



Office for
Life Sciences

BIS | Department for Business
Innovation & Skills



Strategy for UK Life Sciences

Front page image: The i-limb ultra from Touch Bionics

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Ministerial Foreword



The UK has long been a world-leader for innovation in life sciences. That is why many of the most talented scientists from other countries come here to research and develop innovative drugs and technologies. It is also why so many of the great breakthroughs in this field – like Sir Alexander Fleming’s discovery of penicillin and the discovery of the structure of DNA and antibody therapies – have happened here.

We want that enviable record to continue into the future, strengthening our life sciences industries and helping to build a sustainable economic recovery.

With advances in our understanding of biological systems, higher-speed computing and breakthroughs in genomics, we have opened up untold possibilities, but the time and cost of developing new treatments has risen inexorably.

The more we discover about diseases, the more we discover about how they affect different people in different ways. As a result, there are higher regulatory hurdles to overcome, to guarantee public safety. It now takes an average \$1bn and 20 years to develop a new drug; and these new drugs have high attrition rates for issues of both safety and efficacy.

Emerging markets are creating exciting investment environments and western countries such as the US and Germany have developed simpler regulatory processes to approve new therapies. So, if we are to remain



competitive, we must up our game in the UK. We must use our fantastic science base to its fullest potential and be at the forefront of life sciences in this new landscape.

Everyone agrees that the challenge is to put human clinical disease studies back at the heart of medical discovery, where they have always belonged. The race is on to develop an infrastructure which connects academics, industry, investors, clinicians and crucially, the NHS. If we can become better at recognising and rewarding innovation; ensure that good ideas don’t get lost; and adopt them more quickly and efficiently across the NHS, then we can deliver better patient outcomes at home and take a leading role in life sciences globally.

We are committed to achieving the ambitions within this strategy as we believe they provide a catalyst for the changes the UK needs to make. But we will only achieve our ambitions through clear commitment and leadership from Government working with the NHS, regulators, academia, charities and industry.

We would like to thank everyone who has contributed to this strategy, especially those in our research centres, life sciences industries and health services who have taken the time to share their thoughts and ideas with us.

Rt Hon Andrew Lansley CBE MP
Secretary of State for Health

Rt Hon David Willetts MP
Minister of State for Universities and Science



Summary of key actions

We will take action to make the UK a world-leading place for life sciences investment:

Early in 2012 the MHRA will bring forward for consultation proposals for a new 'Early Access Scheme' to increase the speed and efficiency of routes to market approval for innovative, breakthrough therapies.

Through the MHRA, we will work with industry and other international regulators to develop actions which will create a more enabling regulatory environment for the adoption of innovative manufacturing technology. We will do this by the second quarter of 2012.

We will invest £310m to support the discovery, development and commercialisation of research. This covers £130m for Stratified Medicine and £180m for a Biomedical Catalyst Fund.

Through the NIHR, we will re-launch an enhanced web-based UK Clinical Trials Gateway in March 2012. This site will provide patients and the public with authoritative and accessible information about clinical trials in the UK.

We will support patients to have access to novel treatments, and be part of the development of wider patient benefits by consulting on an amendment to the NHS Constitution so that, whilst protecting the right of an individual to opt out, there is a default assumption that:

- > data collected as part of NHS care can be used for approved research, with appropriate protection for patient confidentiality; and
- > patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved.

The Cambridge, Oxford and London BRCs will work with the BRU in Leicester, to develop a national NIHR Bioresource. This will make the UK the 'go-to' place for experimental medicine.

As announced in the Autumn Statement 2011, we will introduce the EU VAT cost-sharing exemption in the Finance Bill 2012.

We will hold a series of investment and policy events to promote the UK's world-leading position in healthcare and life sciences in advance of the London 2012 Olympics.

We will introduce, via Cogent, Higher Level Apprenticeships (HLAs) covering post A-level education. Our ambition is to deliver 420 Apprenticeships over the next five years.

We will appoint two independent Life Sciences Champions: The first of these champions will act as chair of an independent Life Sciences Advisory Board. The second will act as a collaboration champion to foster partnership across the UK clusters and within government.



1 Introduction

For over 40 years, the UK life sciences industry – covering medical devices, medical diagnostics and pharmaceuticals, through to synthetic and industrial biotechnology – has been one of the most successful globally.

The life sciences industry is defined by the application of biology. For the purposes of this strategy, we are focusing on the healthcare applications of this science.

A dynamic industry

The industry is highly innovative and dynamic – it is growing faster than the economy as a whole and is a key source of high-skill, high-tech jobs. Pharmaceuticals, medical biotechnology and medical technology sectors together comprise around 4,500 firms, employing 165,000 staff, with an R&D spend of nearly £5bn and an annual turnover of over £50bn.

Life sciences manufacturing, which accounts for 8% of the UK total (by gross value added) remains important for the UK's growth. The pharmaceuticals sector alone accounts for more UK-based business R&D than any other manufacturing sector (accounting for over 28% of all business R&D); and exports from pharmaceuticals account for a much higher share than is seen globally.

Over 300 pharmaceutical companies are based in the UK and employ nearly 78,000 people, with an annual turnover of £31bn. The medical technology and medical biotechnology sectors represent over 4,000 companies employing 87,000

people with an annual turnover of around £18.4bn. It is essential that we act to ensure that this level of investment is maintained. We will move to a more progressive regulatory environment that not only supports innovation in manufacturing technologies, but openly promotes it.

Our heritage

The UK boasts a strong history of discovery in life sciences. This continues in the 21st century with breathtaking advances, such as work in regenerative medicine. The convergence of digital and healthcare technologies presents us with a great opportunity to demonstrate continued leadership in innovation. New approaches, such as antibody therapies and the application of robotic surgery technology, are now sitting alongside earlier pioneering discoveries: from the structure of DNA to the development of Computer Tomography (CT) and Magnetic Resonance Imaging (MRI). These discoveries demonstrate the important contribution



that UK science and medicine is making to radically improve patient care.

Our changing world

Today, the global life sciences sector is in the midst of significant and rapid change, which presents both opportunities and challenges. Driving this change are supply and demand side pressures, lifestyle choices, longevity and a rise in chronic conditions such as diabetes, obesity and dementia. In confronting these realities, traditional ways of working will become outdated.

We acknowledge that we have under-utilised our strengths. We are therefore taking action through this strategy to create a sustainable operating environment for the life sciences industry now and in the future.

The drive for cost-effective solutions in the NHS combined with the regulatory approvals process can mean that uptake is slow. This is challenging for industry who may sometimes feel the return they are looking for is not there quickly enough to satisfy shareholders and investors. More importantly, patients lose out through late adoption.

The UK can do much more to harness the opportunity that exists in the NHS. There is huge potential to better support the adoption and diffusion of innovation, to access patient data to inform the development phase, and to involve patients in trials and early access schemes for the treatment of chronic diseases, such as cancer.

Whilst the speed of computing and breakthroughs in genomics are opening up untold opportunities, the time and cost of developing new treatments is rising significantly. Traditional models of research and development, based around large scale establishments, are also becoming unsustainable. The future is going to see much more by way of tailored medicines, which target specific characteristics of an individual's genetic blueprint and disease.

Building for the future

The industry is changing and the UK must adapt so that we can compete in this challenging environment. The UK must capitalise on its strengths: its world-class science and clinical research, talent base of pioneering life science researchers, and the NHS, where discovery can be translated into results for patients. The race is on and we need to move quickly to ensure the UK is where innovation happens.

In the future, the NHS will need to play a more active role in realising innovation. It will be the "pull" behind the industry "push" for new therapeutic interventions.

At the heart of this will be the patient. Patients will be offered new choices to participate in the development of novel treatments, with the support of their clinicians. This will mean they gain earlier access to new treatments and improve their chances of recovery. Through the use of anonymised data patients will be making a contribution to the ongoing health of people with similar conditions.

The action we are taking

The Government recognises these opportunities and challenges and is determined that industry and healthcare/research charities thrive in the UK; researchers and clinicians have a vibrant, exciting and world-class environment in which to work; and patients have access to leading-edge treatments early.

The suite of initiatives contained within this document have been developed to support industry to grow in the UK, whether they are small start-ups or large established businesses. It is also designed to support researchers and clinicians and ultimately patients through improved healthcare outcomes.

This strategy sets out a vision where academia, NHS, charities and industry come together to create an unrivalled ecosystem. It offers a number of incentives to business, to researchers and clinicians to come to the UK to work on life sciences. It strengthens our current position and locates us at the heart of a revolution that will make the UK the global hub for life sciences in the

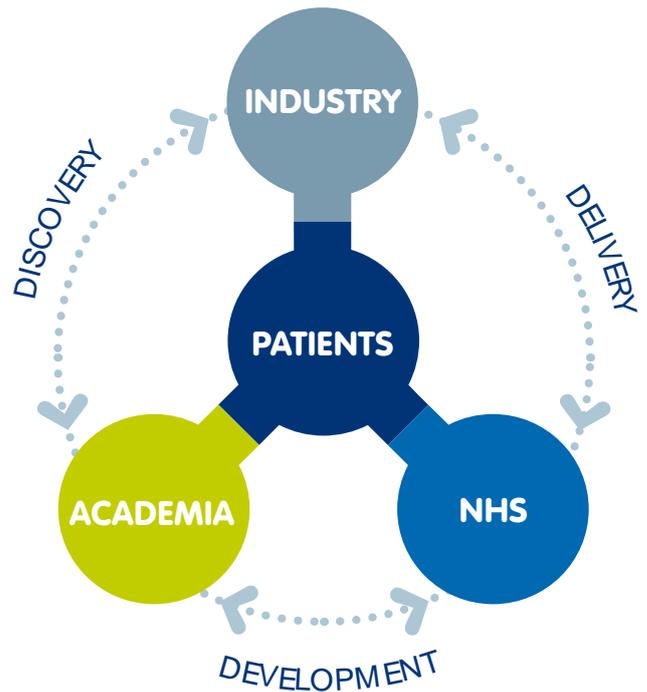
future. The actions contained in this strategy will combine as the catalyst to achieve this vision.

The vision for life sciences in the UK

The UK will become the **global hub for life sciences** in the future, providing an unrivalled ecosystem that brings together business, researchers, clinicians and patients to translate discovery into clinical use for medical innovation within the NHS.

The UK will provide an environment and infrastructure that supports pioneering researchers and clinicians to bring innovation to market earlier and more easily, **making the UK the location of choice for investment.**

Life Sciences will continue to be vibrant in the UK and will be a **key contributor to sustained economic growth.**



What will this mean for you?

For business: you will be able to operate in a streamlined regulatory framework, enabling quick entry to the market for new discoveries and innovations and access to anonymised patient data and patients for clinical trials.

For investors: you will have an opportunity to invest in world-leading, pioneering research with access to new fiscal measures that support risk sharing.

For researchers: you will be able to access the best facilities and world-leading institutions, real life data and an integrated system for bio-medicine.

For clinicians: you will have an active role in innovation and research into pioneering new treatments and truly add value to the ecosystem, whilst improving patient outcomes.

For patients: you will be empowered to have more choice with better and quicker access to new treatments, for better results.

The Government will work closely with the devolved administrations in delivering our vision for the life sciences sector.

We are committed to delivering global leadership in life sciences – we will re-energise the sector and provide the integration it needs to work effectively, the capability it needs to develop and grow, and the incentives to innovate and ultimately deliver better outcomes for healthcare and patients.

The *Strategy for UK life sciences* is designed around 3 key principles:

1. Building a life sciences ecosystem

We will build on our existing strengths and partnerships between universities, the wider research base, businesses and the NHS to establish a cohesive system of integration.

2. Attracting, developing and rewarding the best talent

We will nurture highly skilled researchers, clinicians and technicians and assist them to work collaboratively across traditional boundaries to create value throughout the ecosystem.

3. Overcoming barriers and creating incentives for the promotion of health care innovation

We will create the right environment to translate discovery into real benefits for patients and nurture innovation through the translational funding gap, whilst at the same time reducing regulatory bureaucracy to provide a route for early adoption and diffusion in the NHS.



The specific actions underpinning these principles are contained in the following 3 chapters. Each chapter sets out the new and existing initiatives that will lead to the achievement of our bold ambition. The final chapter sets out how this will be implemented.

This strategy sits alongside NHS Chief Executive's Review *Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS*, the actions for which can be found on page 34.



UK research accounts for 11% of the world's citations within biological sciences.



1928: Scottish biologist and pharmacologist Alexander Fleming discovers penicillin.

2 Building a life sciences ecosystem

There are profound changes taking place in the discovery, development and adoption pathways of medical innovation. New models of working between universities, hospitals and businesses need to be developed to place the UK at the forefront of medical research now and in the future.

In order to ensure that researchers, clinicians, businesses and investors see the UK as the location of choice for life sciences, we must build a fully integrated life sciences ecosystem from our world-class research and clinical infrastructure. We will achieve this by making it easier for researchers to commercialise academic research; placing clinical research at the heart of the NHS; and by empowering patients to participate in research. These actions will encourage adoption and diffusion of innovation in the NHS.

The UK's life sciences ecosystem will be shaped by our greatest assets: our research and academic prowess, joining together with global industries. It will optimise research and data which are a vital part of the system, leading ultimately to the NHS adopting and diffusing new therapies earlier to benefit patients and contribute to a thriving UK economy.

The UK already has some excellent examples of networks and clusters that create such an ecosystem. The Oxford, Cambridge and London triangle houses the UK's largest biomedical cluster, with around 170 medical biotechnology companies linked to universities and other organisations.



Case study: Collaboration now

- > **Imanova** is a partnership between the Medical Research Council (MRC), Imperial College, University College London and King's College London to provide a state of the art imaging research facility, building on current strengths in neuroscience and cancer imaging and developing novel applications. Made possible by GSK transferring its imaging facility in London to the partnership, it will provide a national hub for access to world-class imaging facilities and a focus for academic and commercial collaborations.



Case study: Collaboration in the future

- > The **Francis Crick Institute** is a £700m partnership between Government¹, MRC, Cancer Research UK (CRUK), Wellcome Trust, University College London (UCL), Imperial College London and King's College London. Its aim is to understand the basic biology underlying human health, finding ways to prevent and drive forward better treatment of the most significant diseases affecting people today. This could be the most significant development in UK biomedical science for a generation.

Building on our strengths, we will shape a fully integrated ecosystem in the UK. This chapter sets out our actions to deliver this ambition. It sets out how the UK will:

- 1 Make it easier to commercialise academic research**
- 2 Put clinical research at the heart of innovation in the NHS**
- 3 Encourage adoption and diffusion of innovation in the NHS**
- 4 Promote the UK as the place to invest and deliver life sciences innovation**

1 Making it easier to commercialise academic research

What is the Government doing already?

The transfer of ideas and intellectual property from academia to industry is imperative for innovation to be accessed by the public. The UK's research base ranks second behind the US for excellence (by share of citations) and there are already good knowledge flows

between academia and business. Learning from exemplars and best practice offers the opportunity for universities to improve effectiveness in commercialisation.

For example, Imperial Innovations was a technology transfer office in Imperial University which has successfully been privatised to offer its services more widely. The challenge now is to cultivate similar levels of success in other university-based technology transfer offices.

Funding through public sector, charity and commercial routes is fundamental for the research base in universities to thrive and to continue to deliver leading edge discoveries, which can be developed through clinical studies into products for patient benefit. The research charities sector contributes significantly to medical research, with Cancer Research UK and Wellcome Trust² investing a combined £900m a year in medical research.

What are the new actions that the Government is taking?

Investment and tax measures are key enablers to foster collaboration between industry and academia. Government is making new investments in cross-cutting initiatives such as stratified medicines and emerging technologies e.g. synthetic biology, informatics and regenerative medicine; and will address funding rules which stifle partnership working.

Stratified medicine³ and mechanisms of diseases in people

ACTION: We will invest £310m to support the discovery, development and commercialisation of research. This covers:

- > **£130m for Stratified Medicines; and**
- > **£180m for a Biomedical Catalyst Fund (discussed in Chapter 4).**

¹ £200m of this fund was committed by the Department of Health

² www.wellcome.ac.uk; www.cancerresearchuk.org

³ Stratified medicine research looks at ways to group patients within a disease area through their genes or by their symptoms. It will lead to targeted, more efficient treatment for patients.



The £130m investment in stratified medicines builds on current investment by TSB and the MRC.

MRC will commit £60m over 3 years to allow the best researchers to resolve some of the most difficult questions about the mechanisms of diseases and how we treat them. This will include chronic diseases, such as obesity or diabetes, that impact on a high number of people.

MRC will commit a further £60m over the next 4 years to collaborations in stratified medicine between academia, industry and clinicians. This will advance development of targeted treatments for specific groups of patients who may suffer from the same broad disease e.g. heart disease, asthma or mental health disorders. This will give industry greater certainty about the types of treatment to develop for targeted groups of patients; will provide better diagnostic tools for doctors; and thus improve patient outcomes.

The remaining £10m investment by the MRC is for collaboration with AstraZeneca who are providing 22 compounds to academic researchers to develop medicines.

Such a collaboration has the potential to be transformational in stimulating relationships between academia and industry. The findings of the research will help deliver growth to the pharmaceutical and biotechnology industries, and deliver novel treatments for the benefit of patients.

Case study: Public-private sector open innovation collaboration

The MRC are investing £10m in an unique open innovation collaboration with AstraZeneca. This partnership provides academic researchers with unprecedented access to 22 high quality AstraZeneca clinical and pre-clinical compounds which are the building blocks of new medicines.

Synthetic biology

Synthetic biology aims to apply the principles of engineering with biology. Potential applications include

healthcare, bio-energy and industrial biotechnology. It was recently identified by the TSB as a key emerging technology with the potential to create a billion pound industry within the UK in the next decade.

ACTION: We will commission an independent panel to develop a technology roadmap that will propose actions required to establish a world-leading synthetic biology industry.

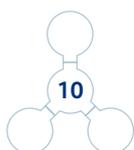
We want to establish a world-leading synthetic biology industry in the UK and are already investing some £45m into the area, but we want to do more.

Case study: Collaboration between academia and industry

> **Stevenage Bioscience Catalyst (SBC)** is the UK's first open innovation bioscience campus, opening for business in the first quarter of 2012. With its unique focus on open innovation, the SBC will foster increased partnership, idea sharing and value generation between academia, big pharma and biotech. Co-location with GSK in Stevenage will help to build strong links and allow tenants to access to big pharmaceutical company expertise. With founder stakeholders of GSK, the Wellcome Trust, BIS, the Technology Strategy Board (TSB) and EEDA, SBC is already an example of collaboration in action.

Cell Therapy Technology Innovation Centre

Building on investments already made in regenerative medicine by the Research Councils, the National Institute for Health Research (NIHR), and the TSB will invest up to £50m over the next 5 years in a Cell Therapy Technology and Innovation Centre (TIC). This will be based in London, in the centre of the UK's largest life sciences cluster. The centre will focus on the development and commercialisation of cell therapies and advanced therapeutics. It will also look at the underpinning technologies for manufacturing, quality control, and address safety and efficacy challenges for these innovative treatments.



ACTION: Through the TSB, we will invest up to £10m per annum in a Cell Therapy TIC, based in London.

Alongside this investment, the MRC, Engineering Physical Sciences Research Council (EPSRC) and Biotechnology and Biological Sciences Research Council (BBSRC) will establish a new national programme in regenerative medicine. This programme will ensure that the UK operates as a single, globally competitive cluster in this area.

ACTION: Through the MRC, EPSRC and BBSRC, we will jointly invest £25m over five years in a programme to maximise the potential of the TIC, and pull through cutting-edge biomedical science and engineering for the delivery of regenerative medicine.

Informatics – ELIXIR

We are moving at pace to deliver a robust informatics infrastructure via ELIXIR. ELIXIR is a programme to assemble and manage biological and genetic information generated by research. UK-funded research breakthroughs have recently led to a revolution in commercially available high-throughput gene sequencing technology. This revolution has created challenges in storing and analysing the huge volume of data generated. It is vital that this data is collected, stored and curated in user-friendly ways that allow its efficient retrieval and rapid exploitation. ELIXIR will allow us to do just this.

ACTION: We will invest £75 million to:

- > **expand the existing European Bioinformatics Institute in Cambridge to provide a new facility for biological data-storage to support life sciences research and its translation; and**
- > **deliver a new technical hub (Hinxton, Cambridge) which will house 200 staff and will coordinate the network.**

Research Council funding rules

The current Research Council funding rules can preclude some small state-of-the-art technology facilities from bidding for funding, where they lack a 'critical mass' of researchers. We will give greater funding opportunities to non-commercial organisations providing research facilities, around which clusters can develop.

ACTION: We will enable small state-of-the-art research facilities to secure recognition and apply for Research Council funding.

We also believe that funding mechanisms for research and innovation should recognise the value of collaborations between organisations. Consortia can tackle large-scale and ground-breaking new research beyond the capabilities of a single institution; they may involve a range of partners, including collaboration internationally and with business. To deliver this, Research Councils UK will establish a new principles-based framework.

ACTION: Research Councils UK, working with UK HE funding bodies, and in discussion with individual universities and consortia, will establish a new principles-based framework for treatment and submission of multi-institutional funding bids.



VAT cost-sharing exemption

Currently a VAT cost arises if organisations such as charities and universities, want to make efficiencies by working together to share services. A VAT exemption on shared services will remove this barrier. This exemption is covered in European Regulations⁴, and Government is already applying it. We will introduce this exemption in UK law in 2012.

ACTION: As announced in the Autumn Statement 2011, we will introduce the EU VAT cost-sharing exemption in the Finance Bill 2012.

Wilson Review

Sir Tim Wilson is undertaking a review into how we make the UK the best place in the world for university-industry collaborations. This will look at a wide range of business-university collaboration, including the links between universities, SMEs and skills. We are already taking action to improve business skills in academia and this is covered in more detail in Chapter 3. Sir Tim Wilson is due to report in early 2012.

2 Putting clinical research at the heart of innovation in the NHS

The second step to integrating our life sciences ecosystem is to build networks between our excellent academic institutions and clinical infrastructure. As a first step we will scale up our South East cluster to attract investment and support patients' outcomes.

Over the period 2006 to 2010, UK publications in bioscience received an average of 9.5 citations each. This is higher than any other country.
(Source: International Comparative Performance of the UK Research Base – 2011 BIS)

What is the Government doing already?

Clinical research infrastructure

The NIHR announced a record investment of £800m over five years from April 2012, for new NIHR Biomedical Research Centres and Units (BRCs and BRUs) and the establishment of two groundbreaking NIHR Translational Research Partnerships (TRPs).

The BRCs and BRUs will boost translational research in areas such as cancer, neuroscience, diabetes, dementia, nutrition, ageing and heart disease. The first two TRPs will focus on inflammatory respiratory disease and joint and related inflammatory diseases. Both will increase the capacity of the NHS to work in collaboration with universities and industry to undertake world-class translational research. The NIHR Office for Clinical Research Infrastructure (NOCRI) provides a single point of contact for this infrastructure.

NOCRI has led work to redevelop the UK Experimental Medicine Resource Finder which provides an optimal entry point for industry and academic investigators seeking information about experimental medicine facilities. The resource finder⁵ contains up-to-date information on over 50 major facilities with details of expertise, resources, techniques and technologies. Site users can search for facilities by location, health or disease research topic, skills or equipment available.

Building on the investment in our clinical research infrastructure, the UK has adopted the internationally recognised model of partnerships between academics and health providers which are known as the Academic Health Science Centres (AHSCs). In 2009, Manchester, Cambridge, Imperial, UCL Partners and King's Health Partners were designated as AHSCs. Their mission is to bring together research, teaching and patient care in order to speed up the process of translating developments in research into benefits for patients, both in the NHS and across the world.

⁴ Principal VAT Directive (PVD)

⁵ www.ukcrcepm.org.uk

Clinical research and patient choice

The analysis of patient data is a vital part of the infrastructure supporting research, development and clinical adoption. Equally important is information about which NHS Trusts are involved in clinical research and how are they performing. The NIHR Clinical Research Network (CRN) is partnering with *The Guardian* to create The Clinical Research Zone. This will publish data on individual NHS Trust participation in clinical research, and sit beneath the existing Guardian Healthcare Network site⁶.

To enable patients and the public to access information about clinical trials, the NIHR UK Clinical Trials Gateway test site launched in March 2011. The site is being updated and will be re-launched in spring 2012. Furthermore, the NIHR has developed a smartphone application, now available free-of-charge to iPhone (and shortly Android) users, to further increase access to information about clinical trials in a convenient and contemporary way.

What are the new actions that the Government is taking?

Clinical research infrastructure

The AHSCs and NIHR BRCs and BRUs all play a vital role in undertaking translational and clinical research studies, and drive innovation in biomedicine into NHS practice. Our vision is to strengthen the networks and, in turn, collaboration between the AHSCs and industry partners.

In the Growth Review, we committed the Chief Executive of the NHS to review and report on how the NHS could accelerate adoption and diffusion of innovation within the NHS. The NHS Chief Executive's Review, which is being published alongside this strategy, is clear that we should preserve the AHSC brand.

Building on the AHSC model of adoption and diffusion, we will establish a number of academic health science networks (AHSNs) across the country. The NHS Chief Executive and the Chief Medical Officer will work with

the NHS and industry to designate these networks with the first going live during 2012/13.

The AHSNs will present a unique opportunity to align clinical research, informatics innovation, training and education and healthcare delivery. The aspiration is for AHSNs to be the gateway for any NHS organisation needing support with innovation and to provide industry with clear points of access to the NHS. This will facilitate NHS-industry collaborations to develop health care solutions.

Key to making progress on this is the use of the NHS' patient database for clinical trials and investigations. A robust and flexible patient data system will bring more clinical studies into the UK and support the development of innovative treatments.

To encourage innovation and investment in UK life sciences, the Health and Social Care Information Centre will set up a secure data linkage service as part of its core delivery. By September 2012, it will deliver data extracts using linked data from primary and secondary care and other sources, on a routine basis at an unidentifiable, individual level. This service can also be used by the specialist research service (CPRD – see below). The service will be available to all users of health and care information in order to drive improvements in care, enterprise and innovation, and will operate on a self-financing basis where users would pay the cost of the linking process.

In addition, a complementary new secure data service – Clinical Practice Research Datalink (CPRD) – will be introduced by the Medicines and Healthcare products Regulatory Agency (MHRA), in partnership with NIHR, to service the specialised needs of the research and life sciences communities. This is a £60m investment which will offer data services. These will include: providing access to data for researchers (NHS, social care and others); data matching and linkage services, and data validation to support the clinical trial and observational study work of the life sciences research community.

⁶ www.guardian.co.uk/healthcare-network

ACTION: There will be the provision of secure data linkage services by:

- > **the Health and Social Care Information Centre by September 2012;**
- > **the Clinical Practice Research Datalink (CPRD) which is a £60 million investment by NIHR and MHRA.**

In order to maximise opportunities for utilising patient data to support research, we have launched a cross-funder call for Centres in e-health⁷, which will commit £15m to Centres. These aim to build and sustain a vibrant health informatics research capability in the UK. Outline proposals are being considered at present and awards will be made in mid-2012.

Case study: Scotland HSS

Scotland is internationally renowned for the excellence of its scientific research and development. Through the formation of pioneering collaborations Scotland's world-class life sciences capabilities are being fully realised.

One such example is Health Science Scotland (HSS), a partnership between scientists and academics that will soon pilot a new SME engagement function. It aims to provide a single point of contact for pharmaceutical and biotechnology companies to develop translational research programmes. In collaboration with university medical schools and clinicians in the NHS these innovative research programmes will speed up the delivery of novel treatments to patients, through clinical trials. Obtaining the evidence to demonstrate the value of innovative products will improve adoption and benefit the wider community.

In London, the three AHSCs have signed a concordat setting out their commitment to work together with the Mayor and NHS London to maximise the economic impact of London's life sciences sector. As a priority they will explore the potential to develop an information system that will build on the NHS record and pull together patient level data for London's population. This project will enable large groups of patients to be engaged in world-class clinical research on disease-specific and personalised treatments. Use of the data by biomedical firms will drive innovation, add economic value and attract inward investment enabling further growth.

ACTION: London's three AHSCs (Imperial, Kings Health Partners and UCL Partners) will explore the potential to develop information systems that build on the NHS record and pull together patient level data for London's population. This will enable large groups of patients to be engaged in world-class clinical research on disease-specific and personalised biological therapies, regenerative medicine and medical devices.

This partnership is an important first step in strengthening the connections between the academic health science system across the UK, and represents the beginning of our ambition to scale up our South East cluster. We must also demonstrate our leadership globally if we are to succeed. We want the UK to compete internationally not only on academic and clinical excellence, but also on the ability to attract companies to base their R&D and commercialisation here. Key to this is an enabling environment with strong links into industry, ease of access to funding sources and the ability to engage with other businesses at a similar stage in development.

⁷ MRC in partnership with Arthritis Research UK, the British Heart Foundation, Cancer Research UK, the Economic and Social Research Council, the EPSRC, the NIHR, the National Institute for Social Care and Health Research (Welsh Assembly Government), the Chief Scientist Office (Scottish Government Health Directorates) and the Wellcome Trust

ACTION: We will appoint two independent Life Sciences Champions: The first of these champions will act as chair of an independent Life Sciences Advisory Board. The second will act as a collaboration champion to foster partnership across the UK clusters and within government.

Research and patient choice

Empowering patients to participate in research is central to enabling the translation of promising treatments. In order to support patient participation in clinical research, the NIHR is developing tools which will provide clear information to patients about clinical trials.

ACTION: Through the NIHR, we will re-launch an enhanced web-based UK Clinical Trials Gateway in March 2012. This site will provide patients and the public with authoritative and accessible information about clinical trials in the UK.



1953: Crick and Watson, two Cambridge scientists, reveal the double helix of DNA in Nature Magazine.

Case study: Clinical research and patient choice:

Scotland use a unique patient identifier to support multi-disciplinary, integrated patient care. This has allowed the creation of a clinical information system which supports the care of all patients with diabetes in the country. The informatics system, developed and supported by NHS Scotland and University of Dundee, links information between Scottish GPs and hospitals. This has greatly improved patient outcomes and fostered greater collaboration between industry, the NHS and universities. Evidence from Tayside over the past six years demonstrates fewer complications associated with diabetes in Scotland, including a 40% reduction in patients requiring amputations and a 43% reduction in people needing treatments for eye disease.

The same informatics capability provides a mature research platform to perform clinical trials and studies in diabetes and its associated complications. This platform is further supported by the year on year increase in the number of people participating in clinical trials in Scotland and, in Tayside alone, some 40,000 individuals have consented to the donation of their DNA and its linkage to e-health records.

Following a government pump-priming investment of £2.5million, the Cambridge BRC⁸ is working with BRCs in Oxford and London and with the BRU⁹ in Leicester to develop a national NIHR Bioresource. The South London and Maudsley/King's College London BRC is developing the bioinformatics to support this.

ACTION: The Cambridge, Oxford and London BRCs will work with the BRU in Leicester, to develop a national NIHR Bioresource. This will make the UK the 'go-to' place for experimental medicine.

⁸ NIHR Biomedical Research Centre

⁹ NIHR Biomedical Research Unit

This Bioresource will provide a national cohort of healthy volunteers, patients and their relatives who wish to participate in experimental medicine research, and are willing to provide clinical information and samples that will enable them to be recalled for specific studies. The Bioresource will support companies and researchers in recruiting healthy participants to undertake stratified studies. These studies will have the potential to rapidly advance the understanding of disease mechanisms, identify potential drug targets, and improve insight into the therapeutic potential and limitations of existing and emerging therapies.

The NHS has a vital role in supporting patients who wish to be involved in clinical research. We will take action to make this a reality.

ACTION: We will support patients to have access to novel treatments, and be part of the development of wider patient benefits by consulting on amending the NHS Constitution so that there is a default assumption (with ability to opt out):

- > **for data collected as part of NHS care to be used for approved research, with appropriate protection for patient confidentiality; and**
- > **that patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved in a research study.**

Equally there must be clinical leadership to ensure that research is a core part of the NHS' role to drive innovation and develop novel treatments. Our key opinion leaders in the NHS have an important role in setting the standards that the NHS should meet so that they are developing and using these treatments for the benefit of patients.

3 Encouraging adoption and diffusion of innovation in the NHS

The third step to a successful ecosystem is to ensure that the NHS realises its role as an engine for innovation by accelerating adoption and diffusion of innovations.

What is the Government doing already?

The NHS Life Sciences Innovation Delivery Board is already strengthening NHS and industry engagement, as well as encouraging NHS organisations to become rapid and consistent adopters of cost-effective health innovations.

What are the new actions that the Government is taking?

The NHS Chief Executive's Review sets out a package of proposals that will be developed to support the adoption and diffusion of innovation in the NHS. A summary of the actions can be found at the back of this document.

The actions will require NHS leaders to identify and tackle the behaviours and cultures that stand in the way of innovation. It will look at system incentives to ensure that they are aligned to support and encourage innovation. The review highlights the need to create 'pull' for new ideas from patients and the NHS, rather than relying on the traditional top-down 'push'.

The review also identifies the need to reward those individuals and organisations that adopt best practice and new ideas, and calls for those organisations that do not to explain why. It outlines the need to take a longer-term view on investments and to ensure that staff are supported to introduce and scale up new ideas and technologies. These will be developed further during the implementation phase.

4 Promoting the UK as the place to invest and deliver life sciences innovation

Clear leadership on the global stage to foster collaboration with internationally renowned partners is imperative if the UK is to be a real choice for investment. Emerging economies such as Brazil, India and China offer a wealth of opportunities for collaboration and growth.

What is the Government doing already?

Through UKTI, the UK will enjoy a strong presence at the world's leading trade events for life sciences to ensure UK expertise is showcased effectively. Forthcoming events we are supporting include BIO 2012 (biotechnology) in Boston, Medica (medical technology) in Dusseldorf, and Arab Health (medical technology) in Dubai.

What are the new actions that the Government is taking?

We will provide the platform and support to promote and showcase the competitive strengths of the UK. The life sciences champions will play a key role here.

ACTION: Through UKTI, we will work with business ambassadors and members of the Catalyst Programme (a network of business leaders, influencers and academics) to promote the UK's status as Europe's leading destination for inward investment in the sector.

ACTION: We will hold a series of investment and policy events to promote the UK's world-leading position in healthcare and life sciences in advance of the London 2012 Olympics.

In our forthcoming strategy on innovation and research we attach considerable significance to international collaboration. An important signal of our leadership has been the proactive engagement by high growth and emerging economies as they invest in the development of their healthcare systems and capabilities in life sciences. We will build international partnerships and collaborations to increase bilateral trade, investment and R&D in this field – for example in translational and personalised medicine with China.

ACTION: We will create new partnerships in translational medicine and biopharmaceuticals, underpinned by the Memorandum of Understanding between the UK and China.

Through UKTI, we will work with NHS Global to identify and pursue high-value international opportunities in healthcare. Support will be given to the formation of consortia that access opportunities spanning the whole healthcare supply chain – from the design, development and management of health systems and facilities, to pharmaceuticals and medical technology. A pilot is under-way to present a compelling and complete UK healthcare proposition to Saudi Arabia. This has been developed with input from industry and some of the UK's leading clinical institutions.

Summary

This suite of actions will meet our ambition to build a fully integrated life sciences ecosystem in the UK. It will be shaped from our world-class research and clinical base joining together with global industries.

It will optimise research and data leading ultimately to the NHS adopting and diffusing new therapies earlier. This will benefit patients and contribute to a thriving UK economy.

3 Attracting, developing and rewarding talent

The best talent in life sciences tends to be highly mobile. The UK needs to develop, recruit and reward these individuals to make the UK world-leading in healthcare and life sciences.

The Government will introduce a suite of incentives to ensure that the UK attracts and nurtures world-leading talent and develops scientific excellence; and that it offers exciting and rewarding careers for clinicians, scientists and technicians from all around the world. There will be multiple entry points for careers in the sector, and training will be designed to accommodate practical experience and mentoring, focusing on both commercial rigour and scientific excellence.

The UK has a high concentration of research excellence and pioneering clinicians. Excellence alone is not enough. The workforce needs to create value throughout the development pathway. People need to have the training to meet the needs of employers and the incentives to collaborate across disciplines and organisational boundaries. Technological and system innovations are leading to a convergence of sectors. This is driving the development of new multi-disciplinary qualifications and expertise. The advanced manufacturing sector, for example, will require a workforce that is skilled in engineering as well as in areas such as biological and cell-based medicines, high-tech medical devices and information-driven health systems.

The Government will work with our partners to develop greater experience in technical skills and commercial expertise to create the right talent base for the UK life sciences industry. We will also put in place actions to cover the life sciences talent pipeline for the future. This chapter sets out how the UK will:

- 1 Attract world-leading talent in areas of strategic priority for the UK**
- 2 Develop scientific excellence alongside commercial rigour**

Case study: Wales HSS

The Institute of Life Science is the innovative research arm of Swansea University's College of Medicine. A unique collaboration between IBM, Swansea University and the Welsh Government, it has already delivered a state-of-the-art building, housing specialists in medical research, business incubation and technology transfer. This partnership brings together talent from across a number of disciplines to find new solutions to old problems in medical research.

1 Attracting world-leading talent in areas of strategic priority for the UK

What is the Government doing already?

Investment and mobility are important factors in attracting world-leading talent. The UK has strong investment in developing talented researchers in life sciences – both for clinically qualified and non-clinically

qualified scientists. MRC committed just over £70m in the last year to support 1900 PhD posts and 320 fellowships for both clinical and non-clinical scientists. A similar amount was also committed by NIHR to support over 1600 posts for research training in clinical and applied health research.

This investment is complemented by strong, additional support from the charity sector. For example, the Wellcome Trust provided £114m¹⁰ and CRUK over £20m for fellowships in the last year.

We have a number of schemes to attract world-leading talent into important areas of research such as cancer, heart disease and Alzheimer's. These schemes are available to excellent UK and international scientists.

Case study: Fellowships

The **Royal Society and the Wellcome Trust** launched the Sir Henry Dale Fellowships in October 2011. This is a major new joint scheme offering grants of up to around £1m each to outstanding young biomedical scientists. The scheme is available for individuals in the UK or overseas wishing to build an independent research career in Britain to understand the basis for some of the most important diseases affecting the world today.

The **Royal Society Research Professorship scheme** enables world-class scientists from the UK and around the world to benefit from a period of long-term support (usually 10 years). This allows them to focus on research and collaboration based at a UK institution. Previous holders include five Nobel Laureates and five Presidents of the Royal Society.

The NIHR will be awarding Research Professorships to fund selected leaders, who are capable of making a real difference to the effective translation of research, in the early part of their careers. These awards will help to strengthen research leadership at the highest academic levels.

Research Excellence Framework (REF)

Recognition of the impact of life sciences research will be critical to secure appropriate funding for Higher Education Institutions (HEIs) through the Higher Education Funding Council for England (HEFCE) assessment process (REF).

In life sciences, impact relates especially to improvements to healthcare and economic, commercial and production benefits. The funding bodies have agreed that for the first time REF 2014 will include explicit assessment of the impact arising from excellent research. This accounts for 20% of the assessment with the intention of increasing this to 25% in subsequent exercises whilst recognising that this aspect is developmental. Industry bodies, such as Confederation of British Industry (CBI), have endorsed this approach.

HEFCE has already appointed user members to the assessment panels, including representation from GSK, AstraZeneca, Pfizer, Department of Health, British Heart Foundation and INVOLVE. Additional user experts (including industry) will be appointed for the impact assessment phase – to ensure that impact assessment is undertaken by a broadly equal number of users and academics.

Increasing workforce mobility

The ease of recruiting global talent is important for business and scientific communities. Foreign scientists make a vital contribution to the UK economy. Equally important is attracting the best researchers to Research Council Institutes. Public sector recruitment controls are therefore being applied with a light touch in relation to front-line scientists, such that their recruitment can be approved within the Research Council (if their salary is below £100,000) without the need to refer to Government.

Life sciences researchers with the appropriate skills, and skilled migrants with a job offer, have two main routes to enter the UK to work in the sector. Recent changes to immigration policy mean that those scientists and academics entering the UK on a temporary basis are also

¹⁰ The Wellcome Trust's £114m funded Principal (£39m), clinical (£31m), and non-clinical scientists (£44m) fellowships

able to do so¹¹, for example as a guest lecturer, an external examiner or via an intra-company transfer route. This demonstrates the flexibility that recruiters have in order to access the best talent available worldwide.

What are the new actions that the Government is taking?

We have a strong base of research-active universities, with 4 of the top 20 universities in the world, and 32 universities in the top 200¹². Building on our significant investment in excellence, it is important that life sciences is an attractive career choice for young people.

We want to nurture a life sciences talent pipeline which meets the needs of employers in the future. We will therefore promote life sciences as an exciting career option.

Promoting life sciences as a career option

Having the right information to make the right career choices and select the right training provision or industrial placement is critical. Equally important is to ensure that students have access to high-quality courses, valued by industry. We have invested in tools which support careers advice and guidance and now want to encourage employers to signal which courses best meet their needs. This will ensure there is a pipeline of undergraduates with the right mix of technical and entrepreneurial skills that are really valued by industry.

ACTION: Through Cogent we will provide information on careers in life sciences, for students, employers and educators.

Industry is particularly concerned about the varied quality of practical training offered by biology degrees, as well as standards of numerical and analytical skills. There are also concerns that universities may reduce the amount of practical training, as experiments become increasingly sophisticated and expensive.

To address this, the Society of Biology is piloting an accreditation programme for undergraduate biology degrees, with biochemistry and *in vivo* subjects being the first subjects accredited. The accreditation programme will evaluate biology courses against both core and analytical skills. It will identify courses with a sizeable practical research element which provide the opportunities to develop skills in a range of research techniques. The first courses will be accredited in March 2012, and plans to expand the scheme are currently under-way.

ACTION: Through the Society of Biology, we will improve practical teaching standards, by expanding the accreditation programme for undergraduate biology degrees.

In addition to assuring the quality of courses in specific subject areas, we also want to be able to signal which courses – from across life sciences more generally – provide the skills, experience and knowledge that are valued by businesses. Kite-marking courses which have the right mix of technical and commercial skills, for example, is a good way to signal to students which courses are most valued by their future employers.

ACTION: Together with Cogent and others, we will develop a process to kite-mark FE and HE programmes. This will be piloted in 2012.

2 Developing scientific excellence alongside commercial rigour

What is the Government doing already?

We have already highlighted the importance of fostering inter-disciplinary qualifications. If UK innovators are to increase their chances of commercial success, training must go beyond academic discipline and include leadership, entrepreneurialism and business skills.

¹¹ www.ukba.homeoffice.gov.uk/visas-immigration/working/

¹² Times Higher Education World University Rankings 2011-12



This is important for managers, scientists and clinicians in the NHS who can add tremendous value to the economy. The NHS Chief Executive's Review recognises the need to invest not only in current managers and leaders in the NHS, but also in the future cohort of staff. It highlights the need to hardwire innovation into managerial and clinical curricula and through continuing professional development. It also recognises the benefit of external engagement and sets out plans for joint education programmes with industry.

Researchers/academia

The Research Councils and the Royal Society are already funding interdisciplinary qualifications in areas such as translational research, which are achieved through collaboration between industry and academia.

The Royal Society manages a range of schemes designed to encourage commercialisation of research. These include: the Industry Fellowship scheme for academic scientists who want to work on a collaborative project with industry, or for scientists in industry who want to work on a collaborative project with an academic organisation.



Translational research

Both the MRC and the BBSRC provide training for early-stage scientists who wish to establish themselves as independent researchers, and they encourage collaborative research between industry and academia.

Case study: Liverpool-Manchester MRC doctoral training programme in Clinical Pharmacology and Therapeutics

The £3m MRC three-year doctoral training programme in Clinical Pharmacology and Therapeutics led jointly by the Universities of Liverpool and Manchester began in 2010 in partnership with AstraZeneca, ICON, the Medicine Evaluations Unit (MEU) and GSK. The programme will train 12 Clinical Fellows who will be ideally positioned to lead research at the forefront of translational medicine within academia, industry or regulation. Training is provided in leading edge laboratory research and includes industry placements. Fellows also contribute to clinical research studies/trials during their studies.

Academia/NHS

Clinical/academic training programmes are open to selected medical trainees who are interested in a combined research and clinical career. There are around 400 research posts advertised each year at foundation stage.

In addition, around 270 academic clinical fellowships are funded and advertised nationally each year, and we now have over 750 clinical fellows in the system. The joint research/clinical posts are funded by the NIHR. In addition, the NIHR and a number of other research funders, such as Wellcome Trust and CRUK, support the intermediate PhD fellowships.

Modernising scientific careers for the NHS healthcare science workforce

Within the NHS, there are over 55,000 non-medical scientists working in healthcare science. This represents the largest group of scientists working for a single employer in the UK. There are some 45 scientific specialisms embracing biology, physiology, physics and engineering. Through the Modernising Scientific Careers (MSC) programme, we are committed to attracting, developing and retaining some of the best and brightest science graduates and young people in the UK with an interest in STEM¹³ subjects.

This programme will ensure that the NHS has a specialist scientific workforce that can use its skills more broadly through a clear focus on innovation, research and development, and effective partnership working with industry. It represents a joint investment approach with the HE sector and introduces comprehensive academic science in health-based programmes from vocational awards to doctoral level qualifications combined with co-ordinated workplace training.

What are the new actions that the Government is taking?

Providing exciting career opportunities and the incentives for people at all levels to develop scientific excellence alongside commercial skills is imperative if we are to be a nation that cultivates entrepreneurialism. Responding to this challenge, Sir Tim Wilson is undertaking a review on university-industry collaboration; and Cogent is proactively taking steps to promote transfer between academia and industry and improve the business acumen of SMEs.

As mentioned in Chapter 2, the Wilson Review will cover how we make the UK the best place in the world for university-industry collaboration. This will make some recommendations about the provision of sandwich courses and placements, which enable students to work in industry as part of their studies.

¹³ Science, Technology, Engineering and Maths

¹⁴ Developed by Kent University

¹⁵ Cogent's Apprentice Training Agency (ATA) a separate company (Technical Apprenticeship Service) within Cogent Group and a wholly owned subsidiary of Cogent.

Undergraduate placements

Industry placements are an excellent route for embedding practical and employability skills into academic programmes.

ACTION: Through Cogent, we will develop a strategy to increase the uptake of industry placements in the UK.

Technician level

We have invested nearly £900,000 in the development of a Higher Level Apprenticeship (HLA) programme for life sciences. This will provide an alternative pathway to enter the industry at the technician level.

A new HLA in life sciences has been developed by Cogent. It includes a life science foundation degree¹⁴, as well as work-based learning and employability. A pilot programme will be launched in January 2012 and will be delivered by City and Islington College. Cogent will also undertake a review of skills gaps across the wider biosciences landscape.

ACTION: We will introduce, via Cogent, Higher Level Apprenticeships (HLAs) covering post A-level education. Our ambition is to deliver 420 Apprenticeships over the next five years.

Help for employers to find apprentices

To make the apprenticeship programme more accessible to business, Cogent will establish a new Technical Apprenticeship Service¹⁵ (TAS) which will become a one stop shop for employers in science-based sectors. The TAS will offer a complete service, from identifying and supplying talent to providing a bespoke brokerage scheme. It will be employer led and therefore attuned to employers' needs and demands. It will be particularly focused on helping SMEs to engage with apprenticeships

and will work through local clusters of employers and providers.

ACTION: Through Cogent, we will establish the Technical Apprenticeship Service 'one-stop shop' for employers in science-based sectors. This will be operational from January 2012.

Mentoring

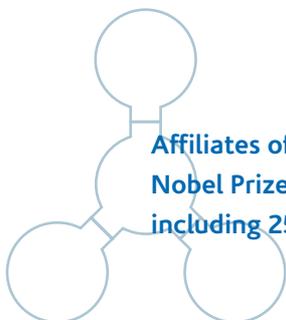
SMEs in the life sciences sector are often strong on scientific and research skills but may be lacking in business and management skills. We need to improve the three-year failure rate from current levels (39 per cent)¹⁶ by creating a stronger support network and providing SMEs with the commercial skills they need to survive.

Following extensive consultation with the life sciences industry and a comprehensive review of other sectors' mentoring programmes, Cogent will develop a tailored mentoring scheme in 2012. It will aim to have an offer for companies available early in 2013, and 100 SMEs engaged in the scheme within the first two years.

ACTION: Through Cogent, we will develop and implement a tailored mentoring programme that will provide SMEs with the management skills they need to enhance their competitiveness.

Summary

This suite of actions will build on our world-leading talent base to create value in the economy. By investing in our future pipeline, we will attract the best international talent and develop home-grown excellence.



Affiliates of the University of Cambridge have won more Nobel Prizes than those of any other institution globally, including 25 prizes in physiology/medicine.

¹⁶ Source:ONS Business Demography data 2011. Note that this data does not capture figures for high-tech R&D and specialist SMEs

4 Overcoming barriers and creating incentives for the promotion of healthcare innovation

It has become increasingly challenging for life sciences companies, particularly SMEs, to discover, develop and commercialise medical innovation.

The Government is introducing a suite of fiscal measures to stimulate innovation and growth for start-ups and SMEs through to large global enterprise. We will incentivise early-stage investment and nurture the best innovations through the translational funding gap to a point at which they can secure follow-on investment. We will continue to reduce the bureaucracy of setting up clinical trials to ensure that patients have access to promising, cost-effective new treatments.

The UK business environment for life sciences companies continues to pose a challenge. The Plan for Growth¹⁷ identified that the UK had lost tax competitiveness. R&D is increasingly expensive for the life sciences industry, with SMEs being particularly vulnerable. The “escalator” models of funding and collaboration are no longer suitable for the commercial environment in which globally mobile companies are operating; and the regulatory framework needs to adapt so that it keeps pace with the dynamism of science and business.

The UK needs measures which stimulate innovation. Tax incentives coupled with an integrated funding environment that supports early-stage science and translation in academic and commercial sectors, will make the UK a globally competitive environment for investment.

To develop a proportionate regulatory system to reduce the cost of clinical trials, we will incentivise the development of promising new treatments which are safe and cost-effective.

This chapter sets out how the UK will:

- 1 **Change tax to incentivise investment in R&D**
- 2 **Incentivise early-stage investment**
- 3 **Regulate**

1 Tax changes to incentivise investment in R&D

What is the Government doing already?

In Budget 2011, we announced a series of measures through the taxation system to create the necessary conditions for business growth and to encourage investment in the UK. We have improved the R&D Tax Credit for SMEs by increasing the level of super-deduction relief available to 200 per cent (225 per cent from April 2012) and removing the minimum spend requirement.

We are committed to introducing the Patent Box, a measure which will reduce corporation tax on profits from patents to 10 per cent from 1 April 2013. It will create a competitive tax environment for companies,

¹⁷ www.bis.gov.uk/policies/growth/the-plan-for-growth

and encourage them to locate high-value jobs and activity associated with the development, manufacture and exploitation of patents in the UK.

The life sciences industry will be a major beneficiary of the Patent Box. Smaller companies will benefit as patents developed collaboratively will be included within the regime. Profits from the sale of patents will be eligible for the reduced tax rate, allowing easier realisation of investment in a company.

What are the new actions that the Government is taking?

Government has further consulted on improvements to the R&D tax credit scheme and the tax-advantaged venture capital schemes and will take action in the following areas:

ACTIONS:¹⁸

- > **In 2012, we will help smaller high-risk early-stage companies by introducing a new Seed Enterprise Investment Scheme (SEIS), offering a 50 per cent income tax relief on investments. To kick start the scheme, the Government will offer a capital gains tax exemption on gains realised from the disposal of an asset in 2012/13 invested in SEIS in the same year.**
- > **In 2013, we will introduce an above the line R&D tax credit, to improve the visibility and certainty of R&D tax relief to attract large scale investment in innovation.**
- > **We will provide further details on giving the relief to Contract Research Organisations and others when routine R&D testing is subcontracted.**
- > **We will provide further details on a simpler pre-clearance system for smaller companies (such as spin-outs) making their first claim.**

2 Funding to incentivise early-stage investment

What is the Government doing already?

We have supported the development of a suite of venture capital opportunities to help fund innovative and high-growth companies at important stages of their development. These leverage private sector investment and will commit nearly £1bn over the next four years across all sectors of the economy, including measures addressing the equity gap.

For SMEs, this includes the £300m Enterprise Capital Funds programme and the £50m Business Angel Co-Investment Fund. These funds provide venture capital and angel investment into the equity gap for early stage innovative SMEs with the highest growth potential; the Business Angel Co-Investment Fund focuses particularly on regions most affected by reduced public spending.

Medicines originating from UK companies captured a 16% value share of the world's 100 top selling drugs in 2008.
(Source ABPI)



¹⁸ Autumn Statement November 2011 www.hm-treasury.gov.uk/autumn_statement.pdf

Case study: Oxford BioTherapeutics – Unlocking Venture Capital

Oxford BioTherapeutics (OBT) is focused on the development of targeted medicines in the field of cancer. A government-supported Venture Capital Fund backed the OBT as a lead investor from its inception in 2004 and the company has unlocked further funding from an Enterprise Capital Fund and EIS investors.

OBT, with support from the above programmes, has become a leading international biotechnology company which is able to access cutting-edge antibody technologies and expertise. The company has signed strategic partnerships with Seattle Genetics, Medarex (now BMS), Biosite (now Alere) and Amgen to build a broad pipeline of novel cancer-fighting drugs using its unique technology platform. OBT has also recently secured a boost in resources through alliances with Sanofi and with GSK in a deal worth up to £244m.

Through UKTI, we have established a new Venture Capital team to assist innovative SMEs with the capacity for high growth to access overseas finance. The team's objective is two-fold: they will work with partners such as the TSB, to identify and support SMEs best suited to presenting to international investors; and will build strategic relationships with overseas decision makers, including fostering links between US and UK technology clusters.

We have established the UK Future Technologies Fund (UKFTF) to increase the scale of investment, enable co-investment, and enable private investors to spread risk over a broader portfolio. This fund invests in specialist private sector technology funds, such as Advent Life Sciences and Gilde Healthcare III, with the expertise and track record to invest in technology companies. UKFTF is part of the UK Innovation Investment Fund (UKIIF) – one of the largest technology 'fund of funds' in Europe, it was

established with £150m from Government and a further £180m of private investment.

'Valley of death' funding gap

We recognise that SMEs in particular are finding it a challenge to secure financing in the early years, when they are focused on their R&D and have no revenue from sales or licensing¹⁹. This means that a number of ideas are failing before they have an opportunity to be commercialised. This is often referred to as the 'valley of death'.

What are the new actions that the Government is taking?

The emerging 'open innovation' model of R&D, where companies engage with a wider research environment, is strengthening the life sciences ecosystem particularly for SMEs. While this adds to the richness that is necessary to encourage creativity and innovation, we need to ensure that public investment is maximised and supports the most promising developments for patient benefit and commercial success. This is of particular relevance given the difficulties in securing private finance.

We want to leverage the strength of the science base for business by encouraging greater collaboration between the MRC, BBSRC and TSB, as well as charities and industry. In Chapter 2, we announced a £310m investment to support the discovery, development and commercialisation of research. Of this, £180m will be used to fund an initiative that will target the valley of death.

ACTION: We will invest £180m over the next three years in a joint MRC/TSB Biomedical Catalyst Fund. This will nurture innovative technologies from the academic or commercial sector through to companies with products or technology platforms in order to attract private equity.

¹⁹ Recent data from the BVCA shows that the supply of early-stage venture capital investment to SMEs decreased by 31 per cent in 2010 from 2009

3 Regulation

What is the Government doing already?

Regulation is essential to protect patients and ensure appropriate practice. Regulation pathways can sometimes create a delay to clinical trials and the uptake of new products, potentially to the detriment of both industry and patients.

Research

We made a commitment in the Growth Review to open up information on clinical research in order to promote collaboration and innovation. This includes work by NIHR to transform incentives for efficiency in NHS research initiation and delivery. The NIHR will publish clinical trial information against public benchmarks; and from 2013, NIHR funding to providers of NHS services will be conditional on meeting a 70-day benchmark to recruit first patients for trials.

We have established a new Health Research Authority, initially as a Special Health Authority, to combine and streamline the approvals for health research. It will build on the success of the National Research Ethics Service and its Integrated Research Application System and will work closely with the MHRA.

The Clinical Trials Directive is not being applied consistently across the single market. This is resulting in added complexity, increased costs and delays to trials. The European Commission will publish proposals in 2012 to revise the Directive. Through the MHRA, we are playing a leading role in Europe in order to ensure that regulatory oversight is proportionate to risk.

We are aiming to reduce the use of animals in scientific research, and are supportive of all work directed at developing alternatives and improving standards. The Government does, however, recognise the strong scientific case for the carefully regulated use of animals where no alternative is available, and the significant benefits to human health that such research can bring.

What are the new actions that the Government is taking?

We will work with industry, other regulators, NHS and academia to ensure that regulation does not prevent patients from accessing the treatments they need. We will continue to streamline bureaucracy, and whilst safety and efficacy remain paramount, we will be creative in our approach so that regulation follows science at a pace beneficial to patients.

Streamlining regulation

While we are taking action on clinical research regulation we will continue to review regulations that impact patients and the life sciences sector more generally.

ACTION: Through the MHRA, we will launch a regulatory audit and Red Tape Challenge in March 2012.

Manufacturing

Manufacturing regulations and guidelines do not always keep pace with rapid developments in manufacturing science, and can create a hurdle to the adoption of the innovative technologies within the pharmaceutical industry. This can lead to companies being unwilling to make new investments in the UK. The Growth Review recognised the importance of advanced manufacturing to the UK and proposed a number of actions to improve the UK's performance²⁰. We will build on this work to address those factors stifling manufacturing innovation in the UK, creating a progressive regulatory environment that not only supports innovation, but openly promotes it.

ACTION: Through the MHRA, we will work with industry and other international regulators to develop actions which will create a more enabling regulatory environment for the adoption of innovative manufacturing technology. We will do this by the second quarter of 2012.

²⁰ The Plan for Growth – March 2011, P89. www.bis.gov.uk/policies/growth/the-plan-for-growth



NICE Compliance Regime

NICE is recognised as a best practice leader for health technology approvals. A number of countries have now adopted similar appraisal systems, and yet in the UK there is considerable variation in the implementation of some of its recommendations. The NHS Chief Executive's Review outlines measures which aim to reduce variation in the NHS and drive greater compliance with NICE technology appraisal guidance, to ensure rapid and consistent implementation throughout the NHS.

The review has recommended the following actions:

- > Introduce a NICE Compliance Regime to reduce variation and drive up compliance with NICE Technology Appraisals.
- > Require that all NICE Technology Appraisal recommendations are incorporated automatically into relevant local NHS formularies in a planned way that supports safe and clinically appropriate practice.
- > Establish a NICE Implementation Collaborative to support implementation of NICE guidance.

Providing transparent data requirements for health technology appraisals is particularly helpful for the bio-pharmaceutical sector. This has made the argument

to provide a similar service for the medical technology industry even more compelling.

ACTION: Through NICE, we will establish an advice service for medical technology companies. This means that businesses and investors will understand the data requirements needed to demonstrate the value of their technology.

Routes to market

The assessment process that drugs go through to receive market approval and a health technology assessment is an important one to ensure safety, efficacy and effectiveness. It offers patients the security of receiving a product where the clinical risks and benefits have been appropriately assessed. However this process is often long and expensive; clinical development occurs across multiple sites with large patient cohorts, typically lasting several years and costing hundreds of millions of pounds. This approach was viable when the industry was producing so-called 'blockbuster drugs' that could be used across large patient populations, but it poses particular challenges in the era of 'stratified medicines', where new drugs may be effective in a small segment of patients with specific genetic characteristics. When producing regulatory guidance or assessing company applications for medicines, the MHRA and EU regulators take account of the size of the population that will be treated by the medicine, and make sure that the population data requirements imposed upon the companies are adjusted accordingly.

However, smaller biotechnology companies find it hard to fund Phase III research, and are less well-placed to bear the cost of a long development process from discovery to market. As our ability to diagnose diseases more accurately improves, and we can more effectively target particular drugs to ever smaller groups of patients, regulators, government and industry will need to find more efficient routes to get innovative medicines to patients quickly. The UK is determined to lead this global debate.

Indeed, several schemes already exist in the EU and the UK to support patient access to innovative breakthrough therapies as quickly as possible. These include the EMA conditional authorisation and schemes for accelerated assessment of products, as well as national systems to make drugs available on a named patient basis. There are concerns that these schemes may be used less frequently than their equivalents operated by the Food and Drugs Administration in the United States. This may be due to low awareness of the schemes operating in the EU and UK, particularly amongst SMEs.

ACTION: MHRA will take proactive steps to highlight to SMEs the existing regulatory tools to support patient access to innovative breakthrough products, and will report to Andrew Lansley and David Willetts by March 2012 on the range of activities undertaken.

ACTION: In addition, early in 2012 the MHRA will bring forward for consultation proposals for an 'Early Access Scheme'.

This new approach will support the use of promising new drugs to treat, diagnose or prevent life-threatening or seriously debilitating conditions where these conditions lack effective medical treatments. Typically this scheme would be available for drugs prior to authorisation but at the end of Phase III trials. This will mean that the MHRA has sufficient data to reach an informed opinion, and avoids conflict with the clinical trial programme required for licensing. However, where supported by suitable evidence of patient benefit and safety, the scheme could be extended to drugs at an earlier stage of development.

The proposed guiding principles for the scheme are as follows: eligible products will be determined by a scientific opinion that the likely clinical benefits outweigh the risks identified to date where there is a high unmet clinical need; NHS funding for products must be cost-effective; and the UK economy should benefit from the scheme. Under the Early Access Scheme, companies will be reimbursed at an earlier stage in development at a

price that recognises the uncertainty of the effectiveness of early stage products. It will also ensure that patients receive the next generation of breakthrough therapies in the UK, while supporting overarching industry objectives.

Leading the debate on regulatory innovation will of course require ongoing work. A group of experts drawn from government, regulators, the NHS, industry and the academic and third sector communities will meet quarterly to discuss healthcare regulation issues, including the development of new initiatives and innovations. The Ministerial (Biopharmaceutical) Industry Strategy Group Innovative Technology Forum will be responsible for ensuring the delivery of these initiatives, and will provide an annual report to DH and BIS ministers. This will set out measures of performance such as the use of conditional authorisation pathways, and uptake of the Early Access Scheme, alongside 'next steps' proposals for further regulatory innovation.

ACTION: A group of experts drawn from government, regulators, the NHS, industry, and the academic and third sector communities will meet quarterly to discuss healthcare regulation issues, including the development of new initiatives and innovations.

Summary

This suite of actions will stimulate innovation and growth from start-ups and SMEs through to large global enterprises. By ensuring that regulation keeps pace with innovation, we will position the UK to realise emerging opportunities in advanced manufacturing and the changing drug development model.

Implementation

In this strategy, we have set out a number of ambitious actions. Delivering on them will be vital to achieving our vision of the UK as the global hub for life sciences.

We must succeed in creating a fully integrated ecosystem to bring business, researchers, clinicians and patients together in true collaboration, and to translate discovery into clinical use within the NHS.

It is imperative for us to create the environment and infrastructure to attract and nurture pioneering researchers and clinicians. We want to bring innovations to market earlier and more easily, thereby making the UK the location of choice for investment in life sciences.

The Government is committed to making these ambitions a reality. We will act now to ensure the UK is not left behind.

The *Strategy for UK Life Sciences* has been launched alongside the NHS Chief Executive's Review. To make sure that the implementation is as strong as the ambition, we are appointing two Life Sciences Champions to support the delivery.

The first of these champions will act as chair of an independent Life Sciences Advisory Board, comprising representatives from industry, academia, NHS, MRC, TSB, NIHR and Government Departments. The Advisory Board will report back on progress via a formal annual report to Rt. Hon. David Willetts MP (Minister of State for Universities and Science) and Rt. Hon. Andrew Lansley CBE MP (Secretary of State of Health). The report will also be submitted to the Prime Minister and made available publicly.

The second Life Sciences Champion, who will be a member of the Advisory Board, will act as a collaboration champion and an ambassador to foster partnership across the UK clusters and government.

As Government is committed to reducing bureaucracy rather than adding to it, we are looking to utilise an existing committee or group to act as the Advisory Board. The composition and terms of reference will be worked up during the early part of 2012 ready for full commission by April 2012.

This governance process will not alter the existing accountability arrangements within departments or implementation arrangements for the NHS Chief Executive's Review.



Summary of actions from the Strategy for UK Life Sciences

Table of actions from the Strategy for UK Life Sciences

We will invest £310m to support the discovery, development and commercialisation of research. This covers £130m for Stratified Medicines and £180m for a Biomedical Catalyst Fund.

We will commission an independent panel to develop a technology roadmap that will propose actions required to establish a world leading synthetic biology industry.

Through the TSB, we will invest up to £10m per annum in a Cell Therapy Technology and Innovation Centre (TIC), based in London.

Through the MRC, EPSRC and BBSRC, we will jointly invest £25m over five years in a programme to maximise the potential of the TIC, and pull through cutting edge biomedical science and engineering for the delivery of regenerative medicine.

We will invest £75 million to: expand the existing European Bioinformatics Institute in Cambridge to provide a new facility for biological data-storage to support life sciences research and its translation; and deliver a new technical hub (Hinxton, Cambridge) which will house 200 staff and will coordinate the network.

We will enable small state-of-the-art research facilities to secure recognition and apply for Research Council funding.

Research Councils UK, working with UK HE funding bodies, and in discussion with individual universities and consortia, will establish a new principles-based framework for treatment and submission of multi-institutional funding bids.

As announced in the Autumn Statement 2011, we will introduce the EU VAT cost-sharing exemption in the Finance Bill 2012.

There will be the provision of secure data linkage services by the Health and Social Care Information Centre by September 2012 and by the Clinical Practice Research Datalink (CPRD), which is a £60 million investment by NIHR and MHRA.

London's three AHSCs, (Imperial, Kings Health Partners and UCL Partners) will explore the potential to develop information systems that build on the NHS record and pull together patient level data for London's population. This will enable large groups of patients to be engaged in world-class clinical research on disease-specific and personalised biological therapies, regenerative medicine and medical devices.

Table of actions from the Strategy for UK Life Sciences

We will appoint two independent Life Sciences Champions: The first of these champions will act as chair of an independent Life Sciences Advisory Board. The second will act as a collaboration champion to foster partnership across the UK clusters and within government.

Through the NIHR, we will re-launch an enhanced web-based UK Clinical Trials Gateway in March 2012. This site will provide patients and the public with authoritative and accessible information about clinical trials in the UK.

The Cambridge, Oxford and London BRCs will work with the BRU in Leicester, to develop a national NIHR Bioresource. This will make the UK the 'go-to' place for experimental medicine.

We will support patients to have access to novel treatments, and be part of the development of wider patient benefits by consulting on amending the NHS Constitution so that there is a default assumption (with ability to opt out):

- > for data collected as part of NHS care to be used for approved research, with appropriate protection for patient confidentiality.
- > that patients are content to be approached about research studies for which they may be eligible, to enable them to decide whether they want a discussion about consenting to be involved in a research study.

Through UKTI, we will work with business ambassadors and members of the Catalyst Programme (a network of business leaders, influencers and academics) to promote the UK's status as Europe's leading destination for inward investment in the sector.

We will hold a series of investment and policy events to promote the UK's world-leading position in healthcare and life sciences in advance of the London 2012 Olympics.

We will create new partnerships in translational medicine and biopharmaceuticals, underpinned by the Memorandum of Understanding between the UK and China.

Through Cogent we will provide information on careers in life sciences, for students, employers and educators.

Through the Society of Biology, we will improve practical teaching standards, by expanding the accreditation programme for undergraduate biology degrees.

Together with Cogent and others, we will develop a process to kite-mark FE and HE programmes. This will be piloted in 2012.

Through Cogent, we will develop a strategy to increase the uptake of industry placements in the UK.

We will introduce, via Cogent, Higher Level Apprenticeships (HLAs) covering post A-level education. Our ambition is to deliver 420 Apprenticeships over the next five years.

Through Cogent, we will establish the Technical Apprenticeship Service 'one-stop shop' for employers in science-based sectors. This will be operational from January 2012.

Through Cogent, we will develop and implement a tailored mentoring programme that will provide SMEs with the management skills they need to enhance their competitiveness.

Table of actions from the Strategy for UK Life Sciences

- > In 2012, we will help smaller high risk early stage companies by introducing a new Seed Enterprise Investment Scheme (SEIS), offering a 50 per cent income tax relief on investments. To kick start the scheme, the Government will offer a capital gains tax exemption on gains realised from the disposal of an asset in 2012-13 invested in SEIS in the same year.
- > In 2013, we will introduce an above the line R&D tax credit, to improve the visibility and certainty of R&D tax relief to attract large scale investment in innovation.
- > We will provide further details on giving the relief to Contract Research Organisations and others when routine R&D testing is subcontracted; and
- > We will provide further details on a simpler pre-clearance system for smaller companies (such as spin-outs) making their first claim.

Through the MHRA, we will launch a regulatory audit and Red Tape Challenge in March 2012.

Through the MHRA, we will work with industry and other international regulators to develop actions which will create a more enabling regulatory environment for the adoption of innovative manufacturing technology. We will do this by the second quarter of 2012.

Through NICE, we will establish an advice service for medical technology companies. This means that businesses and investors will understand the data requirements needed to demonstrate the value of their technology.

MHRA will take proactive steps to highlight to SMEs the existing regulatory tools to support patient access to innovative breakthrough products, and will report to Andrew Lansley and David Willetts by March 2012 on the range of activities undertaken.

In addition, early in 2012 the MHRA will bring forward for consultation proposals for an 'Early Access Scheme'.

A group of experts drawn from government, regulators, the NHS, industry, and the academic and third sector communities will meet quarterly to discuss healthcare regulation issues, including the development of new initiatives and innovations.

Accountability for the implementation of these actions lies with: Rt Hon David Willetts MP, Minister of State for Universities and Science and Rt Hon Andrew Lansley CBE MP, Secretary of State for Health.

Summary of actions from NHS Chief Executive Review of Innovation

Reducing variation and strengthening compliance

- > We will introduce a NICE Compliance Regime to reduce variation and drive up compliance with NICE Technology Appraisals.
- > We will require that all NICE Technology Appraisal recommendations are incorporated automatically into relevant local NHS formularies in a planned way that supports safe and clinically appropriate practice.
- > We will establish a NICE Implementation Collaborative to support prompt implementation of NICE guidance.

Metrics and Information

- > We will develop and publish an innovation scorecard to track compliance with NICE Technology Appraisals.
- > We will procure a single comprehensive and publicly available web portal for innovation in the NHS.
- > We will work with Which? to raise awareness among the public and patients of innovations in healthcare.
- > We will establish the Clinical Practice Research Datalink (CPRD), a new secure data service within the Medicines and Health Care Products Regulatory Agency (MHRA).

Creating a system for delivery of innovation

- > We will establish a number of Academic Health Science Networks (AHSNs) across the country.
- > We will publish the AHSN designation process in March 2012.
- > We will undertake a sunset review of all NHS/DH funded or sponsored innovation bodies.
- > With immediate effect, NICE will take responsibility for the iTAPP programme.

Incentives and investment

- > We will align financial, operational and performance incentives to support the adoption and diffusion of innovation.
- > We will increase the profile of, and maintain investment in, the NHS Innovation Challenge Prizes.
- > We will extend the 'never events' regime and encourage disinvestment in activities that no longer add value.
- > We will establish a Specialised Services Commissioning Innovation Fund.

Procurement

- > We will publish a procurement strategy in March 2012.
- > We will double our investment in the Small Business Research Initiative.
- > We will review the existing NHS intellectual property strategy and develop a model for contracts that is fit for purpose.

Developing our People

- > We will ensure that innovation is 'hard-wired' into educational curricula, training programmes and competency frameworks at every level.
- > We will establish joint industry and NHS training and education programmes for senior managers.
- > We will establish an NHS Innovation Fellowship Scheme.

Leadership for Innovation

- > The NHS operating framework asks the NHS to prioritise the adoption and spread of effective innovation and good practice.
- > Clinical Commissioning Groups will be under a duty to seek out and adopt best practice, and promote innovation.
- > We will strengthen leadership and accountability for innovation at Board level throughout the NHS.

High Impact innovations

- > We will rapidly accelerate the use of assistive technologies in the NHS, aiming to improve at least 3 million lives over the next five years.
- > We will launch a national drive to get full implementation of ODM monitoring, or similar fluid management monitoring technology, into practice across the NHS.
- > We will launch a 'child in a chair in a day' programme to transform the delivery of wheelchair services throughout the NHS.
- > We will require NHS organisations to explore opportunities to increase national and international healthcare activity and will host a summit with UK trade and investment in the new year.
- > We will require the NHS to work towards reducing inappropriate face-to-face contacts and to switch to higher quality, more convenient, lower cost alternatives.
- > We will require the NHS to commission services in line with NICE-SCIE guidance on supporting people with dementia.
- > From April 2013, compliance with the high impact innovations will become a pre-qualification requirement for CQUIN.

Accountability for the implementation of these actions lies with the NHS Chief Executive David Nicholson.

Whilst these actions sit alongside the *Strategy for UK Life Sciences*, they are subject to separate governance arrangements.

Glossary of abbreviations

AHSC	Academic Health Science Centre
AHSN	Academic Health Science Network
BBSRC	Biotechnology and Biological Sciences Research Council
BRC	NIHR Biomedical Research Centre
BRU	NIHR Biomedical Research Unit
CPRD	Clinical Practice Research Datalink
CRN	NIHR Clinical Research Network
CRUK	Cancer Research UK
EMA	European Medicines Agency
EPSRC	Engineering and Physical Sciences Research Council
FE	Further Education
HE	Higher Education
HEFCE	Higher Education Funding Council for England
HEI	Higher Education Institution
MHRA	Medicines and Healthcare Products Regulatory Agency
MRC	Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NOCRI	NIHR Office for Clinical Research Infrastructure
R&D	Research and Development
REF	Research Excellence Framework
SME	Small and Medium Sized Enterprise
STEM	Science, Technology, Engineering and Maths
TIC	Technology and Innovation Centre
TRP	NIHR Translational Research Partnership
TSB	Technology Strategy Board
UKTI	UK Trade and Investment

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