schemes already exist to facilitate technology transfer:

- The MRC Development Pathway Funding Scheme (DPFS) is designed to directly support work that has a clear goal of delivering fundamental research towards the clinic. Investment is aimed at projects that target significant and unmet health needs by improving prevention, diagnosis, prognosis or treatment of patients, or by developing the relevant research tools.
- Since 2008/2009 the Higher Education Innovation Fund (HEIF) has been allocated to all English HEIs, enabling universities to plan and develop their knowledge transfer capability.

However, it was felt more could be done to encourage universities to manage and incubate a portfolio of ideas to a later stage at which they can be picked up by industry. With life sciences companies increasingly looking for opportunities to externalise R&D there are a greater number of opportunities for the UK academic sector. Participants argued that industry can benefit from the UK's strength in basic science and productive links should be forged between the science base and business. It was felt that more could be done to support technology transfer and to encourage universities to develop a portfolio of ideas and bridge the gap between idea generation and commercial financing. Strong and coherent programmes to support early phase innovation in universities will leverage further inward investment in the UK.

The NHS provides the UK with a competitive advantage in the delivery of healthcare and has the potential to serve as unique resource for fostering research and innovation in drug discovery, medical devices and services. Lord Darzi's NHS *'Next stage review'* includes a number of recommendations designed to help foster an enterprise and innovation culture with the NHS. Steps taken to support innovation include:

- The creation of Academic Health Science Centres (AHSCs) to bring together a small number of health and academic partners to focus on world-class research, teaching and patient care.
- The formation of Health Innovation and Education Clusters (HIECS). These will be collaborations across primary, community and secondary care, universities and industry that set shared strategic goals. Members will run joint innovation programmes that reflect local needs and expertise.

- Driving innovation regionally by giving Strategic Health Authorities a legal duty to promote innovation. A new regional innovation fund will be held by SHAs to identify and promote innovation.

The success of these initiatives and programs such as 'Connecting for Health' will be an important step towards capitalising on the benefits offered by the NHS.

There are a number of impressive examples of industry-academic collaborations and commercialisation of academic research in the UK. However, participants agreed that in the longer-term more needs to be done to foster a collaborative culture. The mobility of researchers is an important part of this interface - exchanging skills, forging opportunities and promoting mutual awareness. The Academy of Medical Sciences has long promoted relations between academia and industry through the work of its FORUM and has previously identified considerable scope for improving mobility between the two sectors. The Academy report, 'Careers for biomedical scientists and clinicians in industry: promoting greater mobility'[8] recommended a range of strategies to foster interactions between researchers in industry and academia, to increase flexibility in careers options and to promote industry as an attractive career destination.

[8] Academy of Medical Sciences (2007). *Careers for biomedical scientists and clinicians in industry: promoting greater mobility.* http://www.acmedsci.ac.uk/index.php?pid=114

## Skills and the wider environment

Participants emphasised the need to ensure a pool of talented bioscience professional and foster a streamlined regulatory framework for health research and innovation. The BIGTR2 report identifies three elements to this: encouraging the return of UK talent working overseas, the recycling of existing leaders within the industry, and the provision of excellent training. Experienced management and high calibre scientists are needed to deliver new medicines. Some participants felt that many of the UK´s talented managers and scientists in this sector are currently working overseas. Attention was drawn to the need for active programmes to encourage people to return to the UK and to encourage experienced managers within the sector to reapply their skills.

In terms of the wider medical research environment concerns were expressed in relation to:

- The fall in the UK's global share in clinical trials: decreasing from 6% (in 2002) to 2% (2006).[9]
- Delays in the uptake of new drugs: data on the uptake of new cancer medicines between 2005-2007 was used to suggest that the UK lags behind the rest of Europe in the uptake of new medicines.[9]
- The potential impact of delays in drug appraisal, leading to a shortening of products' patent protected life cycle and a subsequent increase in drug price.

Many participants at the roundtable felt that the balance of risk and reward had shifted, with the current regulatory regime increasing the degree of risk for the investor. The perception was that drug development in this country has become less attractive, in part due to difficulties in setting up clinical trials and the slow appraisal and uptake of new treatments.

It was suggested that there was an opportunity for the UK to take the lead in improving the drug development pathway. It was also argued that further consideration needs to be given to the role of intellectual property (IP) in incentivising innovation. Participants cited a system recently introduced in Belgium that encourages companies to locate more activity there by offering a tax incentive on IP.

The UK has a world-class science base, with strong Government commitment and support for research. A diverse research base has been supported by an increased budget and the formation of bodies such as the UKCRC and OSCHR is designed to enhance the research environment. To attract investment to the UK, it is important that our excellence in research is celebrated and the platform for translation science is strengthened. In addition to benefits for health, attracting industry investment to the UK provides opportunities for growth and jobs that will help balance our economy and fund future public investments.

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

# Appendix I meeting programme

**Biotechnology innovation: challenges and opportunities**
Tuesday 3 March, 2009, Royal Society of Medicine, London

15.00 Welcome and introductions
Professor Sir John Bell FRS PMedSci, President, Academy of Medical Sciences

15.10 The review and refresh of Bioscience 2015
Sir David Cooksey FMedSci, Chairman, Bioscience Industry and Growth Team

15.20 Biotechnology innovation: views from across the sectors

- Ms Aisling Burnand, Chief Executive Officer, BioIndustry Association
- Professor Patrick Vallance FMedSci, Senior VP, Drug Discovery, GlaxoSmithKline
- Dr Stephen Reeders, Partner, MVM Life Sciences
- Dr Helmut Schühsler, Managing Partner, TVM Capital

16.00 Discussion

17.00 End

The roundtable was followed by the 2009 FORUM Annual Lecture *'UK life sciences – ensuring a healthy future'* delivered by Lord Drayson, Minister of State for Science & Innovation.

## Appendix II meeting delegates

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| Professor Sir John Bell FRS PMedSci | President, Academy of Medical Sciences |
| Mr Jerry Benjamin | General Partner, Advent Venture Partners |
| Professor Graham Boulnois | Partner, SVM Life Sciences |
| Mr Chris Brinsmead | President, Association of the British Pharmaceutical Industry |
| Mr Steven Bunting | Managing Partner, Abingworth |
| Ms Aisling Burnard | Chief Executive, BioIndustry Association |
| Sir William Castell FMedSci | Chairman, Wellcome Trust |
| Sir David Cooksey FMedSci | Chairman, Bioscience Industry and Growth Team |
| Mr Clive Dix | Chairman, BioIndustry Association |
| Dr Annette Doherty | Vice President, Global Research & Development, Pfizer |
| Lord Drayson of Kensington | Minister of State for Science and Innovation, Department for Innovation, Universities and Skills |
| Dr Anders Ekblom | Executive Vice President, Development, Astra Zeneca |
| Dr Rob Frost | Senior Officer, FORUM, Academy of Medical Sciences |
| Mr Jeremy Haigh | Vice President, International Chief Operating Officer, Amgen |
| Mr John Jeans | Deputy Chief Executive, Medical Research Council |
| Dr Melanie Lee FMedSci | Executive Vice President, UCB Group |
| Mrs Mary Manning | Executive Director, Academy of Medical Sciences |
| Mr Mark Payton | Chief Executive, Oxagen |
| Sir Keith Peters FRS FMedSci | Senior Consultant, GlaxoSmithKline |

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| Dr Stephen Reeders | Partner, MVM Life Sciences |
| Lord Sainsbury FRS FMedSci | Former Minister for Science and Innovation |
| Professor Adrian Smith | Director General for Science and Research, Department for Innovation, Universities and Skills |
| Mr Laurie Smith | Manager, Medical Science Policy, Academy of Medical Sciences |
| Dr Helmut Schühsler | Managing Partner, TVM Capital |
| Dr Dave Tapolczay | Chief Executive, MRC Technology |
| Professor Patrick Vallance FMedSci | Senior Vice President, Drug Discovery, GSK |
| Professor Sir Gregory Winter FRS FMedSci | Laboratory of Molecular Biology, Cambridge |
| Professor Kent Woods FMedSci | Chief Executive, Medicines and Healthcare products Regulatory Agency |

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