HM Government

Life Sciences 2010:

Delivering the Blueprint

Building Britain's Future

January 2010

Office for Life Sciences key actions to improve the environment for Life Sciences in the UK

- UK Life Sciences Super Cluster
- Patent Box
- RegenMed programme of investment
- Innovation Pass
- NHS Life Sciences Innovation Delivery Board
- Industry and Higher Education Forum
- Accreditation of bioscience degrees
- Life Sciences Business and Leadership Programme
- UK Innovation Investment Fund
- Life Sciences marketing programme

Front cover photograph supplied courtesy of A. Cavanagh, Wellcome Images.
Scanning electron micrograph of Purkinje neurons. 2008.

Office for
Life Sciences

Many of the policies and statements set out in the *Life Sciences Blueprint* extend over the whole of the United Kingdom but, for some, responsibility is devolved in Northern Ireland, Scotland and Wales. Thus not all commitments will automatically apply across the UK.

We continue to work closely with the Devolved Administrations, respecting their responsibilities and administrative structures, towards the goals of promoting and supporting a thriving Life Sciences industry in the UK.

Foreword

The UK Life Sciences industry is a world-leading, high-tech industry that will be vital to Britain's future economy. Working in collaboration with academia and the NHS, the Life Sciences industry develops innovative medicines and medical technologies that bring benefits to patients here and around the world. It is a strong driver of economic growth and provides highly-skilled employment.

Our world-leading position in Life Sciences is built on considerable existing strengths. The UK has an excellent science base, a huge pool of talented people and a National Health Service committed to providing high-quality care. Making the most of these strengths means making sure that Britain is one of the best places in the world to research and develop medicines and medical technologies. The creation of the Office for Life Sciences one year ago was a signal of the Government's commitment to an active policy that supports innovation and collaboration in Life Sciences.

In July 2009, we published the *Life Sciences Blueprint*, an ambitious and comprehensive package of actions to secure the UK as the location of choice for global Life Sciences investment in the future. *Life Sciences 2010* marks a year of action and achievement for Life Sciences in the UK.

The UK Life Sciences Super Cluster, the Patent Box, the Innovation Pass, and the NHS Life Sciences Innovation Delivery Board are all changing the landscape for Life Sciences. They are already having a positive impact on investment decisions.

The Office for Life Sciences has played an important role in this work. It has ensured that Government speaks with one voice on Life Sciences issues and brought added momentum and co-ordination. It has defined a new level of ambition for UK Life Sciences that we are committed to maintaining in the future.

We are committed to maintaining the momentum we have generated over the past year. The Office for Life Sciences will be strengthened by the direct involvement of teams across Government working with the Life Sciences industry. At Ministerial level, Lord Drayson will maintain responsibility for the Office, and the Departments for Business, Innovation and Skills, and Health, will continue to share responsibility for the Life Sciences sectors within Government.

Lord Mandelson
First Secretary of State
Secretary of State for Business, Innovation & Skills

Andy Burnham
Secretary of State for Health

Preface

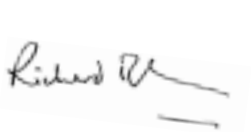
The UK Life Sciences industry welcomes the publication of *Life Sciences 2010*, which demonstrates the real progress that has been made since Government created the Office for Life Sciences under Lord Drayson's leadership in January 2009. The creation of the Office resulted from a summit, held by the Prime Minister, at which worldwide industry leaders set out the need for firm action to ensure that the UK retains its position as a leading player in the global industry.

In July 2009, following several months of intensive joint working by Government, industry and academia, the Office published the *Life Sciences Blueprint*: a set of actions designed to, improve collaboration between industry and academia, strengthen the partnership between industry and the NHS, benefit patients, and enhance significantly the environment for medical biotechnology, pharmaceutical, medical devices and diagnostics businesses in the UK.

Life Sciences 2010 is the culmination of a year's partnership. The process has been eye-opening, challenging and encouraging, and has led to welcome recent announcements on the Innovation Pass, the UK Innovation Investment Fund, the Patent Box, and the creation of a NHS Life Sciences Innovation Delivery Board.

We are pleased with the strong progress that has been made to date in delivering the *Blueprint* actions. For many actions, delivery is still ongoing; it is therefore critically important that the partnership between industry and the various Government departments involved continues to flourish and to show results. The *Blueprint* actions form a package of measures and all actions must be taken forward if it is to be fully effective. Indeed, further actions will be needed in the future to strengthen the UK environment for Life Sciences in an era of steadily growing international competition for new investment.

The Office for Life Sciences, led by Lord Drayson, has brought a fresh sense of urgency to the key challenge of securing a flourishing Life Sciences industry in the UK, and we look forward to continuing our partnership with Government.



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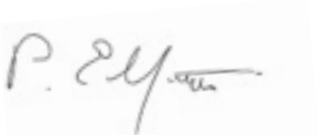

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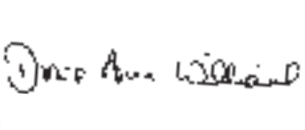

Doris-Ann Williams
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Executive summary

The Office for Life Sciences and its partners have achieved a great deal in the last year. Working with industry, the NHS, academia and wider Government, the Office formulated the *Life Sciences Blueprint* – an ambitious and comprehensive set of measures to transform the UK operating environment for Life Sciences.

This document describes the progress made in taking these measures forward.

- The **UK Life Sciences Super Cluster** will boost collaboration and leadership in translational research by harnessing UK capabilities in areas of clinical need. A pilot, co-ordinated by £1 million investment and launching in early 2010, will target research in immunology and inflammation, focusing on disease areas such as asthma and rheumatoid arthritis;

- A **Patent Box**, applying a 10% rate of corporation tax to patent income from April 2013, will strengthen incentives for companies to invest in innovative activity and locate in the UK. Government will consult with business on the detailed design of the Box in time for Finance Bill 2011;

- A £21.5 million **RegenMed programme** will support our growing and strategically-important regenerative medicine industry. We launched two competitions, involving over 40 companies, in 2009. We will hold further competitions in 2010;

- An **Innovation Pass** will give patients earlier access to promising licensed medicines. A consultation on this initiative began in November 2009. A one-year pilot will start in April 2010 with funding of £25 million;

- The **NHS Life Sciences Innovation Delivery Board** will strengthen the relationship between industry and the NHS, and accelerate NHS uptake of cost-effective, innovative medicines and medical technologies. The Delivery Board will publish its workplan in Spring 2010;

- The **Industry and Higher Education Forum** will ensure that university graduates have the skills and knowledge necessary for a career in Life Sciences. It will agree recommendations for *in vivo* sciences and clinical pharmacology in February 2010, with actions to follow;

- The Society of Biology is developing the world's first **accreditation model for undergraduate biological sciences degrees** to strengthen the UK workforce and boost competitive advantage. A consultation began in December 2009, ahead of a pilot scheme for the 2010/11 academic year;

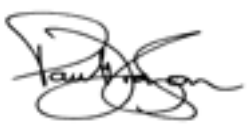
- A **Life Sciences Business and Leadership Programme** will ensure that small and medium-sized businesses have the key skills to underpin commercial success. A proposal to integrate the programme into an upcoming bid to extend the Process Industry National Skills Academy will be submitted in March 2010;

- The **UK Innovation Investment Fund**, announced in June 2009, will provide much-needed finance to high-tech businesses, including start-ups and spin-outs. Fund of Funds Managers are now in place, and have raised £175 million on top of the Government's £150 million cornerstone investment; and

- A national **marketing programme** to promote UK life sciences, attract inward investment, and build our reputation overseas is underway and will continue in 2010.

This list of actions is testament to the rapid impact made by the Office for Life Sciences. It demonstrates what we can accomplish through genuine collaboration – when industry, the NHS and academia work closely together, and when industry speaks with one voice to Government.

I am grateful to the many people in Government, industry, academia and the NHS who have brought such dynamism to this agenda.



Lord Drayson
Minister for Science and Innovation,
and Lead Minister for the Office for Life Sciences

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UK Life Sciences – Driving economic growth and patient benefit

The UK Life Sciences industry – A world leader

The UK Life Sciences industry is a world-leading, high-tech industry employing over 120,000 people and investing at least £4.6 billion in research and development (R&D) in the UK[1]. It is a strong driver of economic growth, provides highly-skilled employment opportunities and, through the development of innovative medicines and medical technologies, contributes to the delivery of high-quality healthcare.

The UK's strengths in Life Sciences are evident in the individual sectors that make up the industry: pharmaceutical, medical technology, and medical biotechnology sectors.

- The pharmaceutical sector in the UK consists of around 600 companies with combined annual sales of around £15.6 billion[2]. This represents an estimated 4% of global sales and 14% of total European sales[3]. The sector employs some 67,000 people[4]. It is the leading UK sector for investment in R&D, investing £4.3 billion in the UK in 2008 alone, which represents over a quarter of all business R&D expenditure in the UK[5]. Furthermore, the UK's two largest pharmaceutical companies rank 2nd and 4th in the world in terms of global market share in sales of pharmaceuticals[6].
- The medical biotechnology sector in the UK comprises around 780 companies with a combined annual turnover of around £4.2 billion, representing an estimated 9% of the global turnover and 30% of the total European turnover. The sector employs 24,000 people representing an estimated 25% of the total for Europe[7]. The sector also leads Europe in the number of drugs in all stages of clinical development[8].
- The medical technology sector in the UK comprises around 2,800 companies, the majority of which are small and medium enterprises (SMEs), employing 52,000 people and generating around £10.6 billion of turnover.

1 Estimate based on data from: BIS/DH/UKTI Bioscience and Health technology database; *Annual Business Inquiry*. ONS. 2007; and the Association of British Healthcare Industries.
2 Annual Business Inquiry. 2007.
3 Data Monitor. 2008; excludes over-the-counter drugs.
4 Annual Business Inquiry. 2007.
5 *UK Business Enterprise Research and Development*. ONS Statistical Bulletin. 2008.
6 Association of the British Pharmaceutical Industry, based on IMS data.
7 *Strength and Opportunity: The landscape of medical technology, medical biotechnology and industrial biotechnology enterprises in the UK*. BIS. 2009.
8 *Beyond borders. Global biotechnology report 2009.* Ernst and Young.

In addition, around 25% of all European medical technology companies are based in the UK[9].

The full economic analysis of UK Life Sciences that accompanies this publication sets out these strengths in more detail[10].

It is clear that the individual sectors of the UK industry are strong in their own right. These strengths are enhanced when the industry works across its component sectors to create an industry that is more than the sum of its parts. Such interactions are becoming more common and more important as, for example, diagnostics companies work with pharmaceutical and medical biotechnology companies in the area of personalised medicine, or as pharmaceutical companies increasingly look to medical biotechnology companies to replenish their pipelines.

The UK Life Sciences ecosystem – Building on UK strengths

Life Sciences companies are a crucial element of a broader UK Life Sciences ecosystem which also includes academia, the NHS, and many other parties including patient groups, medical research charities, and research funders such as England's National Institute for Health Research (NIHR), the Health Departments of the Devolved Administrations (Northern Ireland, Scotland and Wales), and the Medical Research Council (MRC). There is already extensive interaction between these various elements of the Life Sciences ecosystem and this brings benefits to all parties. In the future, collaborative and effective working between the different elements within the ecosystem will be increasingly important for the success of Life Sciences in the UK.

The UK Life Sciences ecosystem is built upon significant strengths:

- The UK has a strong scientific heritage, boosted by significant investment in the science base over the past decade, which has led to the UK ranking second in the world in the strength of its universities, with particular strength in Life Sciences[11];
- Investment in the UK science base boosts the numbers of skilled workers able to pursue a career in Life Sciences, an industry that is highly knowledge-intensive and dependent on access to highly-skilled and innovative scientists, clinicians and technologists. Investment also stimulates innovation and its commercialisation. In the last ten years, bioscience departments within UK universities have generated over 200 spin-out companies, which employ over 1,000 people[12];
- The NHS is the UK's largest customer of medicines and medical technologies, and has a unique patient database and dedicated research

9 *Strengths and Opportunities: The landscape of medical technology, medical biotechnology and industrial biotechnology enterprises in the UK.* BIS. 2009.
10 *Life Sciences in the UK – Economic analysis and evidence for Life Sciences 2010: Delivering the Blueprint. BIS Economics Paper No. 2.* BIS. 2010.
11 *QS World University Rankings.* Times Higher Education. 2009.
12 *Economic Impact Baseline, 2009 Update.* Biotechnology and Biological Sciences Research Council.

facilities that provide a strong platform for clinical trials. Alongside its primary remit to deliver high-quality healthcare, it has an important role to play as an engine for economic growth, directly contributing to the success of the industry in the UK. In turn, the industry, as a strategic partner to the NHS, delivers innovations in medicines and medical technologies that bring benefits to patients and enable greater NHS productivity; and

- In 2006, Government published a new health research strategy, *Best Research for Best Health*[13]. Since 2008, there has been an unprecedented commitment to health research in terms of funding, infrastructure, research programmes, and the volume of health research commissioned. The total uplift for health research has been £300 million per annum, creating total funds for health research that will rise to more than £1.7 billion per annum by 2011. Overseen by the Office for Strategic Coordination of Health Research (OSCHR), this increase includes additional funding which will drive more effective translation of health research into patient and economic benefits in the UK, and increase the competitiveness of UK health research. Under the auspices of OSCHR, the public funders are also building on strong partnerships with the Life Sciences industry and the charity sector.

The need to take action

It is clear that the UK offers significant strengths and opportunities in Life Sciences. However, the industry is a global one and has been targeted by several major countries as a priority industry of the future. It is therefore vital that the UK continues to offer a competitive environment for companies to do business in order to maintain current investment, and attract new investment, which will drive future growth and deliver patient benefit.

In January 2009, the Office for Life Sciences (OLS) was created by the Prime Minister, signalling both the importance of Life Sciences to the UK, and the recognition that more needed to be done to support a thriving UK environment. The OLS' work was characterised by pace and momentum, as well as by its coherence, with Government departments, the different industry sectors and representatives from academia working together as never before to develop a package of measures to transform the UK environment.

These actions were published in July 2009 in the *Life Sciences Blueprint*[14], in which Government and others committed to a comprehensive and ambitious set of actions that touch on all aspects of the Life Sciences ecosystem, delivering real change to:

- Enhance the work of the NHS as an innovation champion;
- Transform the relationship between the NHS and industry for mutual benefit;

13 Further information can be found at: http://www.dh.gov.uk/en/Researchanddevelopment/ResearchAndDevelopmentStrategy/DH_4127109

14 *Life Sciences Blueprint: A Statement by the Office for Life Sciences.* BIS. 2009.

- Boost integration and collaboration in Life Sciences;
- Create a sustainable supply of highly-skilled workers;
- Stimulate access to finance to support innovation and enterprise; and
- Ensure that the UK tax regime incentivises innovation.

It also contained commitments to market these actions internationally to raise awareness of the strengths of UK Life Sciences and boost inward investment.

Since July, the pace and momentum which characterised the first six months of the OLS' work has continued, with significant progress made in delivering the *Blueprint* actions. This document provides detail of that progress, as well as setting out next steps where delivery is ongoing.

Maintaining momentum to realise the benefits

This document marks a year of action for UK Life Sciences and celebrates new ways of working, bold measures and, most importantly, strong and comprehensive delivery on commitments.

Our record on delivery of the *Blueprint* commitments demonstrates Government's determination to build on the UK's strengths and maintain its world-leading position in Life Sciences. That determination will now be focused on securing the full benefits of the *Blueprint* actions, whether in enhanced uptake and diffusion of medicines and technologies by the NHS, in improved NHS and industry interaction to help meet the quality and productivity challenge faced by the NHS, in collaboration on early-stage research, or in steps to improve skills supply. Acknowledging the contribution of UK Life Sciences to our joint aims of economic growth and patient benefit, it will also be vital to have a robust process in place to monitor progress and assess the benefits and success of the *Blueprint* actions in driving both these aims.

The Office for Life Sciences will be strengthened by the direct involvement of teams across Government working with the Life Sciences industry. At Ministerial level, Lord Drayson will maintain responsibility for the Office, working closely with the Secretaries of State for Business, Innovation and Skills, and for Health, who continue to share responsibility for the Life Sciences sectors within Government.

Delivering the *Life Sciences Blueprint* actions

At the heart of Life Sciences in the UK is excellence in research and development, whether carried out in academic institutions, in private companies, or in the NHS. Excellence in research drives the development of innovative medicines and medical technologies with the potential to deliver patient benefit and economic growth.

However, the UK will only realise this potential if: all members of the UK Life Sciences ecosystem work together in a truly collaborative and innovative way; research and development creates a stream of cost-effective products; and these products are rapidly and effectively taken up and diffused by the NHS. There are also a number of essential underpinning enablers that are required to build a flourishing ecosystem where initial research leads to economic and patient benefit: a skilled workforce; access to finance; and a supportive fiscal environment.

The *Life Sciences Blueprint*, published in July 2009, committed Government and others to an ambitious package of actions to transform the UK Life Sciences environment. Since July, the pace and momentum which characterised the first six months of the OLS' work has continued, with significant progress made in delivering the *Blueprint* actions. This document provides details of that progress, as well as setting out next steps where delivery is ongoing.

1. Enhancing collaboration in Life Sciences

The UK Life Sciences Super Cluster

The success of UK Life Sciences in the future lies in building a commercial and cultural environment where strong and sustained collaboration between UK Life Sciences industry, academia and the NHS is the norm.

Global competition for investment in translational medicine[15] is intensifying, with a greater number of countries now conducting high-quality research in Life Sciences. For the UK to effectively compete on a global stage and attract inward investment, it must set an ambitious aim: to further develop truly world-leading capabilities in translational research.

In the *Blueprint,* Government signalled the beginning of a new approach to collaboration between industry and the public sector by committing to develop a UK Life Sciences Super Cluster. Led by the Office for Strategic Coordination of Health Research (OSCHR), and developed in collaboration with industry, academia and the

15 The process of taking the findings from basic research and using them to produce innovation in healthcare settings, often seen as the interface between basic and applied research.

NHS, the UK Life Sciences Super Cluster initiative will be a key driver to achieving UK leadership in translational research.

At the heart of the UK Life Sciences Super Cluster will be the creation of Therapeutic Capability Clusters. These Capability Clusters will be made up of a small number of selected academic and NHS centres of excellence that will collectively provide a single point of contact and focus for industry collaboration in critical therapeutic areas. The Capability Clusters will harness UK capabilities in specific therapeutic areas by bringing these centres of excellence together with industry to work on early-stage clinical development and experimental medicine.

The Capability Clusters will be formed in areas where:

- There is strong, existing scientific expertise in the UK research community;
- Industry has significant research interests and pipeline activity in areas of unmet medical need; and
- There is significant infrastructure in place, for example, to provide well-characterised patient cohorts for clinical trials.

These Capability Clusters will provide a vital co-ordination function to facilitate world-class academic-NHS-industry collaborative research. They will enable researchers to better understand the effectiveness and efficacy of potential new medicines or interventions in humans, and to ensure the UK leads in translating these findings into successful products.

This new initiative, bringing together a critical mass of experience, expertise and infrastructure, has the potential to accelerate new clinical developments as well as create new opportunities for investment. Building on the strong co-ordination in the NHS provided by the Biomedical Research Centres (BRCs), Biomedical Research Units (BRUs) and Clinical Research Facilities (CRFs), this initiative will raise the profile of UK expertise in specified therapeutic areas across the globe. It will increase awareness of the UK's capabilities, contribute to the development of a UK communications strategy for Life Sciences research, and improve the UK's attractiveness as an investment location.

To kick-start the establishment of the UK Life Sciences Super Cluster, a call for initial applications to establish a pilot Therapeutic Capability Cluster will be launched in early 2010, managed by OSCHR. The pilot will target research in immunology and inflammation, focusing on diseases such as asthma and rheumatoid arthritis.

Applications from interested academic and NHS research organisations will be peer reviewed by a panel of industry experts and international/independent clinical academics, and assessed by the Super Cluster Delivery and Oversight Group. Full details of the call, including the selection criteria and process, will be communicated to the research community in Spring 2010. It is expected that the pilot will be operational by Summer 2010 and the review of the pilot set up will begin in late 2010.

The clinical research infrastructure to support the Capability Clusters has been enabled primarily by the £160 million per annum of National Institute for Health Research (NIHR) support, which is channelled through the existing BRCs, BRUs and CRFs. Activities are also underway by the Medical Research Council (MRC) and the Technology Strategy Board (TSB) to develop co-ordinated approaches to stratified medicine, and the Association of the British Pharmaceutical Industry (ABPI) and the MRC are developing their inflammation and immunity initiative. All of these activities and investment will complement the Capability Cluster pilot activities as well as increase capabilities in other relevant therapeutic areas, which will support the initiative in the longer term.

Government will directly support this pilot by providing £1 million from the Strategic Investment Fund (SIF), to be administered by the TSB, to deliver the strategic co-ordination and evaluation of the pilot.

The Blueprint contained two further measures, in addition to the development of a UK Life Sciences Super Cluster, to boost the UK's ability to offer a culture of strong and sustained collaboration:

Supporting the translation of research: the Research Excellence Framework

In the *Blueprint*, the importance of assessing the impact of past research on the economy and society, and its potential impact on research translation and on collaboration between industry and academia was recognised.

Between September and December 2009, the Higher Education Funding Council for England (HEFCE) consulted, on behalf of the four UK funding bodies, on its proposals for a new Research Excellence Framework (REF), the successor to the Research Assessment Exercise. HEFCE proposed that under the REF, for the first time, impact would be an explicit element of the total assessment, in order to take better account of the impact that excellent research has on the economy and society.

HEFCE will develop its proposals further in light of the responses to the consultation, as well as the outcomes of the pilot exercise that will test and develop the method of assessing the research impact and collaborative excellence elements of the REF, announced with the consultation. The pilot, which will involve 29 universities from across the UK and cover five broad subjects including Clinical Medicine, will be completed by mid-2010.

Encouraging partnerships for health research

In the *Blueprint*, Government outlined its intent to ensure that continued funding from England's NIHR for BRCs, BRUs and CRFs would be partly contingent on demonstrable working with industry. The Government remains committed to this.

Promoting collaboration: Activity in the Devolved Administrations

Scotland and Wales are taking steps to promote collaboration between industry, the NHS and academia:

The Scottish Translational Medicine Research Collaboration

The Translational Medicine Research Collaboration (TMRC) partners are the Universities of Aberdeen, Dundee, Edinburgh and Glasgow; the four associated NHS Boards; Scottish Enterprise; and Wyeth (now part of Pfizer Inc.). It combines clinical and research excellence with ready access to patients and data brought together in a unified model for commercial interaction. This unique £50 million partnership has been highly successful in exceeding many of the original forecasts, with economic impacts including employment benefits, investment benefits, increased business activity, and intellectual property benefits. The initiative demonstrates that Scotland can compete successfully with global locations to develop new medicines and to define new business models that share risk and reward between pharmaceutical companies, Government, and academic and clinical organisations.

The success of the TMRC led to the launch of the Scottish Academic Health Sciences Collaboration (SAHSC) in 2009, providing a world-leading clinical research platform for patient-oriented research that unites all of NHS Scotland with academic partners at the four Scottish Universities. It provides a single access path to NHS research facilities, streamlining the engagement process for pharmaceutical companies. SAHSC is supported by significant investment in NHS scanning capability, tissue banking and IT capacity, underpinned by agreed principles of access. Co-ordinating capacity and capability in this way offers major efficiencies to industry in accessing and contracting with the research base across Scotland.

The Welsh National Institute for Social Care and Health Research

The newly-created National Institute for Social Care and Health Research (NISCHR) in Wales aims to promote collaboration between NHS, industry and academia. NISCHR will include a dedicated unit to lead strategy in commercial trials, NHS innovation and intellectual property.

The future of Life Sciences lies in the UK's ability to provide a strong commercial and complementary cultural environment where industry, academia and the NHS can work together on early stage translation of research. There are already extensive interactions and partnerships between industry, the NHS and academia. However, to maintain our competitive edge in Life Sciences, the UK must continue to build on these interactions and partnerships, as well as assessing and rewarding their impact, so that innovative collaborations drive the creation of a thriving Life Sciences ecosystem.

2. Improving the UK environment for undertaking clinical trials

Clinical trials are a central component of the UK clinical research environment. If we are to build a culture of strong research collaboration in the UK, it is vital that the UK is viewed as a competitive and world-class location to conduct these trials. Whilst significant progress has been made, for example the establishment of Clinical Research Networks, the *Blueprint* acknowledged that in recent years, the UK has lost ground internationally as a valued location in which to undertake clinical trials for later-phase medicines and medical technologies. In particular, trial start-up times, recruitment, reliability, and cost are having a negative impact. Government therefore committed to a number of actions to address these issues.

Research and clinical trials in the NHS Operating Framework

The NHS Operating Framework for 2009/10 communicated Government's ambition to double the number of patients taking part in clinical research in England within the next five years. Specifically to achieve this goal, the Department of Health has been consulting on proposals to include data about participation in clinical trials in each NHS provider's published Quality Accounts. This will bring a vital flow of data, acting as a spur to increased participation in clinical trials at local level, both from patients and from hospital organisations. Just as hospital boards will use Quality Accounts to regularly review improvement in the quality of care they provide, so they will also regularly review their involvement in commercial and non-commercial clinical trials.

This year's Operating Framework for 2010/11 reinforced the clear expectation to all NHS providers that they will increase their participation and performance in hosting research from both commercial and non-commercial funders. The measures in the Quality Accounts, coupled with the support of Strategic Health Authorities (SHAs), will develop the collaborative capacity of the NHS to participate in research studies and trials. This will begin to integrate research and clinical trials into the NHS as a core activity, helping it meet high-performance levels in speed and recruitment.

Furthermore, within Northern Ireland, Scotland and Wales, robust infrastructure for clinical trials is also in place, together with initiatives to ensure the participation and support of healthcare providers.

NIHR Research Support Services – Creating a national framework for the professional local management of health research

Under the auspices of the National Institute for Health Research (NIHR), a managed Clinical Research Network (CRN) is in place. This is a proven approach; the National Cancer Research Network more than doubled the number of participants in cancer research studies.

To support the CRN infrastructure, Government committed in the *Blueprint* to build a national framework to help improve the quality, speed and efficiency of research processes. In August 2009, the Department of Health published an implementation plan and launched a programme of work to create this national framework.

The national framework will result in the transitioning of Research and Development (R&D) departments in England to become NIHR Research Support Services.

It complements other measures in a wider programme to transform the health research environment which is being delivered through the NIHR, for example reforms to research ethics and NHS permissions.

NHS R&D departments are at the front-line of setting up research and clinical trials, and their practices are governed by the standards in the Department of Health's *Research Governance Framework for Health and Social Care*[16] (and similar standards across the Devolved Administrations). A number of factors have resulted in excessively bureaucratic processes for setting up research and trials in some NHS Trusts and R&D departments.

The *Blueprint* commitment will ensure that there are harmonised and streamlined processes for research in the NHS that is supported by NIHR systems. This includes improving the capability of people involved in the processes by establishing competency requirements that are supported by training. This will result in R&D departments that are better able to make proportionate and risk-based decisions on undertaking research including trials.

Industry, NHS research managers, the research networks, Government, and others are actively driving this programme of work. By April 2010, NIHR will agree timelines for the delivery of national research governance standards by NIHR Research Support Services. NIHR will publish a toolkit of standard operating procedures to support the delivery of the standards nationally. The toolkits will be supported by guides for risk management, competencies and training requirements to improve the understanding of risk management and research processes by R&D departments.

During 2010/11, NIHR will embed the national standards within NHS Trust R&D departments, facilitating their transition to NIHR Research Support Services. They will be equipped with national systems to improve management information for research managers and NIHR Networks that can be used to assess their performance. This performance information will be collected and published nationally to demonstrate and recognise delivery of the NIHR standards for research support services.

The NHS will benefit by being able to assess its performance in setting up clinical trials, and industry can use this to gauge the sites with which it should engage. In addition, patients have an indication that research is done using effective risk management processes. Overall, capability will be improved and confidence in the system as a whole will be raised.

16 Further information can be found at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008777

The North West Exemplar Programme – Improving clinical trial Performance

In North West England, an Exemplar Programme is demonstrating that the NHS can compete effectively on the global stage as an environment for clinical trials, when the Clinical Research Network works closely with companies and has the support of the local NHS leadership. The North West Exemplar Programme was initiated by the NIHR/NHS Biopharmaceutical Industry R&D Leadership Forum as a response to emerging evidence that the UK is losing relative market share of the global biopharmaceutical R&D market, with a consequential reduction in investment and jobs.

Programme focus

The Programme brings together all aspects of the NIHR Clinical Research Network with partners in the pharmaceutical and medical biotechnology sectors and across NHS North West. The Programme focuses on 20 commercially-sponsored studies that have been adopted into the NIHR Portfolio and have sites in the North West. It will closely monitor their progress through set-up and delivery, and will measure key performance indicators. The Programme is designed to provide hard evidence and case studies of improved performance, particularly around recruitment reliability and trial cycle time. The knowledge and experience gained from this Programme will spread good practice more widely across the NHS, NIHR and industry.

Commercial involvement

Although data is only currently available on the set-up of the first seven studies, results look promising and have been of great encouragement to industry partners. All seven studies have received NHS permission to date, and the time between the first submission for R&D approval and issue of the NHS permission letter has been a median time of 51 days. This has been positively viewed by industry sponsors Novartis, GlaxoSmithKline, Abbott, Boehringer Ingelheim, Schering-Plough and Janssen- Cilag, because it has exceeded their original target of 70 days.

For the first time in five years, the UK has achieved recruitment of the first patient in a global trial. This success is coupled with exceptional timelines, with initial submission for UK regulatory approval for first-patient-first-visit completed within nine weeks.

Emerging findings

The programme is still in its early stages. Phase 1 (effective study set-up) is on track to ensure set-up and first-patient-first-visit for all 20 exemplar studies by April 2010. NIHR Clinical Research Networks, NHS Trust R&D departments and industry have worked closely together to ensure the smooth set-up and delivery of industry-sponsored clinical trials.

An escalation process was put in place to ensure that any issues or barriers encountered either by Clinical Research Networks and NHS R&D departments, or by industry, could be escalated within 24 hours, to the Trust Chief Executive, Network Director or the Medical Director of the company. This has meant that problems have been resolved extremely quickly.

Set-up times for studies have been significantly improved, but there has been an additional workload for staff, particularly in Comprehensive Local Research Networks.

Next steps

It is expected that the first phase of the Programme will be completed and reported on in April 2010, when all 20 studies will have finalised study set-up and moved into the delivery phase. Achieving faster set-up and more reliable recruitment to industry-sponsored clinical trials that are part of the North West Exemplar Programme will provide industry colleagues with the evidence they need to demonstrate the competitiveness of the UK for clinical research.

The successes and lessons learned from this Programme will be used to inform work to improve clinical trials performance across the NHS.

One year on from the establishment of the Office for Life Sciences, key measures are now in place to: help NHS providers understand the importance of clinical trials to UK Life Sciences and the benefits to their organisations of participating in non-commercial and commercial research; support providers in expanding the hosting of clinical trials and in improving their performance; and improve the flow of relevant measures and metrics.

3. The National Institute for Health and Clinical Excellence – Supporting the NHS as an innovation champion

In the ten years since its inception, the National Institute for Health and Clinical Excellence (NICE)[17] has established itself as a world leader in health technology appraisal, and its work is influential in healthcare systems around the world. In order to realise patient benefits from research and development, there needs to be a flow of cost-effective medicines and technologies into the NHS. NICE provides guidance on the promotion of good health and the prevention and treatment of ill health, and therefore has a crucial role to play in supporting the NHS as an innovation champion.

The Innovation Pass

In the *Blueprint*, it was recognised that whilst most significant new medicines will go through NICE's existing processes, there will be drugs for small patient populations which have the potential to deliver improved patient outcomes but where data to demonstrate cost-effectiveness is so far limited. Market access may therefore be inhibited, mainly because of the small number of patients and other clinical factors. Government therefore committed to introduce an "Innovation Pass", giving patients earlier access to innovative, licensed medicines. The Innovation Pass is a three-year initiative for selected medicines, funded from a ring-fenced budget, before going through a full NICE technology appraisal. The Pass will be piloted with a budget of £25 million in 2010/11.

Consultation on the Innovation Pass

With the launch of the Innovation Pass consultation[18] on 28 November 2009, the key milestone ahead of the pilot was achieved. The proposals set out in the consultation have been developed with input from NICE, the NHS and industry. Focusing on potentially important new drugs where the evidence of cost-effectiveness at the time of launch is limited, these proposals will give patients with the greatest need earlier access to innovative drugs, and facilitate the collection of further information to support a subsequent NICE appraisal. This will provide a more robust evidence base on which to make recommendations to the NHS.

The consultation closes on 8 February 2010, after which Government will publish its response. Responses received during the consultation will inform the operation of the pilot in 2010/11. The application process for the Innovation Pass is expected to commence in April 2010.

The Innovation Pass will be reviewed over the 12 months of the pilot to inform the future Innovation Pass process. Funding for future years will be determined in the context of the next Spending Review.

17 NICE operates in England and Wales; in Scotland, the Scottish Medicines Consortium (SMC) takes that role.

18 Further information can be found at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_109236

NICE appraisal process

The *Blueprint* also highlighted that there was scope to develop a more constructive dialogue between industry, NICE and the assessment teams whose work supports NICE appraisals. The *Blueprint* set out a commitment that:

- Companies with medicines and medical technologies undergoing appraisal would be able to attend NICE Appraisal Committee meetings to respond to any questions from the Committee, and to comment on matters of factual accuracy;
- Academic Evidence Review Groups would be asked to attend the scoping meetings for NICE Single Technology Appraisals; and
- Companies would also have an opportunity to have a debrief meeting with NICE once an appraisal had concluded.

These actions were agreed by the NICE Board at the time the *Blueprint* was published. Updated Appraisal Committee process documents were published in October 2009.

Since then:

- Companies have been invited to attend Committee meetings to answer questions, given an opportunity to comment on issues of factual accuracy, and offered a post-guidance debrief meeting;
- All four NICE Appraisal Committees met in both November 2009 and January 2010 to discuss a total of sixteen topics. These Committees used the opportunity to clarify the evidence base with companies which were in attendance;
- Representatives of the Evidence Review Groups were invited to, and attended, all three scoping workshops held at the start of November 2009; and
- Two technology appraisals were published in October 2009 and post-guidance debrief meetings were held with the companies involved.

These measures will be kept under review by NICE and included in the scope of the periodic consultations NICE undertakes on the development of its technology appraisal process.

NICE methodologies

The Life Sciences industry has expressed concerns over whether methodologies to determine cost-effectiveness and value of innovation take into account a wide enough range of factors.

On 22 July 2009, Professor Sir Ian Kennedy published his report into aspects of value and innovation that NICE should take into account in its work. In the *Blueprint*, published prior to the Kennedy Report, NICE committed to conduct a one-month public

consultation on its response to the Kennedy Report, and to implement improvements in the way in which it explains the impact of specific factors in its decision-making.

The NICE response to the Kennedy Report was published for consultation on 30 September 2009, and the consultation closed on 13 January 2010. The consultation was extended to three months following feedback from stakeholders including industry. At its meeting in March, the NICE Board will consider the comments received and then publish a response, addressing any points made by consultees and setting out any changes in the action it proposes to take.

As a commitment to good practice, from January 2010, NICE is inviting consultees to set out what they consider to be the key elements of a product's value proposition, as part of the topic-scoping consultation.

Proposals are also being developed to improve the ways in which NICE explains the impact of specific factors which influence the Appraisal Committees' decision-making. These improvements are being implemented for technologies that have had their first discussion at Appraisal Committees in January 2010.

NICE has a vital role in supporting the NHS as a champion for innovation, and Government and NICE are committed to facilitating this. The added opportunities for strengthening the engagement and dialogue, the action taken to develop the NICE appraisal processes, and the development of Innovation Pass will help the NHS achieve this and ultimately benefit patients.

4. Improving uptake and diffusion of innovative, cost-effective medicines and medical technologies by the NHS

The core remit of the NHS is to deliver high-quality health services to the people of this country. By providing these services, it is a key contributor to the economy as a major employer and as the largest customer for the Life Sciences industry in the UK. It therefore has a crucial role to play both as an innovation champion in providing its services, and as an engine for economic growth.

Accelerating the uptake and diffusion of innovative and cost-effective medicines and medical technologies can play a role in sustaining a thriving UK Life Sciences industry, as well as driving up improvements in the quality of patient care. Realising the benefits of innovative technologies means that the NHS can provide high-quality care and make use of novel technologies that may have the potential to deliver efficiencies. At the same time, industry is incentivised to undertake research and develop new and innovative products to address the healthcare needs of tomorrow.

The *Blueprint* built on Lord Darzi's *High quality care for all: NHS Next Stage Review final report*[19] by making a number of new commitments that would help embed into the NHS the valuable outputs from the work already underway. The actions included spreading good practice, using incentives and enablers such as metrics to compare uptake, and building innovation into commissioning education.

NHS Life Sciences Innovation Delivery Board

The establishment of the NHS Life Sciences Innovation Delivery Board in November 2009 was a significant *Blueprint* delivery milestone. The Delivery Board forms a central component in Government's work to drive uptake and diffusion by strengthening NHS and industry engagement, as well as encouraging NHS organisations to become rapid and consistent adopters of cost-effective health innovations.

Since the publication of the *Blueprint*, significant progress has been made:

- The Chief Executive of NHS North West has been appointed as Chair of the Delivery Board;
- A number of high-level figures have been appointed as members of the Delivery Board, including Strategic Health Authority (SHA) Chief Executives and senior officials from both Government and industry;
- The Delivery Board held its inaugural meeting on 25 November 2009;
- A full time Programme Director was appointed on 15 December 2009; and
- Work is underway to make appointments to the Delivery Unit that will take forward the work programme of the Delivery Board.

19 Further information can be found at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825

To ensure that the Delivery Board is appropriately resourced to meet its objectives, the Department of Health has committed to support the Board in 2010/11. Funding for future years will be determined in the context of the next Spending Review. The Department's contribution will be matched by contributions from the Life Sciences industry in the form of expertise and skill-sets to drive forward this agenda.

The Delivery Board is now developing its work programme. One of its key roles will be to support a business-to-business relationship between the NHS and the Life Sciences industry to help the NHS address the quality and productivity challenge – achieving high-quality care through innovation and prevention in a leaner financial climate (see Section 5). The growing partnership between the NHS and the Life Sciences industry is also of vital importance in ensuring industry can make the maximum contribution to meeting the challenge.

To enable this to happen most effectively, the Delivery Board will report to the NHS Operations Board. Furthermore, the appointment of Jim Easton, NHS National Director for Improvement and Efficiency, as a member of the Delivery Board provides a clear link to the quality and productivity challenge. The Delivery Board will also link to the Ministerial Industry Strategy Group (MISG) for pharmaceuticals and Ministerial Medical Technology Strategy Group (MMTSG).

In developing its work programme, which will be published in Spring 2010, the Board will also look at how it can:

- Improve the uptake of innovative, cost-effective medicines by a variety of means, such as by using the outputs from Lord Darzi's *Next Stage Review* and the Pharmaceutical Price Regulation Scheme innovation package;
- Support implementation of those medical technologies that have received a positive appraisal through the new National Institute for Health and Clinical Excellence (NICE) Evaluation Pathway once operational from Summer 2010;
- Support the work being taken forward through Government's health research strategy, *Best Research for Best Health*[20], to improve the establishment and recruitment to clinical trials in the NHS (see Section 2);
- Improve the strategic relationship between the NHS and the industry through joint-working projects which can support the NHS in meeting the quality and productivity challenge; and
- Consider how it will take forward the commitments set out in the *Blueprint* for the Delivery Board, such as the development and communication of an NHS Small Business Research Initiative (SBRI) prospectus.

20 Further information can be found at: http://www.dh.gov.uk/en/Researchanddevelopment/ResearchAndDevelopmentStrategy/DH_4127109

Accelerating uptake of medical technologies

Accelerating systematic uptake of medical technologies[21], with good evidence of clinical and cost-effective benefits, needs strong engagement by companies with relevant NHS healthcare professionals, both during the product development stage and subsequent marketing to realise the benefits.

One such example is oesophageal doppler guided intra-operative fluid management.

- This is a technology designed to maintain blood flow to the vital organs in patients undergoing major surgery.
- It is designed to improve patient safety and speed up post-operative recovery.

The technology has been implemented as standard of care at three NHS Trusts, with the support of the NHS Technology Adoption Centre (NTAC).

The following benefits were demonstrated:

- A reduction in bed stay by an average of three days for major surgery;
- A reduction in re-admission by 33%; and
- A reduction in re-operation rate of 25%.

The findings of this work were distilled into NTAC's *How to Why to Guide*[22] which aims to enable other Trusts to implement this technology successfully, and to realise the significant benefits in this lean fiscal environment.

Metrics on the uptake of cost-effective medicines and medical technologies

Comparative information is one of the key drivers in determining prescribing behaviours, as demonstrated by the work of Professor Sir Mike Richards, National Clinical Director for Cancer, on the uptake of cancer drugs. Building on the *Blueprint* commitment, Government is continuing its work on developing metrics to provide a comparison of the uptake of cost-effective medicines, both within the NHS, and on an international basis.

The work on international and domestic pharmaceutical metrics, and domestic and EU medical technology metrics, has been yielding fruitful results:

21 The medical technology sector is characterised by a high proportion of small and medium enterprises. These tend to operate mainly within their local health economy in establishing initial interest in their products and developing the market.

22 Further information can be found at: http://www.technologyadoptionhub.nhs.uk/doppler-guided-intraoperative-fluid-management/executive-summary.html

- The first report on national pharmaceutical metrics[23] in the NHS in England was published on 9 September 2009. This showed a variable picture of uptake. Of the 12 appraisals where a comparison could be made, actual use was higher than that predicted for seven medicines, and lower for five. The MISG Metrics Working Group is now considering developments to the methodology for the next report, which will be published in October 2010;
- The international metrics programme, which assesses comparative information for some specific medicines across a range of countries, is also approaching a substantial milestone. A steering group co-chaired by Professor Sir Mike Richards and John Melville, Managing Director, Roche Pharmaceuticals UK, will report by Spring 2010 on the extent and causes of international variation in drug usage;
- In addition, there is continuing progress in the development of national and EU metrics for medical technologies. The Department of Health, in conjunction with industry, has identified six pilot technologies to identify the data sources across the system to enable measurement of uptake and diffusion across the NHS, and to compare to other EU countries. The conclusions of this work will be set out in a report by April 2010; and
- In parallel to this work, the Department of Health is developing a proposal for the sustainable collection of information on the uptake of innovation in medical technology, and is also developing a formula to establish a baseline for comparative analysis. The information that this metrics programme delivers will play a valuable role in encouraging the systematic uptake of medical technologies. This work should be completed by Autumn 2010. Once the methods for sustainable collection have been identified and the data becomes available, it will enable NHS organisations and SHA Innovation Leads to compare uptake, identify barriers and drive change.

Commercial Support Units – Driving regional approaches to support uptake and diffusion of innovative and cost-effective medical technologies

Expertise in NHS commissioning and procurement is vital for successful uptake and diffusion. To support this, the Department of Health has worked with the NHS to establish Commercial Support Units (CSUs). CSUs will provide commercial support to NHS commissioning and provider organisations at a regional level, building capacity and capability. They will encourage collaboration between regional innovation mechanisms, such as SHA Innovation Leads, and NHS procurement mechanisms. They will help identify, understand and dismantle systematic and commercial barriers and disincentives to the uptake and diffusion of innovative, cost-effective medical technologies, such as the difficulties associated with the need to re-design care pathways where a new technology offers the opportunity to provide healthcare diagnosis and treatments in primary care settings where this has previously not been possible.

23 *The use of NICE-appraised medicines in the NHS in England – Experimental Statistics: Health and Social Care Information Centre*. The Health and Social Care Information Centre. Prescribing Support Unit. 2009.

The aim is to develop a way of working that enables beneficial, commercially-provided innovations to be rapidly taken up and diffused. Working with SHA Innovation Leads and stakeholders relevant to the selected technologies, CSUs will be able to mobilise the local health system to address barriers to adoption, whilst also helping to meet the quality and productivity challenge. They will provide, for the first time, a regional focus for business-to-business engagement between companies and the NHS on commercial and strategic issues. The precise form of this engagement has yet to be determined, and the views of key stakeholders in the NHS and industry will be sought during March 2010 in formulating advice for the CSUs. This should lead to a better understanding of unmet clinical need, potential technology solutions and the contribution of NHS-company partnerships to successful uptake and diffusion.

The newly-established NHS Life Sciences Innovation Delivery Board will be instrumental in this process, working with CSUs to help deliver consistency of uptake across all regions. In addition, the Procurement, Investment and Commercial Division at the Department of Health, in conjunction with SHAs, will keep this area under review, advising on any appropriate follow-up action to ensure there is an improvement in uptake and diffusion.

Pathfinder Commercial Support Units

The *Blueprint* committed the Government to ensure that at least two of the new CSUs would develop and test regional approaches to support uptake of innovations from the medical technology sector. To deliver this commitment, the Department of Health issued a call to the medical technology sector, asking companies to submit their suggestions for innovative medical technologies that could make a significant contribution to improving quality and productivity in the NHS. Industry responded very positively and submitted approximately 100 proposals.

The Department of Health considered that, with such a high number of identified medical technologies, the commitment to develop CSU support in this area should be extended to all CSUs. The Department is therefore working with the NHS to prioritise these proposals and will then work with all CSUs and SHA Innovation Leads to prepare plans for delivering the first wave of technologies. The expectation is that uptake and diffusion issues will be identified and plans prepared for NHS-wide introduction of the selected technologies by the end of March 2010. The CSUs will start to implement these as they become operational from April 2010. Procurement processes and other mechanisms will be mapped out and delivered by Autumn 2010. The relevant NHS organisations will then be prepared for the introduction and diffusion of selected technologies by the end of 2010.

Working initially on the prioritised technologies will enable the NHS to identify future responsibilities, particularly for CSUs, to ensure this approach to successful uptake and diffusion becomes sustainable.

Strategic Health Authority duty to promote innovation

The role of the CSUs will be strengthened by the recently-established legal duty on SHAs to promote innovation. Innovation Leads within each SHA are responsible for championing innovation and developing the necessary environment, both culture and infrastructure. They also administer the Regional Innovation Fund, established to support the uptake and diffusion of innovation at a local and regional level – a crucial element in meeting the quality and productivity challenge facing the NHS. The SHAs will agree strategic priorities and will work closely with CSUs to facilitate the uptake of clinically and cost-effective new medical technologies.

Health Innovation and Education Clusters

In addition to the work outlined above, in December 2009 the Department of Health approved the creation of 17 Health Innovation and Education Clusters (HIECs), following the assessment of applications by an independent national award panel. HIECs were first proposed in the *High quality care for all: NHS Next Stage Review final report*[24]. They bring together organisations from across several sectors based on partnerships between NHS organisations, academia, industry, and others. HIECs will promote innovation in healthcare and co-ordinate and provide professional education and training. This has the aim of improving the development of high-quality care and services through quickly bringing the benefits of research and innovation directly to patients.

The use of cost-effective, innovative medicines and medical technologies improves the quality of care provided to patients, and can also realise efficiencies for the NHS. Government has been working closely with the NHS and the Life Sciences industry to improve uptake and diffusion of new health technologies across the NHS. The implementation of the commitments in the Blueprint will take further the work developed by the Ministerial Industry Strategy Group for pharmaceuticals and the Ministerial Medical Technology Strategy Group, and will help to ensure that patients across the NHS have access to the latest cost-effective medicines and medical technologies.

24 Further information can be found at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825

5. Meeting the quality and productivity challenge

The *Blueprint* identified the potential for the Life Sciences industry to make a significant contribution to NHS's drive to improve quality and productivity through a focus on innovation and prevention. The NHS Chief Executive is leading this work and is taking personal responsibility for the NHS Quality, Innovation, Productivity and Prevention (QIPP) programme to achieve this.

In December 2009, the Department of Health launched *NHS 2010-2015: From good to great*,[25] its vision for achieving high-quality care through innovation and prevention in a leaner financial climate. This document identifies opportunities for transforming the quality of care for those with diabetes, heart failure, respiratory disease, cancer as a chronic disease, and dementia, through technological and service-led improvements. The growing partnership between the NHS and the Life Sciences industry, underpinned by an improved business-to-business relationship, is also of vital importance in ensuring industry can make the maximum contribution to meeting this challenge.

Good progress has been made:

- A new NHS Operations Board has been set up to oversee the day-to-day running of the NHS operational issues, allowing the NHS Management Board to focus on the QIPP programme;
- In order to drive delivery of this agenda, Jim Easton was appointed as the new NHS National Director for Improvement and Efficiency to build on the success and strong progress made in implementing the commitments as set out in Lord Darzi's *High quality care for all: NHS Next Stage Review final report*[26]; and
- NHS Boards have engaged with their staff on how innovation can be harnessed to meet the quality and productivity challenge. Industry will be able to contribute ideas through the NHS Life Sciences Innovation Delivery Board (see Section 4), which will provide the mechanism for ongoing strategic industry-NHS engagement. In particular, industry contributions will be sought on uptake and diffusion measures, metrics and procurement.

25 Further information can be found at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_109876

26 Further information can be found at: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825

Improving productivity in care pathways

In 2009, the NHS Technology Adoption Centre (NTAC) led a project on the heart failure pathway to address unmet clinical need. This involved over 80 multidisciplinary NHS professionals from across the pathway, including GPs and specialist heart failure nurses engaging with medical technology companies, Primary and Acute Trusts.

This collaboration resulted in a "clinical decision support" tool to enable better patient management and referrals across a range of organisations including primary, secondary and tertiary care. The tool is currently being integrated into the National Heart Failure Audit database, which supports clinicians to assess and improve patient outcomes.

This example demonstrates strengthening NHS and industry engagement around specific disease areas in order to support delivery of the "18-week referral to treatment" target for a selection of care pathways. This approach demonstrated how the pathways could be improved by the use of medical technology.

Key generic benefits include identification of:

- Existing medical technologies not in mainstream use which could shorten or improve the patient journey;
- Gaps or unmet clinical needs where medical technology could provide a solution;
- Business opportunities for companies in respect of existing technologies and potential for collaboration on the development of new innovative technology solutions;
- Areas where further research would benefit the technology aspects of the pathway; and
- Other organisations, processes and tools to support the introduction of the technologies.

This approach offers industry the opportunity to address unmet clinical need working alongside clinicians to improve productivity and patient outcomes.

Payment by Results

On 14 January 2010, the Department of Health held a strategic workshop to consider how better use could be made of the existing flexibilities in Payment by Results (PbR), and how it could be aligned with other parts of the system to help meet the quality and productivity challenge. Industry and members of the NHS who attended the workshop, including provider, commissioning, and clinical perspectives, agreed that there was scope for improving the operation of PbR systems to facilitate technology and service-led improvements.

The ideas proposed at the workshop will be taken forward by Department of Health policy teams during 2010.

NHS Leadership Council

The NHS and industry share common goals – to improve patient outcomes through high-quality and cost-effective treatment and management. The industry is able to contribute skills and expertise, and the NHS can work with industry to better understand it and maximise its potential contribution. There are therefore benefits in improving mutual understanding, maturing the industry–NHS relationship, and exploring ways in which the NHS and industry can work together to achieve common objectives.

The *Blueprint* committed that the NHS Leadership Council (NLC) would take steps to intensify the sharing of skills and experience with industry leaders to support more strategic collaboration, driving innovation and bringing benefits to patients.

This action is being delivered through the Ministerial Industry Strategy Group's Partnership Working Group, which has developed a senior executive "shadowing programme". The aim of the shadowing programme is to improve the mutual understanding of senior industry and NHS managers, and their respective organisations.

Five industry Chief Executives, two Strategic Health Authority (SHA) Chief Executives, two SHA Medical Directors, and an SHA Director of Strategy and System Reform have all put themselves forward to participate in the first tranche of the programme. An evaluation exercise will be conducted in Spring 2010 to measure to what extent the objectives of the shadowing exercise have been met, with the potential for extending the programme during 2010.

In addition, the Department of Health and the pharmaceutical industry are looking at how to build stronger links and collaboration between the NHS and industry around leadership. Work is underway to establish the links and this work will also be reported back to the NLC.

The QIPP programme is vital to enabling the NHS to deliver significant efficiency savings, in the order of £15-20 billion in 2013/14, whilst improving the quality of care for patients. Strategic engagement in the QIPP programme by industry and the NHS will take place through the NHS Life Sciences Innovation Delivery Board.

To ensure the UK offers a collaborative and innovative environment for Life Sciences, where scientific excellence leads to cost-effective products that are taken up by the NHS, the actions described above must be supported by a number of essential underpinning enablers. Details of progress on delivery these enablers is set out in the sections that follow.

6. E-health records – Exploiting the UK's position as a world leader in health informatics

To ensure the UK fully exploits its position as a world leader in health informatics, Government committed in the *Blueprint* to implement and resource the Strategic Framework for Health Informatics in Support of Research; and to ensure the development of a clear implementation plan by the end of 2009, with joint piloting with industry.

Not only will this ensure that the necessary investment is made for building a cadre of highly-trained academic and clinical researchers and infrastructure; it will also ensure that all stakeholders are engaged and working effectively together. As a result, the UK will be able to maximise the potential of research to improve the current and future health and care of the population.

Research Capability Programme pilots

The Research Capability Programme's objective is to enable research to achieve its full potential as a core activity for healthcare, alongside other uses of NHS data such as safety of care. It aims to do this through building national infrastructure known as the Health Research Support Service (HRSS). This will not only facilitate the recruitment of patients to clinical trials, but will also aid the gathering of data to support ground-breaking work on the health of the population and effectiveness of health interventions.

A pilot programme of the HRSS has been established to demonstrate the viability and benefits of the infrastructure. More than ten pilot studies have been identified for the programme and have been extensively shaped by industry and academia. For example, industry has proposed studies to demonstrate: clinical trial feasibility and recruitment at site and patient level; and the provision of linked data for both health and related material such as social deprivation and geo-spatial factors. The programme is starting with a small pilot in Spring 2010, and the learning from the pilot will feed into the full HRSS programme.

A Strategic Framework for Health Informatics in Support of Research

In early 2009, the major UK funders[27] signed up to *A Strategic Framework for Health Informatics in Support of Research*[28]. The Strategic Framework is designed to realise the research opportunities for clinicians, industry, and academia offered by the Research Capability Programme (England), and analogous initiatives in Scotland and Wales, to develop infrastructure to link electronic health data for research purposes.

A Strategic Coordination Group of funders was established by the Office for Strategic Coordination of Health Research (OSCHR) to oversee the development and implementation of the Strategic Framework. Since the publication of the *Blueprint* in July 2009, good progress has been made in a number of areas:

- Industry is now a member of the Strategic Coordination Group alongside the main charity and Government funders. An industry working group, convened by the Association of the British Pharmaceutical Industry (ABPI), is providing specific input into the group's deliberations;
- A mapping exercise has been initiated by the Strategic Coordination Group to better understand the existing UK research capability and requirements to support e-health records research. Outputs from this work will inform the implementation of the Framework in the areas of research funding and capacity building. A report from the mapping exercise is expected in late Spring 2010;
- As a first step towards building a cadre of trained researchers to support a research pipeline to maximise the potential of the Health Research Support Services, the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC) have funded six MSc and ten PhD Studentships for 2009/10 respectively. A longer-term training strategy will emerge from the mapping exercise;
- A Communications Advisory Group with representatives from public sector and charity funders, industry, and patient groups has been established to provide input into the Research Capability Programme communications strategy. The Group will focus on how best to promote the services of the Research Capability Programme to the research community, and shape the services in response to the community's feedback; and
- A UK E-Health Dataset Consortium was established in Summer 2009 to consider linkages between the established UK electronic health record programmes – the English Research Capability Programme, the Scottish Health Information System for Research, and the Welsh Secure Anonymised Information Linkage programme – in order to maximise the

27 Cancer Research UK; Chief Scientist's Office, Scottish Government Health Directorates; the Engineering and Physical Sciences Research Council (EPSRC); the Economic and Social Research Council (ESRC); the Medical Research Council (MRC); the National Institute for Health Research (NIHR); the National Institute of Social Care and Health Research (NISCHR) in Wales; and the Wellcome Trust.

28 Further information can be found at: http://www.mrc.ac.uk/About/Strategy/Governmentfunding/index.htm

potential of the emerging infrastructure for delivering world-leading public health research.

The maturity of the datasets provided by the NHS in the UK, combined with the commitment by Government and charitable research funders and pharmaceutical research organisations to work towards a shared vision to deliver a comprehensive e-health records database, places the UK in a unique position internationally to undertake ground-breaking health informatics research.

E-health records research

In recent years, the UK has been at the forefront of work that utilises large data sets for the benefits of improving public health, and addressing social problems more generally. The Research Councils and major charity funders have, over a number of years, invested in research, infrastructure and methodological development. Now, working together under the auspices of the Office for Strategic Coordination of Health Research (OSCHR), the major funders are creating a unique environment in the UK to facilitate health informatics research.

The English Research Capability Programme (RCP), the Scottish Health Information System for Research (SHIS-R), and the Welsh Secure Anonymised Information Linkage programme (SAIL) will provide infrastructure to facilitate access by researchers to a range of federated NHS data sources unrivalled anywhere in the world. Over time, additional non-NHS datasets will be added to the emerging research services, thus creating a powerful UK Health Research Informatics Platform and a unique selling point for UK health research.

Use of e-health data records in practice

Launched in 2006, Generation Scotland uses a large, family-based intensively-phenotyped cohort. Cardiovascular, metabolic, musculo-skeletal and mental health phenotypes, and biological materials, including DNA, are being systematically extracted and stored from all participants. This uniquely rich dataset will be fully integrated with routine retrospective and prospective electronic health records, including prescribing records, to build a rich store of material to explore the inherited nature of common diseases, and to enable examination of how lifestyle factors influence the development of chronic disease.

The deep phenotyping of samples in the Generation Scotland cohort opens up the prospect of an unrivalled resource for Life Sciences companies to:

- Develop hitherto elusive biomarkers for a wide variety of conditions;
- Develop earlier and better disease diagnosis in patients;
- Discover more effective and better targeted medicines; and
- Enhanced monitoring of adverse drug reactions.

The Strategic Framework is crucial to the UK unlocking the potential that the UK Health Research Informatics Platform will offer for research, patient safety and public health. It will provide unparalleled opportunities for important new ethical, medical and social research activities such as observational studies and interventional clinical trials. The research community will be able to interrogate health records while ensuring that information is treated and handled in an appropriate way to protect the rights and confidentiality of patients. This will lead to improved clinical trial recruitment and management, and improved drug safety. In addition, the National Institute for Health and Clinical Excellence's (NICE) engagement in the Research Capability Programme will enable NICE to use data that is routinely collected by the NHS to speed up its appraisal process.

7. Building a sustainable Life Sciences skills base

People are our greatest asset. In a knowledge economy, the bedrock of UK Life Sciences is a world-class supply of highly-motivated, innovative and skilled scientists, clinicians and technologists who have the necessary skills and knowledge required to develop the innovative products and services that will improve patient care in the UK.

The UK has a strong base on which to build: it has a higher education system that is recognised worldwide for excellence and an NHS system that has a reputation for delivering high-quality education and training. Both also have a strong track-record in translating research into commercial application, such that many Life Sciences companies are built on the exploitation of this cutting-edge research and development. Our reputation as a world leader in research therefore creates a strong pull to attract and retain Life Sciences business in the UK.

However, the *Blueprint* highlighted the potential for the UK to do more to build on the successes within our higher education and NHS systems. It outlined a package of actions that would ensure current and future generations of scientists, clinicians and technologists have the core skills in mathematics, laboratory practices and key disciplines, such as *in vivo* sciences and clinical pharmacology, needed to pursue a career in industry, academia or the NHS.

In November 2009, the Government published two important documents that together will build a strong, vibrant and flexible skills system. *Skills for Growth – The National Skills Strategy* and the *Higher Ambitions Framework*[29] comprehensively outline the UK's vision for equipping future generations with the necessary skills required to take up employment opportunities in the key industries which have the potential to drive future growth in our economy. An analogous report of the Joint Future Thinking Taskforce on Universities, *New Horizons*[30], set out a high-level framework for the Scottish Government, universities and the Scottish Funding Council. Life Sciences, as a high-tech and highly-skilled industry, is in an excellent position to capitalise on this focus which provided a welcome boost to the delivery of the *Blueprint* actions.

Establishing the Industry and Higher Education Forum

In the *Blueprint*, Government committed to establish an Industry and Higher Education Forum for Life Sciences. This Forum would enable employers, universities and public sector funders to agree what specialised course content is needed to ensure undergraduates and postgraduates undertaking relevant degrees and courses, such as biological sciences, gain the necessary skills and knowledge to pursue a career in Life Sciences.

29 Further information can be found at: http://www.bis.gov.uk/policies/skills-for-growth; and http://www.bis.gov.uk/policies/higher-ambitions

30 Further information can be found at: http://www.scotland.gov.uk/Resource/Doc/82254/0069165.pdf

The Forum was established in December 2009 and comprises three elements:

- *The Forum Executive Board* comprises senior representatives from university mission groups, the Department of Health, industry, student bodies and Government. It will meet for the first time in February 2010 to set its remit. It will, as a minimum, oversee development of the Forum Advisory Group and ensure it delivers on its remit, as outlined below.
- *The Forum Advisory Group* brings together strategic and operational delivery representatives from Government, industry, the Department of Health, academia, and public sector bodies, such as relevant Sector Skills Councils and Research Councils.

  The Advisory Group held its inaugural meeting in December 2009 and is currently developing its work plan for 2010. In considering this work plan, it will build on analyses of current and future skills needs to set out how to establish the UK as a world leader in scientific capability. In doing so, it will set priority skills areas where there is a need to encourage students to study those subjects that meet employer demand and national priorities. It will also develop an action plan of activities, which could include the provision of additional graduate modules and postgraduate courses, to address these skills gaps. As an early activity, the Advisory Group will work with the Society of Biology on its development of an accreditation model for biological sciences.

- *The Forum Task and Finish Teams* are time-limited, expert teams reporting to the Advisory Group. These teams will be established to tackle particular skills issues where there is one or more of the following issues:
  - Limited analysis of the skills gaps;
  - A need to seek the views of specialists and experts to understand the current and future skills needs; and
  - A need to take action to address the skills gaps.

The first two Forum Task and Finish Teams were established for *in vivo* sciences and clinical pharmacology following the launch of the *Blueprint*. In February 2010, these Teams will report their findings to the Forum Advisory Group, which will agree how to deliver the recommendations. It is anticipated that the first phase of delivery will take place throughout 2010.

Providing targeted support in areas of greatest need: The Medical Research Council Clinical Pharmacology and Pathology Programme

In order to provide high-quality care and be able to evaluate and prescribe innovative medicines, clinicians must be familiar with the relevant practices in clinical pharmacology

and pathology. The *Blueprint* highlighted, as had several industry reports[31], the precarious state of these skills in the UK. As well as the formation of the Forum Task and Finish Team to address the critical skills gap in the UK, the Medical Research Council (MRC) made provision for two Higher Education Institute-led flagship training programmes in clinical pharmacology and pathology, supported by £1.85 million each, through reprioritisation within the MRC's research career awards budget.

In November 2009, a panel of industry and academic experts met and agreed a shortlist of high-calibre proposals from across the UK. These shortlisted proposals boasted excellent track records of training opportunities, mature NHS and industry partnerships likely to broaden trainees' perspectives and career opportunities, complementary pre-doctoral, doctoral and post-doctoral training posts to achieve run-through from postgraduate to post-doctoral training, as well as innovative approaches to supervision and mentoring to support trainees.

The full proposals will be assessed in March 2010, and it is anticipated that two awards of £1.85 million each will be made in Spring 2010.

Developing a world-first accreditation model for undergraduate biological sciences degrees

Government outlined in the *Blueprint* the intention of the newly-formed Society of Biology to establish an accreditation model that would help ensure undergraduate biological sciences students leave higher education with the core practical and high-level maths skills and specialist competencies needed to prosper in Life Sciences research and development.

The Society of Biology is working with Government, academia and industry to explore how an accreditation process should be delivered for biological sciences degrees. It is planned that this process will recognise academic rigour, experience and expertise within the biological sciences, with a specific focus on laboratory and field work, and on transferable skills related to employability.

The Society of Biology launched an online consultation in December 2009, which will close at the end of February 2010, to seek views from industry and academia as to how the accreditation process should operate. The Society of Biology will build on these initial activities by establishing a pilot accreditation scheme, focusing on Life Sciences and environmental sciences in the 2010/11 academic year. It is expected that the pilots will be rolled out in universities across England, Scotland, Wales and Northern Ireland.

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31 Including:
Clinical pharmacology and therapeutics in a changing world. Royal College of Physicians. 1999. http://www.rcplondon.ac.uk/pubs/contents/60932358-a91e-4e12-aa09-e9428a88884f.pdf;
Skills needs for biomedical research. Association of the British Pharmaceutical Industry. 2008. http://www.abpi.org.uk/Details.asp?ProductID=338; and
Innovating for Health. Royal College of Physicians. 2009
http://www.rcplondon.ac.uk/pubs/contents/76673804-76c5-4ab3-89a0-92d44e45edc3.pdf

Developing the future Healthcare Science and Academic Workforce within the NHS

The UK's potential for supporting health research, as well as the translation of that research and development into services and technologies, is significant. Scientific and technological advances are being made continually and the roles for the healthcare science workforce are changing as a result. The NHS healthcare science workforce will increasingly provide specialised support to patients through new therapeutic interventions, complex diagnostics and clinical engineering.

To meet this challenge, the UK must modernise scientific careers within the NHS to ensure staff have the knowledge and skills to play a significant part in the development, uptake and diffusion of innovative medicines and technologies, and the delivery of 21st century care to patients.

Modernising Scientific Careers in the NHS

The NHS has the largest non-medical scientific workforce in any employment sector across the UK, numbering approximately 55,000 working in the areas of pathology, genetics, physiology, medical physics and clinical engineering.

In March 2009, Government completed a consultation on proposals to ensure that the healthcare science workforce was educated and trained to meet the challenges of modern healthcare. The consultation has led to the development of a UK-wide policy document *Modernising Scientific Careers: the UK Way Forward* and an England Implementation Plan, both to be published early in 2010. These documents will encourage better linkages between the NHS, academia and industry, stronger development and alignment to skills needs in STEM[32] subjects, and improved research and development for the benefit of patients. All of these elements will create a workforce working within, and in partnership with, academia.

Modernising Scientific Careers will introduce changes that simplify career structures and create new education and training programmes within academia and the NHS that will ensure the science workforce in healthcare is equipped to respond to scientific and technological advances across the disciplines, changing healthcare needs and provision, and the scientific evidence base.

32 Science, Technology, Engineering and Mathematics.

Developing innovative, cross-discipline training programmes for the healthcare science workforce

As part of the recognition of the revolution in genetics medicine[28], the Department of Health is investing over £4.5 million to address the training needs of the future healthcare science workforce in genetic laboratories. A pilot programme in clinical genetics involving 33 trainees began in October 2009, combining clinical molecular and clinical cytogenetics disciplines.

This innovative programme brings together two disciplines which have, until now, been trained separately, and will optimise the technological opportunities of both, ensuring a more coherent understanding of genetics as applied to health. Many of the applicants for these programmes had either excellent first degrees or higher degrees, such as Masters and PhDs, and will bring academic skills and rigour into the workforce, as well as the application of cutting-edge teaching of genetics.

Building innovation into education commissioning

The vision for NHS education commissioning[34] is to promote quality and innovation, driving improvements in productivity, and delivering a high-quality NHS workforce able to deliver high-quality care. Awareness and understanding of the value and importance of innovation must be embedded into the education framework for commissioners to ensure innovation can play a role in driving uptake and diffusion across the NHS.

The Department of Health has been working to achieve this on two fronts:

- Published in January 2010, *Education Commissioning for Quality*[35] outlines a comprehensive system of education commissioning, and delivers the *Blueprint* commitment. Its principal role is to support Strategic Health Authority (SHA) commissioners to deliver world-class education commissioning. It contains a section on innovation, drawing particular attention to the need to foster a culture and mentality favourable to innovation and the uptake of innovative products within education systems.

  The guide will support SHA commissioners and Higher Education Institutions to overcome specific local barriers to innovation in education commissioning, for example the lack of a system for encouraging innovation developed in the NHS into the education system. This approach is delivered through specialist education, paid for via a specific NHS training budget, Medical and Professional Education Training (MPET). The development of Health Innovation and Education Clusters (see Section 4) will also be helpful and the review team will consider how this has progressed after 12 months; and

33 The use of genomic information and technologies to determine disease risk and predisposition, diagnosis and prognosis, and the selection and prioritisation of therapeutic options.
34 The process of identifying, defining, purchasing and evaluating the education and learning required by a health community to meet a current and future service need.
35 Further information can be found at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110774

- Building on the principles laid out in *Education Commissioning for Quality*, a mixture of good practice, guidance and new contractual requirements are used to enable delivery of a strengthened education commissioning system. In order to further incentivise the use of innovation, 5% of the higher education funding supplied to the NHS will, for the financial year 2010/11, be contingent on the delivery of quality and innovation within MPET. This will be delivered by SHA Education Commissioners.

Together, these measures will help to ensure that all NHS staff are aware of the value of innovation, and understand their duties to promote its uptake and diffusion.

Life Sciences Business and Leadership Programme

Business and leadership skills are as vital to building a successful small or medium Life Sciences enterprise as the scientific excellence that led to its formation. However, companies feel that developing these business and leadership skills would be difficult to resource. In the *Blueprint*, the Government committed to work with industry to agree how a Business and Leadership Programme could be funded. In response, an industry sponsorship model has been agreed.

The HealthTech and Medicines Knowledge Transfer Network and the BioIndustry Association (BIA) are working with COGENT, the process industry Sector Skills Council, to deliver the Programme and its funding model. They are proposing to integrate the Programme into the Process Industry National Skills Academy. A bid to extend the Skills Academy will be submitted in the forthcoming National Skills Academy 5th Round. Decisions on expressions of interest are expected by the end of March 2010.

If the bid is successful, the Programme will be piloted in Summer 2010 and will be open initially to medical biotechnology companies in the UK. It will be expanded to medical technology and industrial biotechnology companies at a later date. Further details will be available on the COGENT website by the end of March 2010.

People are our greatest asset. It is our duty to ensure that this asset, the next generation of scientists, clinicians and technologists, has the skills and knowledge necessary to pursue a career in the Life Sciences. The skills actions Government is delivering will help to ensure a sustainable pool of scientists able to move across the traditional boundaries of business and academia, contributing significantly to the long-term attraction of the UK as the centre of Life Sciences research and development.

8. Supporting UK regenerative medicine – A growing and strategically important industry

The UK is a world leader in regenerative medicine[36]. The number of UK companies working in this field has been growing in recent years and there is significant potential for the UK to build on this in the future.

However, a number of challenges must be overcome if the UK is to fulfil its potential. The *Blueprint* therefore announced a "RegenMed" programme to underpin and enable the best regenerative medicine businesses in the UK to flourish, and to build a connected community through programmes of work to develop medicines and technology platforms.

The RegenMed Programme

The Programme, managed by the Technology Strategy Board (TSB), comprises a total investment of £21.5 million[37] and aims to create a step-change in the competitiveness of UK regenerative medicine businesses and technology providers, and enhance the ability of UK business to provide global solutions.

A high-level group, comprising industry and academic experts, is providing advice on Programme development. The group is focusing on how best to accelerate translational research for commercial success, as well as ensuring engagement of key participants such as industry, academics, regulators, and clinicians.

Competition launch

In September 2009, the TSB launched the first two competitions for funding business-led projects as part of the RegenMed programme of investment: *Regenerative Medicine Therapies*; and *Value Systems and Business Modelling*.

Regenerative Medicine Therapies: Support will be provided for 30 commercial projects with 26 different lead companies. The projects will explore the feasibility of developing previously-identified therapeutic candidates into regenerative medicine products.

Value Systems and Business Modelling: Two large-scale research and development (R&D) projects will involve a further 16 UK companies, research organisations and academic institutions. These projects will explore where and how value is created in the regenerative medicine value chain, informing the development of business models to enable businesses to best capture that value for themselves and for the UK economy as a whole. The projects in the *Value Systems and Business Modelling* initiative include consortia made up of industry, academia, and NHS organisations.

As a direct result of the first two competitions, over 40 British companies are to receive more than £4.5 million to support R&D into regenerative medicines. The

36 The replacement or regeneration of human cells, tissues or organs to restore or establish normal function.

37 £18 million from the Technology Strategy Board and £3.5 million jointly from the Engineering and Physical Sciences, Biotechnology and Biological Sciences, and Medical Research Councils.

RegenMed Programme will continue to grow in 2010, with the aim that the remaining £17.5 million is committed in 2010/11 to projects lasting 2–3 years. In particular, follow-on competitions in *Regenerative Medicines Therapies* and new competitions in *Tools and Technologies* will be launched.

Regenerative Medicine Therapies – Feasibility case studies

Feasibility studies typically last six months and represent a maximum investment from the Technology Strategy Board (TSB) of £100,000 per project. The projects are aimed at demonstrating the feasibility of developing a particular regenerative medicine product, and will lead to projects and consortia that can participate in larger initiatives to be run by the TSB in 2010.

Therapeutic Human Embryonic stem cells: A Study to Map Sustainable Supply (TEAMSS) – Pfizer Regenerative Medicine

TEAMSS will address a key challenge to sustaining regenerative cell products through clinical trials to approval. It will identify critical points in the product development path based on just-in-time delivery of a candidate human embryonic stem cell therapy for age-related macular degeneration (AMD) and prescribe alternative, regulatory-compliant approaches to product supply.

The PISCES (Preliminary Investigation of Stem Cells for Stroke) trial – Steps to clinical trial initiation – ReNeuron Group plc

Stroke is the third largest cause of death and the single largest cause of adult disability in the developed world. ReNeuron has received regulatory and conditional ethical approvals to commence a Phase I clinical trial in the UK with its lead ReN001 stem cell therapy for disabled stroke patients. The PISCES trial will be the first in the UK using a proprietary neural stem cell therapy and will be conducted through the NHS at Glasgow's Southern General Hospital. The grant will fund the completion of important pre-trial activities, which include the registration of the cell delivery device and the manufacture of a second clinical lot to be used in the clinical trial.

dCELL® Meniscal Repair Device in vivo pilot study – Tissue Regenix

Tissue Regenix Ltd developed the dCELL® process that removes cells, DNA and major immunogenic material from tissue allowing it to be implanted into patients without anti-rejection drugs and with the potential to regenerate inside the patient's body. The dCELL® Meniscus is an acellular scaffold produced from meniscal tissue that matches the strength and unique structural architecture of natural meniscus, preserving biomechanical properties and allowing function on implantation. To develop a dCELL® Meniscus product for clinical trials and subsequent market release, a full biological evaluation package and extended functional model is required. This project takes the next development step and will demonstrate *in vivo* proof of concept for the dCELL® Meniscus in a pilot functional study. If successful, it is estimated that the device could be in human trials within 1–2 years.

Increasing expertise in Life Sciences

In the *Blueprint*, the TSB also committed to increase its expertise in Life Sciences. It has done this through seconding individuals from the Medical Research Council (MRC) and from industry to work on particular strategic projects, including building the case for a potential Innovation Platform in Stratified Medicines. Furthermore, the TSB is currently recruiting for additional technologists to increase coverage of the medical biotechnology, pharmaceutical, and medical technology sectors.

The UK regenerative medicine industry is growing in size and global importance, and is an area of Life Sciences where the UK can lead the world. The RegenMed Programme of investment will help to support the emergence of a thriving industry and ensure the UK can realise its potential.

9. Ensuring access to finance

The UK Innovation Investment Fund

Recognising the difficulty high-tech, innovative companies are facing in securing venture capital investment and the threat this poses to the future of highly innovative and world-leading research and development, in June 2009, Government announced the creation of a UK Innovation Investment Fund (UKIIF).

The UKIIF has been established with a clear focus on the venture capital market, which is essential in driving innovation. The UKIIF will target small growing businesses including start-ups and spin-outs, and pre-profit and pre-revenue stages of development.

Fund of Funds Managers and initial pool of funding

Since the announcement of the Fund, rapid progress has been made in establishing the Fund and leveraging additional funding. In the Pre-Budget Report in December 2009, the Chancellor announced the appointment of Hermes Private Equity and the European Investment Fund (EIF) as the UKIIF Fund of Funds Managers, subject to contract. UKIIF will ensure that venture capital is available by early 2010 to invest in innovative UK businesses in key industries such as Life Sciences.

Government's objective was to raise investment that matched Government's £150 million at first closing. With Government's investment leveraging £175 million in additional money, an initial pool of funding worth £325 million has been created and the target has been exceeded in one of the most difficult fundraising climates for venture capital in a decade.

Investing in Life Sciences

Government will invest £100 million in a £200 million, at first closing, technology fund of funds to be managed by the EIF which will cover Life Sciences, as well as digital/ ICT and advanced manufacturing.

Further private investment will be secured before the Fund closes for investors in 2011. One of the largest pools of venture capital for investment in technology funds in Europe has now been raised, and the ambition remains to create a £1 billion, 15-year Fund. The extension to the life of the Fund, from 10 to 15 years, is a direct result of feedback from the Fund of Fund Managers and the Life Sciences industry recognising the long timescales involved in new product development.

Promoting NHS procurement of Life Sciences innovation

For many small Life Sciences companies, growth depends on access to the NHS market and to clinicians who use their products. The *Blueprint* recognised the opportunity that Government pre-commercial procurement schemes, such as the Small Business Research Initiative (SBRI), offer: for the NHS to deliver a better

service to patients through the procurement of innovative products from Life Sciences companies; and for Life Sciences companies, particularly small and medium enterprises (SMEs), to gain better access to clinicians and procurement opportunities in the NHS.

For the first time, in September 2009, the National Innovation Centre (NIC) proactively sought solutions from SMEs to needs that had been directly identified by clinicians. The NIC ran online competitions to address three Ambulance Service and three paediatric clinical needs identified in Spring 2009. NIC offers a range of pre-commercial approaches for its competitions, one of which is SBRI, to speed up the procurement of innovation in the NHS.

Twenty companies entered the competitions; these were predominantly SMEs but also included some individual innovators. Nine contracts were awarded to both SMEs and individual innovators. Each development is closely project-managed by NIC, with updates provided and further collaborations facilitated via NIC's website. The aim is that this assertive innovation development process should take a product from clinical need to market readiness within 18 months. NIC is planning to launch at least wo more rounds of competitions in 2010/11.

SMEs that already have technology innovations can carry out their own assessment of their products on NIC's technology-ready Scorecard. The NIC Scorecard is reviewed by NHS Supply Chain for placement of products on its NHS catalogue, offering the possibility that the technology will be sold across the NHS.

The UK Life Sciences industry includes many small, innovative companies. Two longstanding barriers to growth of these companies have been access to sufficient finance, and access to procurement opportunities in the NHS. The UKIIF is one way that Government has successfully leveraged private sector investment that will address the under-supply of risk capital in strategically important industries such as Life Sciences. Government also recognises the potential of innovations in small companies to meet patient needs and is increasing the opportunities for small companies to access the NHS and its clinicians by running flexible pre-procurement competitions.

10. Incentivising innovative activity and investment

The Patent Box

The UK is facing competition from overseas to attract innovative activity and investment, including through special tax regimes that offer low corporate tax rates on income derived from intellectual property. Budget 2009 announced that Government would work with business to examine the balance of taxation on innovative activity, including intellectual property, to ensure the ongoing competitiveness of the UK. In particular, the work would consider the role of business tax in encouraging investment in innovation, and the impact on jobs and productivity growth in the UK. It would also consider how the UK tax system compares to other regimes internationally, and the role that taxes play in decisions on where to locate innovative investment, including the location of dedicated research and development and manufacturing centres, and patent development.

As part of this work, Government looked at the case for a reduced rate of corporation tax applied to income from patents (a "Patent Box") and committed in the *Blueprint* to provide an update in the Pre-Budget Report. The Report was published in December 2009 and announced the outcome of this work: the introduction of a Patent Box applying a 10% rate of corporation tax to income from April 2013 to strengthen the incentives to invest in innovative industries and ensure the UK remains an attractive location for innovation.

Government will consult with business in time for Finance Bill 2011 on the detailed design of the Patent Box, including how to define and target the income receiving the reduced rate of tax.

Consortium relief

In the *Blueprint*, industry suggested the investor structure in many small companies could preclude Life Sciences investors from benefiting from consortium relief, and that changes to this feature of group relief would have the potential to incentivise investment in small and medium enterprises by larger companies.

Since the publication of the *Blueprint*, discussions on this issue have continued. Government continues to assess the case for a change to the consortium relief rules. Government welcomes evidence as to how a change in the rules could promote investment and is open to future dialogue with business on this issue.

11. Marketing UK Life Sciences

Under the guidance of the UK Life Sciences Marketing Board, and working alongside the Office for Life Sciences and the Department of Health, UK Trade & Investment (UKTI) has increased marketing activities over the past six months to further build the reputation and brand of UK Life Sciences overseas. Activities undertaken include a co-ordinated programme of Ministerial overseas visits, and an increased UK presence at major international events.

The aim of these activities has been to ensure all key stakeholders are fully aware of the strengths of UK Life Sciences, the significant efforts Government is making to improve the operating environment for the industry, and the benefits to companies of building a Life Sciences business in the UK. This will play a crucial role in ensuring the UK can continue to attract inward investment. This accelerated programme is continuing into 2010 and will include specific events to communicate the strong progress made in delivering the *Blueprint* actions.

Promoting UK strengths and opportunities in Life Sciences

The UKTI marketing activity aims to increase trade and investment by raising awareness of the UK Life Sciences offer and wider business-friendly environment, including current work to deliver the *Blueprint* actions. To ensure international companies hear and understand these messages, a series of high-level events and visits have been organised, focused on the US, Japan and Europe, as well as a substantially increased presence at major international Life Sciences events overseas. This enhanced activity is being funded using £1 million from the Strategic Investment Fund (SIF).

Ministerial overseas visits

In September 2009, Lord Drayson, Minister for Science and Innovation, visited New York and Boston to discuss the broad-ranging work underway to improve the UK operating environment with US-based Life Sciences companies. A delegation of senior officials, academics and NHS Medical Directors also travelled to New Jersey and Boston in November 2009 to meet US companies and promote the changes being made to improve the clinical trials environment in the UK.

In October 2009, Lord Drayson visited Tokyo to meet Japanese Life Sciences companies, and Mike O'Brien, Minister for Health Services, led a UK delegation to France and Switzerland as part of a programme of ongoing Ministerial visits to international pharmaceutical companies to forge closer links between industry and Government.

These high-level missions have allowed overseas companies to better understand the positive changes taking place in the UK and explore potential investment opportunities.

In 2010, UKTI will follow up on the contacts made during the 2009 Ministerial visits. The February US roadshows will offer an early opportunity to do this.

Boosting the UK presence at international Life Sciences events

To complement these strategic high-level visits, the UK has substantially increased its presence at a number of major international Life Sciences events, offering international companies, governments and stakeholders greater opportunities to see first-hand the excellence of UK Life Sciences. The programme of events will continue in 2010.

In October 2009, Sir Bruce Keogh, NHS Medical Director, led a delegation to AdvaMed[38] in Washington. Extra funding from the SIF meant a greater number of UK companies were able to attend the event, showcase products and participate in partnering sessions with US distributors and regulators. This resulted in immediate opportunities for greater technical collaboration, licensing and partnering.

An increased UK presence, funded by the SIF, was also seen at Medica[39] in November 2009 and at the Arab Health Exhibition and Congress[40] in January 2010. These events have enabled the UK to further build the Life Sciences brand internationally and the presence of key UK industry figures, such as Lord Darzi who attended both Arab Health and Medica, has raised both the profile of the UK mission overall, and the profile and trade opportunities of individual UK companies involved in these events.

Life Sciences Roadshows – Promoting UK Life Sciences in the USA in 2010

Continuing in 2010, UKTI is working with colleagues in the USA to organise a series of high-profile Life Sciences roadshows to communicate to medical biotechnology, pharmaceutical and medical technology industry leaders, as well as state officials and relevant trade associations, the announcements surrounding delivery of key *Blueprint* commitments. This will promote UK excellence in the US market and encourage closer engagement around trade and investment opportunities.

2010 UK International Life Sciences Event

In Autumn 2010, UKTI will run a major international event in the UK alongside the NHS-sponsored Innovation Expo. Building on the success of the inaugural Expo event in 2009, UKTI will add a high-level technology partnering dimension to this event, bringing overseas Life Sciences businesses to the UK and showcasing the best of the UK Life Sciences industry. This will be the first pan-UK Life Sciences partnering event of its kind.

38 The leading medical technology, business development, capital formation and policy forum in the US.

39 The world's largest exhibition for the global medical technology industry held annually in Dusseldorf. It has on average 3500 exhibitors each year and attracted over 130,000 attendees in 2008.

40 The largest healthcare exhibition in the Middle East. The 2009 event attracted over 2000 exhibitors and over 56,000 professionals.

Raising the UK profile at international events – Medica 2009

Extra resources from the Strategic Investment Fund (SIF) were devoted to enhancing the UK presence at Medica 2009, the world's largest medical device tradeshow and exhibition held annually in Dusseldorf. The show attracted around 4,300 exhibitors from a wide range of international markets and 138,000 trade visitors from over 100 countries. Over 300 UK-based companies exhibited.

Working closely with trade associations and UK Life Sciences organisations, UKTI used the extra resource provided by the SIF investment to help a greater number of new companies attend this international exhibition and raise the profile of UK Life Sciences companies at the show.

UKTI ran four stands across the exhibition, offering UK companies facilities for pre-brokered meetings; for example, meetings with a range of UKTI experts based in overseas Embassies, High Commissions and Consulates, who advised on opportunities in specific markets, and with accompanying international buyers from twelve different markets who offered potential trade opportunities. The UK presence was greatly enhanced through better branding and marketing, and the presence of Lord Darzi who toured the UK Pavilions and gave an interview to Medica TV to raise awareness amongst the international audience of the participating UK companies. Briefing seminars were also run to help companies understand the UK environment for Life Sciences and a panel of experts helped companies understand NHS procurement practices.

Of the UK companies surveyed at the event, 81% expected to win new business from Medica, with an overall projected value of more than £14 million. This represented substantial success for the UK companies and for UKTI's facilitation activities.

A single industry voice for marketing UK Life Sciences

The importance of presenting a unified voice on UK Life Sciences overseas was highlighted in the *Blueprint*, with Government committing to hold a series of roadshows throughout the English regions and Devolved Administrations from September 2009.

Following an initial roadshow in September, preparations are well underway for a programme of roadshows in 2010. Working closely with the Regional Development Agencies, local trade advisers and the Devolved Administrations, UKTI will run 12 roadshows across all UK regions in February and March 2010, providing an excellent opportunity to publicise the *Blueprint* actions and encourage industry and wider Life Sciences stakeholders to speak with one voice in marketing UK Life Sciences overseas.

Each event is expected to attract a mixed audience from industry, academia and regional trade associations. The events will include formal presentations and panel discussions to ensure that all stakeholders are informed of the action Government is taking to transform the environment for UK Life Sciences and the benefits this will

bring. The roadshows will also offer an opportunity to provide a range of support and guidance to Life Sciences companies looking to internationalise.

Attracting additional investment into the UK

The *Blueprint* set out the importance of facilitating greater access to finance for Life Sciences companies. To complement the UK Innovation Investment Fund (see Section 8), UKTI is facilitating the creation of a separate, privately-financed UK-based Healthcare and Life Sciences Technology Fund. Its primary aim is to provide a potential funding vehicle for UKTI's Global Entrepreneur Programme (GEP) Life Sciences client companies considering relocating to the UK. The Fund has already attracted the interest of a number of major Life Sciences companies, who, through investing in UK healthcare start-ups, could increase their product portfolios.

UKTI, having assisted in the initial strategic development activity, will continue to advance the Fund's creation, and support the individual companies that will benefit from the Fund.

Enhancing the UK's strategic alliances with key US Life Sciences clusters

At the start of October 2009, the three Life Sciences associations for the London, Oxford and Cambridge areas (LBN, OBN, and ERBI) signed a Memorandum of Understanding (MoU) with the Boston-based Massachusetts Biotechnology Council. The MoU will present greater opportunities for international partnering and access to investors, as well as a greater transfer of knowledge between the US and the UK. This activity, facilitated by UKTI, represents a real success and further progress in encouraging deeper partnerships and collaborative working between UK- and US-based companies. Further work to build on the MoU will be taken forward by LBN, OBN and ERBI.

Discussions to build closer ties with other leading US Life Sciences clusters are also underway. For example, two regional representative organisations, Medilink West Midlands and ERBI, have made separate approaches to Life Science Alley in Minnesota[41] to establish partnering arrangements. These would give UK companies better access to the US market and the potential for better communication and increased trade with, and investment from, US companies. More detailed discussions are expected in early 2010 to develop an outline of proposals for possible co-operation.

41 A Minnesota-based industry association with particular expertise in medical technologies (www.lifesciencealley.org/about) and one of the largest in the USA.

In a year of action for Life Sciences, Government has made significant progress on a set of actions to further enhance the operating environment for Life Sciences companies in the UK. It is important that the progress made, and the benefits of this enhanced operating environment, are conveyed to investors and partners throughout the world. Increased marketing activities over the past six months under the guidance of the UK Life Sciences Marketing Board are helping to deliver this message and build the UK's reputation in Life Sciences, thus underpinning trade and investment activities. This effort will continue into 2010 and will include specific activities to communicate the strong progress made.

Annex A

Future delivery milestones

Since the publication of the *Life Sciences Blueprint* in July 2009, significant progress has been made in delivering the commitments set out in the document. Delivery continues for many *Blueprint* actions and next steps for each action are set out below.

	Future delivery milestones
Enhancing collaboration in Life Sciences	
UK Life Sciences Super Cluster	At the heart of the UK Life Sciences Super Cluster will be the creation of Therapeutic Capability Clusters. In early 2010, a call for initial applications to establish a pilot Capability Cluster will be launched, managed by the Office for Strategic Coordination of Health Research (OSCHR). The pilot, expected to be operational by Summer 2010, will target research in immunology and inflammation, focusing on diseases such as asthma and rheumatoid arthritis.
The Research Excellence Framework	In 2009 the Higher Education Funding Council for England (HEFCE) consulted, on behalf of the four UK funding bodies, on its proposals for a new Research Excellence Framework (REF). This REF would explicitly assess the economic and social impact of research. HEFCE will develop its proposals further in light of the responses to the consultation, as well as the outcomes of the pilot exercise that will test and develop the method of assessing the research impact and collaborative excellence elements of the REF, announced with the consultation. The pilot will be completed by mid-2010.
Encouraging partnerships for health research	The Government remains committed to ensuring that continued funding from the National Institute for Health Research (NIHR) for Biomedical Research Centres (BRCs), Biomedical Research Units (BRUs) and Clinical Research Facilities (CRFs) will be partly contingent on demonstrable working with industry.

	Future delivery milestones
Improving the UK environment for undertaking clinical trials	
Research and clinical trials in the NHS Operating Framework	In the future, NHS Trusts will publish performance levels for the number of patients recruited into clinical trials in their Quality Accounts.
NIHR Research Support Services – Creating a national framework for the professional management of health research	The next steps to transition NHS Trust R&D departments to become NIHR Research Support Services are: ● By April 2010, NIHR will agree timelines for the delivery of national research governance standards by these new Research Support Services; ● The NIHR will publish a toolkit, along with guides for risk management, competencies and training requirements, of standard operating procedures to support the delivery of the standards nationally; and ● During 2010/11, the NIHR will embed national research governance stands within NHS Trust R&D departments, facilitating their transition to NIHR Research Support Services.
The National Institute for Health and Clinical Excellence (NICE) – Supporting the NHS as an innovation champion	
The Innovation Pass	In November 2009, Government launched a consultation on the Innovation Pass. Responses received during the consultation will inform the operation of the pilot in 2010/11 and we expect the application process for the Innovation Pass to commence in April 2010. The Pass will be reviewed over the 12 months of the pilot to inform the future Innovation Pass process. Funding for future years will then be determined in the context of the next Spending Review.
NICE appraisal process	A number of measures on improving dialogue industry, NICE and the assessment teams were agreed by the NICE Board at the time of the *Blueprint* publication and have since been implemented. Looking ahead, these measures will be kept under review by NICE and included in the scope of the periodic consultations NICE undertakes on the development of its technology appraisal process.

	Future delivery milestones
NICE methodologies	The NICE response to the Kennedy Report was published for consultation on 30 September 2009, and the consultation closed on 13 January 2010 after three months. The NICE Board will consider the comments received at its meeting in March and will then publish a response, addressing any points made by consultees and setting out any changes in the action it proposes to take. As a commitment to good practice, from January 2010, NICE has invited consultees to set out what they consider to be the key elements of the value proposition, as part of the topic scoping consultation.
Improving uptake and diffusion of innovative, cost-effective medicines and medical technologies by the NHS	
NHS Life Sciences Innovation Delivery Board	The Board's work programme will be published in Spring 2010. Ahead of this, the Board will look at a number of activities including: how it can improve the uptake of cost effective medicines; support implementation of those medical technologies that have received a positive appraisal through the new NICE Evaluation Pathway (once operational); support the work being taken forward through Government's health research strategy, *Best Research for Best Health*; improve the strategic relationship between the NHS and the industry through joint working projects which can support the NHS in meeting the quality and productivity challenge; and consider how it will take forward the commitments set out in the *Blueprint* for the Delivery Board, such as the development and communication of an NHS Small Business Research Initiative (SBRI) prospectus. Funding for the Delivery Board in future years will be determined in the context of the next Spending Review.

	Future delivery milestones
Metrics on the uptake of cost-effective medicines and medical technologies	Throughout 2010, there will be a number of activities underway: ● A steering group, co-chaired by Professor Sir Mike Richards, National Clinical Director for Cancer, and John Melville, Managing Director, Roche Pharmaceuticals UK, will report on the extent and causes of international variation in drug usage by Spring 2010; ● The Department of Health will conclude its work on developing national and EU metrics for medical technologies and will report its findings in April 2010; ● The Ministerial Industrial Strategy Group (MISG) Metrics Working Group will publish the next national pharmaceutical metrics report in October 2010; and ● The Department of Health is developing a proposal for the sustainable collection of information on the uptake of innovation in medical technology and is also developing a formula to establish a baseline for comparative analysis. This work should be completed by Autumn 2010.
Commercial Support Units – Driving regional approaches to support uptake and diffusion of innovative and cost-effective medical technologies	Expertise in NHS commissioning and procurement is vital for successful uptake and diffusion; to support this, the Department of Health has worked with the NHS to establish Commercial Support Units (CSUs) by April 2010. Throughout 2010, there will be a number of activities underway: ● The medical technology sector submitted 100 proposals for a call by the Department of Health for technologies that could make a significant contribution to quality and productivity in the NHS. The Department of Health is currently working with the NHS to prepare uptake and diffusion plans for delivering the first wave of technologies. The plans will be ready for NHS-wide introduction by the end of March 2010; and ● Procurement processes and other mechanisms will be mapped out and delivered by the Autumn 2010. The relevant NHS organisations will be prepared for the introduction and diffusion of selected technologies by the end of 2010.

	Future delivery milestones
Meeting the quality and productivity challenge	
Quality, Innovation, Productivity and Prevention (QIPP)	Industry will be able to contribute ideas through the NHS Life Sciences Innovation Delivery Board. In particular, industry contributions will be sought on uptake and diffusion measures, metrics, and procurement.
Payment by Results	On 14 January 2010, the Department of Health held a strategic workshop to consider how better use could be made of the existing flexibilities in Payment by Results (PbR). The ideas proposed at this workshop are being taken forward by Department of Health policy teams in 2010.
NHS Leadership Council	The NHS Leadership Council committed to taking steps to intensify the sharing of skills and experience with industry leaders. This has been delivered through the Ministerial Industry Strategy Group (MISG) Partnership Working Group, which has developed a senior executive "shadowing programme". In Spring 2010, an evaluation of the programme will be conducted to measure if and to what extent the objectives of the shadowing exercise have been met. This will be used to assess the potential for extending the programme during 2010.
E-health records – Exploiting the UK's position as a world leader in health informatics	
Research Capability Programme pilots	The Research Capability Programme programme is starting with a small pilot in Spring 2010, and the learning from the pilot will feed into the full national infrastructure known as the Health Research Support Service.
A Strategic Framework for Health Informatics in Support of Research	A Strategic Coordination Group of funders was established by the OSCHR to oversee the development and implementation of the Strategic Framework. The Group is conducting a mapping exercise to better understand the existing UK research capability and requirements to support e-health records research. Outputs from this work will inform implementation of the Framework in the areas of research funding and capacity building and a report is expected in late Spring 2010.

	Future delivery milestones
Building a sustainable Life Sciences skills base	
Establishing a Industry and Higher Education Forum	In December 2009, the Industry and Higher Education Forum was established, comprising three elements: the Forum Executive Board; the Forum Advisory Group; and the Forum Task and Finish Teams. The Advisory Group is currently developing its work plan for 2010; it is envisaged that an early activity for the Group will be to work with the Society of Biology on its development of an accreditation model for biological sciences. In February 2010, the Task and Finish Teams will report their findings to the Forum Advisory Group, which will agree how to deliver the recommendations. It is anticipated that the first phase of delivery will take place throughout 2010. The Executive Board will meet in February 2010 to agree its Terms of Reference and review early progress of the Advisory Group and Task and Finish Teams.
Providing targeted support in areas of greatest need: The Medical Research Council Clinical Pharmacology and Pathology Programme	The Medical Research Council (MRC) will launch a £3.5 million flagship programme in clinical pharmacology and pathology, enhancing professional skills and driving collaboration with industry. Proposals will be assessed in March 2010, and it is anticipated that two awards of £1.85 million each will be made in Spring 2010.
Developing a world-first accreditation model for undergraduate biological sciences degrees	The Society of Biology launched an online consultation in December 2009, closing at the end of February 2010, to seek views from industry and academia as the development of an accreditation model for undergraduate biological sciences degrees. The Society of Biology will build on this consultation by establishing a pilot accreditation scheme, focusing on Life Sciences and environmental sciences in the 2010/11 academic year. It is expected that the pilots will be rolled out in universities across England, Scotland, Wales and Northern Ireland.
Modernising Scientific Careers	In March 2009, Government completed a consultation on proposals to ensure that the healthcare science workforce is equipped to respond to scientific and technological advances across the disciplines, changing healthcare needs and provision and the scientific evidence base. The consultation has led to the development of a UK-wide policy document *Modernising Scientific Careers: the UK Way Forward* and an England Implementation Plan, both to be published early in 2010.

	Future delivery milestones
Building innovation into education commissioning	In order to further incentivise the use of innovation, 5% of the higher education funding supplied to the NHS will, for the financial year 2010/11, be contingent on the delivery of quality and innovation within Medical and Professional Education Training. This will be delivered by SHA Education Commissioners.
Life Sciences Business and Leadership Programme	The HealthTech and Medicines Knowledge Transfer Network and the BioIndustry Association (BIA) are working with COGENT, the process industry Sector Skills Council, to deliver the Business and Leadership Programme. They are proposing to integrate the Programme into the Process Industry National Skills Academy, which they plan to extend through a bid in the forthcoming National Skills Academy 5th Round. Decisions on expressions of interest are expected by the end of March 2010. If the bid is successful, the Business and Leadership Programme will be piloted in Summer 2010 and will be open initially to medical biotechnology companies in the UK. It will be expanded to medical technology and industrial biotechnology companies at a later date. Further details will be available on the COGENT website by the end of March 2010.
Supporting UK regenerative medicine – A growing and strategically important industry	
The RegenMed Programme	The £21.5 million RegenMed Programme is aimed at creating a step-change in the competitiveness of UK regenerative medicine businesses and technology providers, and enhancing the ability of UK business to provide global solutions. Following the launch of two competitions in 2009, the Programme will continue to grow in 2010, with the aim that the remaining investment should be committed to projects lasting 2-3 years. In particular, follow-on competitions in *Regenerative Medicines Therapies* and new competitions in *Tools and Technologies* will be launched. Furthermore, the Technology Strategy Board (TSB) is currently recruiting for additional technologists to increase coverage of the medical biotechnology, pharmaceutical, and medical technologies sectors.

	Future delivery milestones
Ensuring access to finance	
The UK Innovation Investment Fund	In June 2009, the Government announced the creation of the UK Innovation Investment Fund (UKIIF). With the Government's investment of £150 million leveraging £175 million in additional money, an initial pool of funding worth £325 million has been created and the target has been exceeded. Further private investment will be secured before the Fund closes for investors in 2011.
Promoting NHS procurement of Life Sciences innovation	In 2009, the National Innovation Centre (NIC) ran online competitions seeking solutions from small companies to needs identified directly by clinicians. Nine contracts were awarded as a result. NIC is planning to launch at least two more rounds of competitions in 2010/11.
Incentivising innovative activity and investment	
Patent Box	The Pre-Budget Report announced the introduction of a Patent Box applying a 10% rate of corporation tax to income from April 2013. Government will consult with business in time for Finance Bill 2011 on the detailed design of the Patent Box.
Consortium relief	Government continues to assess the case for a change to the consortium relief rules. Government welcomes evidence as to how a change in the rules could promote investment and is open to future dialogue with business on this issue.
Attracting Life Sciences investment into the UK – Marketing UK Life Sciences	
Ministerial overseas visits	Between September and October 2009, senior representatives from the UK Government conducted a series of international visit to help overseas companies to better understand the positive changes taking place in the UK and explore potential investment opportunities. In 2010, UK Trade & Investment (UKTI) will follow up on the contacts made during these visits. The February 2010 US roadshows will offer an early opportunity to do this.
Boosting the UK presence at international Life Sciences events	To complement these Ministerial overseas visits, the UK has substantially increased its presence at a number of major international Life Sciences events. The programme of events will continue in 2010.

	Future delivery milestones
Life Sciences Roadshows – Promoting UK Life Sciences in the USA in 2010	Continuing in 2010, UKTI is working with colleagues in the USA to organise a series of high-profile Life Sciences roadshows to communicate to medical biotechnology, pharmaceutical and medical technology industry leaders, as well as state officials and relevant trade associations, the announcements surrounding delivery of key *Blueprint* commitments. This will promote UK excellence in the US market and encourage closer engagement around trade and investment opportunities.
2010 UK International Life Sciences Event	In Autumn 2010, UKTI will run a major international event in the UK alongside the NHS-sponsored Innovation Expo. This will be the first pan-UK Life Sciences partnering event of its kind.
A single industry voice for marketing UK Life Sciences	Following an initial roadshow in September, preparations are well underway for a programme of roadshows in 2010. Working closely with the Regional Development Agencies, local trade advisers and the Devolved Administrations, UKTI will run 12 roadshows across all UK regions in February and March 2010.
Attracting additional investment into the UK	To complement the UK Innovation Investment Fund, UKTI is facilitating the creation of a separate, privately-financed UK-based Healthcare and Life Sciences Technology Fund. This will be aimed specifically at helping to address the funding gap for early-stage UK-based companies. Its primary aim is to provide a potential funding vehicle for UKTI's Global Entrepreneur Programme (GEP) Life Sciences client companies considering relocating to the UK. UKTI, having assisted in the initial strategic development activity, will continue to advance the Fund's creation, and support the individual companies that will benefit from the Fund.
Enhancing the UK's strategic alliances with key US Life Sciences clusters	At the start of October 2009, the three Life Sciences associations for the London, Oxford and Cambridge areas (LBN, OBN, and ERBI) signed a Memorandum of Understanding (MoU) with the Boston-based Massachusetts Biotechnology Council. Further work to build on the Memorandum of Understanding will be taken forward by LBN, OBN and ERBI.

Review and Refresh of Bioscience 2015 – An update on delivery by the Office for Life Sciences

Bioscience 2015 (BIGT), published in 2003, set out a vision for the UK to secure a position of global leadership within the field of medical biotechnology. In 2008, the Bioscience Innovation and Growth Team, a coalition of industry, patient groups, research councils, academia and various government departments, carried out a *Review and Refresh of Bioscience 2015 (BIGTR2)*. The report, published in January 2009, reviewed progress against the original BIGT vision and looked at the particular issues faced by the industry, and the emerging issues impacting on the competitiveness and future of the medical biotechnology sector. The report proposed 23 recommendations and Government responded in May 2009 with a number of commitments. Good progress has been made on delivering Government's *BIGTR2* commitments. A number have been taken forward under the Office for Life Sciences and progress is detailed below. For all other commitments, a separate progress report was published simultaneously on 26 January 2010[42].

Progress against BIGTR2 commitments taken forward under the Office for Life Sciences

Recommendation 1 – Sustain Research Capability

Government committed public and charity funders to develop a Strategic Framework for health informatics in support of health research. A further delivery update is provided in Chapter 2, Section 6: E-Health records – Exploiting the UK's position as a world leader in health informatics.

Recommendation 3 – Maximising Awareness of Opportunities

Government committed to a series of events to roll out a five-year UK Life Sciences Marketing Strategy including, as resources allow, country communication plans to be implemented in target markets. A further delivery update is provided in Chapter 2, Section 11: Marketing UK Life Sciences.

42 Further information can be found at: www.bis.gov.uk/publications.

Recommendation 4 – Include Participating in Research in the NHS Operating Framework

The Government's response to *BIGTR2* noted that the Department of Health would:

- Work with the NHS to require that providers who conduct research include the number of patients recruited in the previous year to clinical research in the annual Quality Accounts, and;
- Write to the NHS to ask Trusts to:
  - Set goals for research in their organisation;
  - Publish the average time it takes for the local research approval process to be completed; and
  - Ensure that they use the National Institute for Health Research's Coordinated System for gaining NHS permission, and that they do not develop unnecessary additional activities or bureaucracies locally.

Professor Dame Sally Davies, Director of Research and Development at the Department of Health, and David Flory, Director General of NHS Finance, Performance and Operations at the Department of Health, wrote to the Chief Executives of NHS Trusts, Mental Health Trusts, Ambulance Trusts, Foundation Trusts, Primary Care Trusts, Strategic Health Authorities, and Special Health Authorities on 9 July 2009 drawing their attention to "recent policy statements and operational requirements regarding research in the NHS" relating to each of the above-mentioned areas.

A further delivery update is provided in Chapter 2, Section 2: Improving the UK environment for undertaking clinical trials.

Recommendation 8 – Attracting Overseas Interest

Government committed:

- With regard to the Finance Workstream of the UKTI Life Sciences Marketing Strategy, that UKTI would develop a plan to take forward research to identify corporate venture contacts, analyse their portfolios and through a series of interviews, identify measures which would encourage further UK activity;
- To introduce, through the UKTI Global Entrepreneur Programme Life Sciences strategy, initiatives aimed at fund raising; further mentoring/adviser opportunities; introducing technologies/businesses to the UK; and helping to develop UK science; and
- To continue to develop close relations with Angel Networks.

A further delivery update is provided in Chapter 2, Section 11: Marketing UK Life Sciences – Attracting additional investment into the UK.

Recommendation 12 – Incentives for Big Pharma to invest in UK medical biotechnology

Government committed in Budget 2009 to consider evidence for changes to the way the tax system encourages innovative activity and the relative attractiveness of the UK to global firms as they make decisions on where to locate their research and development (R&D) and other innovative activities. A further delivery update is provided in Chapter 2, Section 10: Incentivising innovative activity and investment.

Recommendation 15 – Rewarding Academic Collaboration

Government committed that the next Research Assessment Exercise (RAE) would be done under the new Research Excellence Framework, and would take account of the impact of research. A further delivery update is provided in Chapter 2, Section 1: Enhancing collaboration in Life Sciences – Supporting the translation of research: The Research Excellence Framework.

Recommendation 16 – An Independent Enquiry into NICE

Government committed to an independent study, to be carried out by Professor Sir Ian Kennedy, of the value in new innovative health technologies. A further delivery update is provided in Chapter 2, Section 3: The National Institute for the Health and Clinical Excellence – Supporting the NHS as an innovation champion – NICE methodologies.

Recommendation 22 – Pilot Leadership Programme

Government committed to consider how to take forward the Pilot Leadership Programme. A further delivery update is provided in Chapter 2, Section 7: Building a sustainable Life Sciences skills base – Life Sciences Business and Leadership Programme.

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