

Investing in UK Health and Life Sciences



Making the UK a world leading place for life sciences innovation



Life science – and the UK's role in it – is at a crossroads. Behind us lies a great history of discovery, from the unravelling of DNA to MRI scanning and genetic sequencing. We can be proud of our past, but this government is acutely aware that we cannot be complacent about the future.

Your industry is undergoing profound change. The financial crisis is affecting healthcare budgets in the West, many blockbuster drugs are nearing the end of their patents, and new biological insights have dramatically altered the landscape of discovery and development.

As a result of increasing R&D costs, the old 'big pharma' model is becoming more difficult to maintain. In its place is a new focus on translational medicine – more early stage clinical trials with patients, more external innovation, more collaboration.

We understand that the game has changed – and that the UK must change with it. This country has all the ingredients to be an outstanding location for medical innovation: an integrated National Health Service, unlike any other; a highly competitive tax and investment framework; and an unrivalled science base, with four of the world's top ten universities here in Britain.

We have the strengths, but we recognise that too often we have failed to capitalise on them. This is an ambitious strategy to change that and to finally join up life sciences in the UK: to open up universities and business to more collaboration; to invest in the best British ideas at an early stage; to tear down the regulatory barriers you face; and crucially, to open up the NHS to new innovations and new clinical trials.

This strategy is ambitious because it has got to be. We are determined not just to remain a player in the global market, but to remain a leading player. In this endeavour I want to work closely with industry. My door is always open for suggestions on what we can do to make the UK a more attractive place to invest, research and employ – so that we make this great British success story even more successful in the years to come.

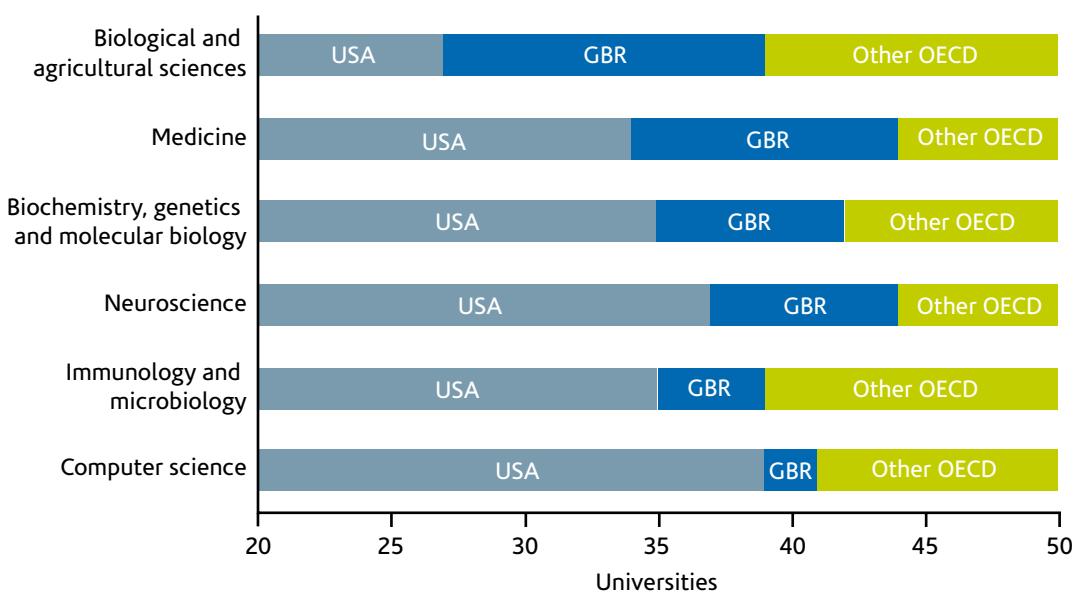
A handwritten signature in black ink that reads "David Cameron".

The actions we are taking to make the UK a **world-leading** place for life science investment

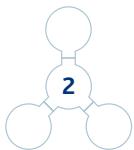
The UK has a world-leading science base and a strong position in manufacturing. In addition, we have the opportunity to be the world's leading centre for understanding, treating and advancing care for patients with chronic disease.

However, this opportunity comes at a time when companies are finding it harder to create value through commercialising innovation. While this is a global phenomenon we also recognise that the UK needs to address a number of challenges of its own.

Location of top-50 universities by main subject areas



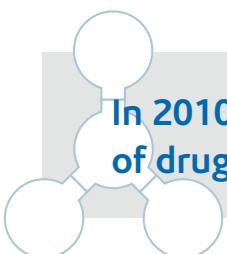
Data Source: OECD Science Technology and Industry Scoreboard 2011





That is why we are taking the urgent action required to ensure that the whole environment for innovation – tax and funding incentives, access to finance, and the culture of adoption in the NHS – is similarly world-class.

This document and the strategies underpinning it represent the start of a journey. The UK Government will take a lead, working closely with industry to ensure that the UK is a world-class centre for discovery, development, manufacture and adoption of medical innovations.



In 2010, UK medical biotech companies led Europe in numbers of drugs in clinical development with over 20% of the total



A world-leading hub for talent

World leading talent is essential to success in health and life sciences. The UK is already home to an unrivalled concentration of academic excellence but changes are needed across the system so that people have the right training and incentives to collaborate across disciplines and organisations. That is why we are taking steps to ensure that we develop, recruit and celebrate the best scientists, clinicians and entrepreneurs.

- i **Innovation will be at the heart of education to develop world-leading entrepreneurs**
 - Through the Royal Society and the Wellcome Trust, **prestigious Sir Henry Dale Fellowships have been launched to offer grants of around £1m each** to outstanding young biomedical scientists wanting to build an independent research career in the UK.
 - **The NIHR will be awarding Research Professorships to fund selected leaders** in the early part of their careers, who are capable of making a real difference to the effective translation of research from the bench to the bedside, or the campus to the clinic. These awards will help to strengthen research leadership at the highest academic levels.
 - Changes to our clinical and post-graduate education are being introduced to **embed commercial skills and ensure that innovation is 'hard-wired' into curricula, training programmes and competency frameworks at every level**. We will also establish joint industry and NHS training and education programmes for senior NHS managers and we will establish an NHS Innovation Fellowship Scheme for continued professional development.
 - The skills of school leavers will also be a focus for development. **We will introduce a higher-level Apprenticeship for Life Sciences**, covering post A-level education and including technical skills and industry involvement. This will ensure that we train high quality technicians to supply the sector with the skilled workforce needed.

ii The UK is well-positioned to attract the best of the global life sciences sector

International scientists, clinicians and businesspeople make a huge contribution to the success of the UK life sciences sector. This is taken into account in the design of our immigration system.

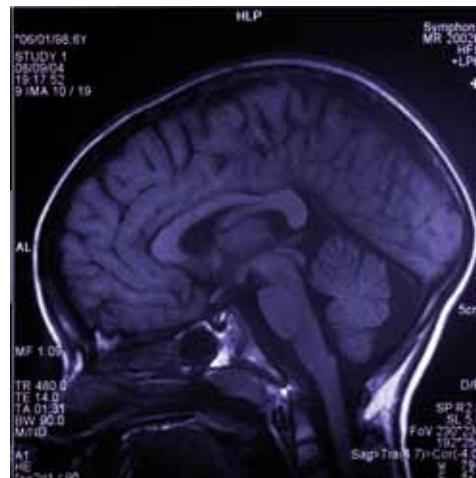
- The system is designed so that **multinational companies can bring to the UK as many of their staff as is needed, for a temporary period through the intra-company transfer route**. This also applies to the number of short-term visitors who can come to the UK, either as business visitors or academic visitors. Under the points-based system life sciences researchers are already able to apply under an 'exceptional talent' visa where they have the appropriate skills. In addition to this, skilled migrants with a job can gain a visa. Although there is a cap on the number of these places this route is currently undersubscribed. And for scientists and academics entering the UK on a temporary basis, as a guest lecturer or external examiner, we have expanded the terms of the Government Authorised Exchange Scheme.

iii The UK environment is helping to celebrate researchers who bring impact

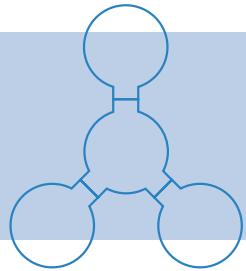
To be at the forefront of the industry the UK has to be able to retain the best talent and focus efforts on creating impact.

- To support academics to deliver impact we are amending the way that they are appraised. **We have introduced a radical change that will make it easier for researchers to collaborate with industry and to take part in applied research** – in fact academics will now be judged to a significant degree on the impact created by the translation of their work into social and economic benefit. And industry will be included in the panel that is making those decisions.

- **To celebrate the achievements of the most eminent scientists the Royal Society Research Professorships are also available.** These provide international recognition for world-class scientists who would benefit from a period of long-term support to allow them to focus on research and collaboration based at an institution in the UK. Previous holders include six Nobel Laureates and five Presidents of the Royal Society.



Examples of our leading talent



The UK has always attracted some of the world's best pioneers in life sciences, as well as growing our own amazing scientists.

This is evident from the number of award winning individuals we can boast: UK scientists have been awarded more than 70 Nobel Prizes for their scientific achievements. The Medical Research Council Laboratory of Molecular Biology alone has supported the work of 14 Nobel prizewinning scientists.

Here are just a few of our leading lights in life sciences research



Sir Robert Geoffrey Edwards, CBE, FRS, a British physiologist and pioneer in Reproductive medicine and in-vitro fertilization (IVF) in particular. Along with surgeon Patrick Steptoe, Edwards successfully pioneered conception through IVF, which led to the birth of

the first test-tube baby, Louise Brown, on 25 July 1978. He was awarded the 2010 Nobel Prize in Physiology or Medicine 'for the development of in vitro fertilization'.



Jack William Szostak is a biologist of Polish British descent and Professor of Genetics at Harvard Medical School and Alexander Rich Distinguished Investigator at Massachusetts General Hospital, Boston. He was awarded the 2009 Nobel Prize for Physiology

or Medicine, along with Elizabeth Blackburn and Carol W. Greider, for the discovery of how chromosomes are protected by telomeres.

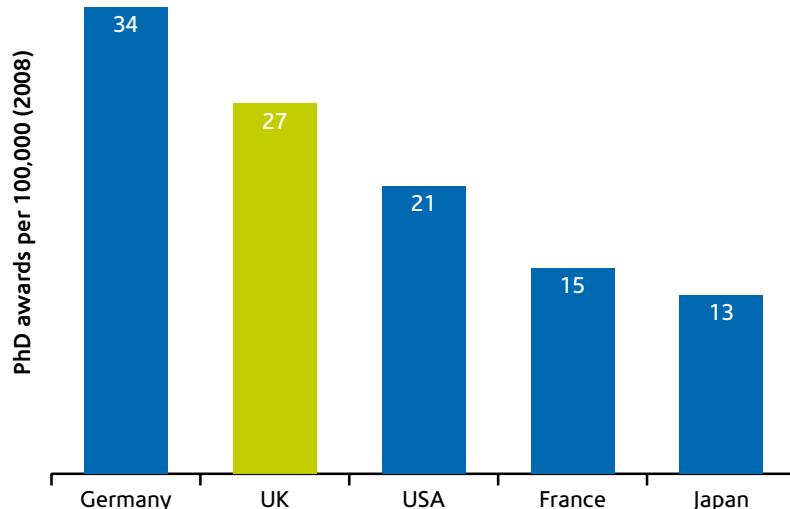


Sir Richard Timothy 'Tim' Hunt, FRS is an English biochemist. Hunt was awarded the 2001 Nobel Prize in Physiology or Medicine with Paul Nurse and Leland H. Hartwell for their discoveries of protein molecules that control the division (duplication) of cells.



Sir Paul Maxime Nurse, PRS is a British geneticist and cell biologist. He was awarded the 2001 Nobel Prize in Physiology or Medicine with Leland H. Hartwell and R. Timothy Hunt for their discoveries of protein molecules that control the division (duplication) of cells in the cell cycle.

Nurse is the current President of the Royal Society and Chief Executive and Director of the Francis Crick Institute.



Compared to our major competitor economies the UK has one of the highest number of PhDs relative to our population



Sir Peter Mansfield, FRS, is a British physicist who was awarded the 2003 Nobel Prize in Physiology or Medicine for his discoveries concerning magnetic resonance imaging (MRI). The Nobel Prize was shared with Paul Lauterbur, who also contributed to the

development of MRI. Sir Peter is a professor at the University of Nottingham.



Sir Richard 'Rich' John Roberts is a British biochemist and molecular biologist. He was awarded the 1993 Nobel Prize in Physiology or Medicine with Phillip Allen Sharp for the discovery of introns in eukaryotic DNA and the mechanism of gene-splicing.



Sir John Edward Sulston FRS is a British biologist. He is a joint winner of the 2002 Nobel Prize in Physiology or Medicine with Sydney Brenner and H. Robert Horvitz, for their discoveries concerning 'genetic regulation of organ development and programmed cell death'.



Francis Harry Compton Crick OM FRS was an English molecular biologist, biophysicist, and neuroscientist, and most noted for being one of two co-discoverers of the structure of the DNA molecule in 1953, together with James D. Watson. He, Watson and Maurice

Wilkins were jointly awarded the 1962 Nobel Prize for Physiology or Medicine 'for their discoveries concerning the molecular structure of nucleic acids and its significance for information transfer in living material'.

The UK produces the highest number of science, mathematics and computing graduates annually in the EU

A world-leading system for discovery and development

The UK is building an integrated system to make it easier to translate discovery into development

- i We are investing in translational research and unlocking patient data
 - > Companies are increasingly seeking to unlock the power of patients and data, working closely with clinicians and researchers. In the UK we are investing to make it easier for industry to partner with our world-leading scientists and clinicians, and to unlock the power of our unique patient data. That is why **the NIHR has committed a record investment of £800m over five years to the creation of Biomedical Research Centres and Units within the UK's leading teaching hospital-university partnerships**, and the establishment of two new Translational Research Partnerships. The National Institute for Health Research Office for Clinical Research Infrastructure (NOCRI) provides a single point of entry to these centres for life sciences companies. We are also making it easier for close relationships to form between large companies, small companies, VCs, academia and clinicians by developing critical mass in locations where the life sciences are strong. To support this we **will create a life science collaboration champion to foster partnership across the UK ecosystem and clusters**.
 - > Patient data is crucial to support the new types of biomedical research necessary to understand the causes of complex diseases like cancer and dementia. That is why **we are launching a new secure service to link primary and secondary care data at an unidentifiable patient level, and investing £60m in a secure Clinical Practice Research Datalink (CPRD)** to provide researchers with access to patient data for clinical trials recruitment and observational studies. And in response to calls from charities we will consult on changes to make it easier for patients to be involved in research, with patient data being opened up as the default, but protecting the individual's right to opt-out.
 - > Our capacity to link patient data to biological samples is also being strengthened. **The NIHR is investing £2.5m pump-priming this year in a new national Bioresource**. This new capacity will help companies to recruit patients for stratified experimental medicine studies as well as providing the potential to study the molecular basis of disease, identify the most appropriate biomarkers

for diagnosis and drug discovery, and to test the mechanism of action and effects of new drugs. This resource will complement the UK Biobank, led by MRC and the Wellcome Trust, a unique resource that will open for research proposals in February 2012.

ii **We are stripping back the bureaucracy and accelerating the setup of clinical trials**

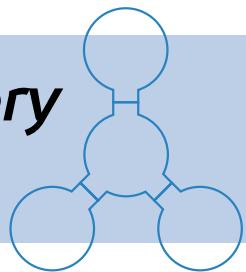
- **A new Health Research Authority has been launched to streamline regulation** and improve the cost effectiveness of clinical trials. This is supported by a new NIHR Research Support Services Framework that will help reduce the unnecessary duplication of R&D checks. Future NIHR research funding to NHS providers will be contingent on performance, for example, ensuring it takes 70 days or less from receipt of a valid research application to the time of first patient recruitment.
- To increase the number of patients who can benefit from being involved in trials the **NIHR have also developed a free Smart Phone App**. It provides a practical and innovative way for patients to access information about clinical trials, via the UK Clinical Trials Gateway.
- In addition, to make sure that our clinical trials performance is transparent the **NIHR has teamed up with the Guardian newspaper to launch The Clinical Research Zone**. This hub publishes data on the participation of individual NHS Trusts in clinical trials and the number of patients recruited. Information will be presented as both a “heat map” of activity and a national league table.



Translational research in clinical haematology

Delivering early phase clinical trials to ensure new therapies are safe and work well has traditionally been challenging for many countries – and this means delays to patients getting access to potentially lifesaving new therapies. One project to address this in the UK is a newly built facility for translational research to help patients with leukaemia and other haematological malignancies. The project was Government funded and developed in close collaboration with the Institute of Cancer Studies at Birmingham University. The new Centre for Clinical Haematology has recruited over 400 patients to take part in clinical trials so far, and has leveraged over £15million of free drugs that were not available on the NHS.

Examples of innovation and discovery from our outstanding science base



The UK is a great place for life sciences research with cutting edge facilities, top universities and strong collaborations across disciplines.

Innovative partnerships between industry and academia

In a landmark initiative the MRC and AstraZeneca have worked together to provide access for UK academic researchers to a high-quality collection of AstraZeneca compounds. Through MRC funding these compounds will be made available to UK academia to support studies to investigate mechanisms of human disease and ultimately the development of potential therapeutic interventions. This exciting new approach marks a new era in medical discovery, open innovation and public-private collaboration. It is hoped that this groundbreaking scientific collaboration sets the tone for industry and academia collaborations of the future and works towards medical discoveries that will improve the lives of millions.

The UK is the leading country in the G8 for research productivity. It produces more publications and citations per researcher and per pound of public funding than any of its major competitors

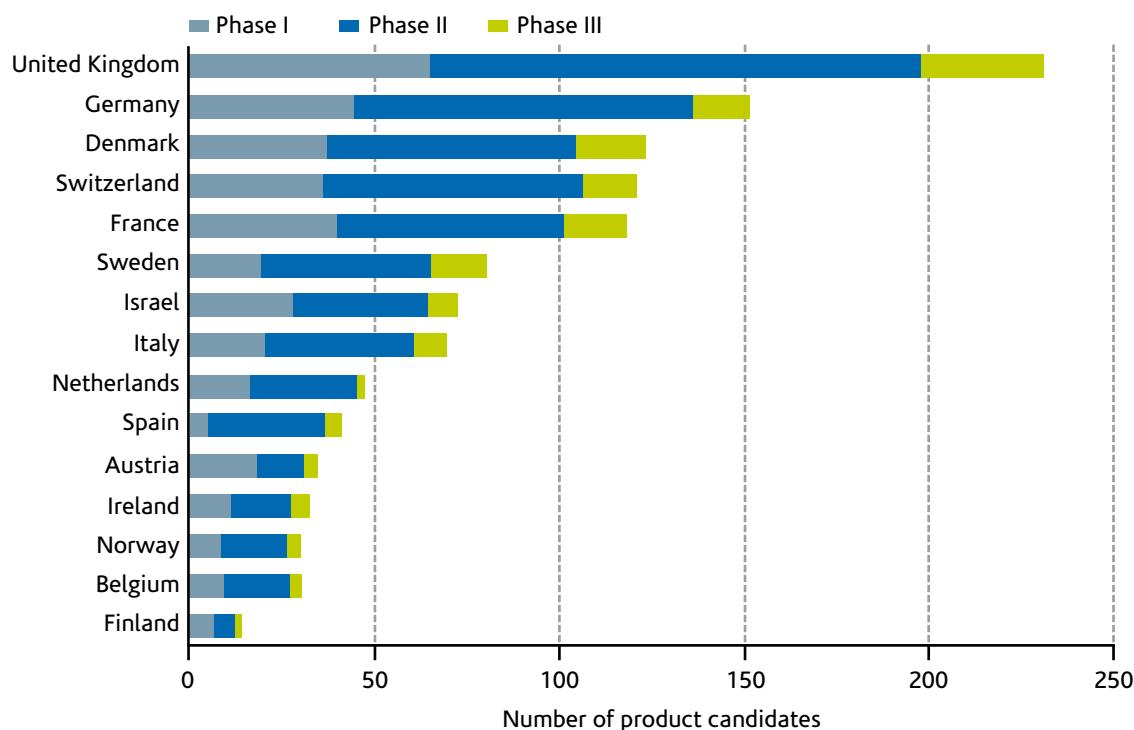


Innovative partnerships in inflammatory research

The University of Manchester, GlaxoSmithKline (GSK) and AstraZeneca announced the creation of the Manchester Collaborative Centre for Inflammation Research in May 2011, a unique collaboration to establish a world-leading translational centre for inflammatory diseases. The project was initiated with an investment of £5m from each partner over a three year period. This collaboration will bring together scientists from both the pharmaceutical industry and academia to work collaboratively on inflammation research and translational medicine, with the ultimate goal of translating findings into new and improved treatments. Such advances could potentially benefit the millions of people worldwide affected by diseases associated with chronic inflammation, including asthma, chronic obstructive pulmonary disease, rheumatoid arthritis and inflammatory bowel disease.

More than half a million people participated in studies supported by the NIHR Clinical Research Network in 2010, a 24% increase on the previous year

European clinical pipeline by country, 2010



Source: Ernst & Young, MedTRACK and company websites

A world-leading system in technology adoption

The UK is building an integrated system to make it easier to translate from development into adoption

i We are changing our approach to pricing to take a broader account of value

- For breakthrough innovations to reach patients the products must be assessed in a way which captures their true value, so that the right investments can be made in development. That is why **we are introducing a new Value Based Pricing (VBP) approach from 2014**, so that pricing takes a broader perspective of value and reflects society's prioritisation of innovative treatments for severe conditions with high unmet need. The Department of Health is working closely with industry in designing this new approach to pricing. In addition the **National Institute for Health and Clinical Excellence (NICE) has begun work on a planned review of its appraisal methods**. This review will include consideration of how NICE appraisals incorporate the contribution of wider non-health impacts in their assessment of cost-effectiveness. This will inform the NICE appraisal process in advance of the introduction of VBP. Working with industry and other stakeholders NICE will bring forward plans for public consultation during 2012.
- In advance of the introduction of VBP **we have introduced a £200m a year Cancer Drugs Fund**. This will ensure that patients have access to the innovative cancer drugs that their clinicians think are needed.

ii We are integrating the infrastructure to drive adoption and diffusion

- Linking the discovery and development system to adoption in the NHS and worldwide is fundamental to deliver patient benefit, commercial sustainability, and UK growth. This means making sure that patients and clinicians can pull through the best innovations into clinical practice. That is why **the UK system complements the translational research expertise in NIHR Biomedical Research Centres and Units with the technology adoption power of Academic Health Science Centres (AHSCs)**. AHSCs are distinguished by their global leadership in research, education, and population health care and are hubs for industry partnership. As focal points for collaboration with industry these centres must demonstrate that they have in place strong governance and IP management, a

track record of productive research collaborations with industry, and emerging clinical data informatics platforms. We will make the designation of AHSCs dependent upon meeting such challenging criteria.

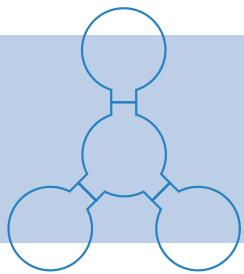
- > In addition we will support Biomedical Research Centres and Units, and AHSCs, and build on their models of accelerating adoption and diffusion. **We will establish a number of Academic Health Science Networks (AHSNs) across the country.** The NHS Chief Executive and the Chief Medical Officer will work with the NHS and industry to designate these networks with the first to go live during 2012/13.

iii We are removing the obstacles to technology adoption and diffusion

- > NICE plays a significant role identifying cost-effective interventions in the NHS. We are therefore removing the local duplication to make sure that adoption of cost-effective treatments happens at scale and pace. This will mean that **all NICE Technology Appraisal recommendations are adopted automatically into appropriate local formularies** in a planned way that supports safe and clinically appropriate practice, and a new NICE compliance regime will be introduced to reduce variation across the NHS.
- > Innovation will also be supported with strengthened incentives for NHS hospitals through the 'CQUIN' quality payments they receive, and through investment in NHS Innovation Challenge Prizes. In addition, **a new Specialised Services Commissioning Innovation Fund will be established centrally**, overseen by an Advisory Board and reporting to the NHS Medical Director.
- > And for high impact technologies that have demonstrated clinical effectiveness, such as telehealth, the NHS Commissioning Board will accelerate adoption throughout the NHS. This will be done in partnership with industry using a new approach that will aim to deliver this technology across the country to **improve 3 million lives over the next five years**. Delivery on this industrial scale has not been attempted anywhere else and would put the NHS at the forefront of the management of chronic disease globally.



Examples of the NHS as a driver of innovation



Home to world-leading specialists, the NHS supports a wide range of innovative technologies and services to benefit health outcomes, with a focus through the NHS Life Sciences Innovation Board on extending the strategic relationship between industry and the NHS to accelerate the uptake of cost effective medicines and innovation in medical technology.



On average, the NHS serves one million patients every second. It has grown substantially over the last six decades and now employs 1.2 million people, making it the fourth-largest organisation in the world. The NHS has 160,000 beds across hospital and community care, and in an average year there are more than 300 million General Practitioner (GP) appointments, over 35 million diagnostics appointments, 18 million visits to the emergency room (A&E) and 18 million hospital consultants.

The National Health Service is the world's largest publicly funded healthcare system, with coverage of more than 60 million people

Clinical development driving the adoption of medical devices

Barts & the London Biomedical Research Unit in Cardiovascular Disease has been involved in a landmark randomised clinical trial, published in the Lancet in collaboration with the medical device company Ardian, to demonstrate the effectiveness of their new catheter-based treatment for therapy-resistant hypertension. The Symplicity Catheter System is used to perform a procedure termed renal denervation. Once in place within the renal artery, the device delivers low-power radio-frequency energy to deactivate the surrounding renal sympathetic nerves. This, in turn, reduces activity of the sympathetic nervous system, which reduces blood pressure. The trial demonstrated the potential of this medical device to significantly impact the standard of care for the large number of patients suffering from hypertension and who are resistant to current available therapies.

Clinical development driving the adoption of medical diagnostics

The NIHR supports Collaborations for Leadership in Applied Health Research and Care (CLAHRCs). In collaboration with Merck Sharp and Dohme, the Leicestershire-Northamptonshire-Rutland CLAHRC is performing a randomised clinical trial to determine the effectiveness of Near Patient Testing as a screening tool for use in community pharmacies. This randomised study will compare the effectiveness of the current self-assessment tool used for GP referral and the immunoassay-based Near Patient Testing for opportunistic screening for patients with Type 2 Diabetes and impaired glucose regulation. The trial will investigate if screening using a self-assessed risk score followed by the Near Patient Testing in pharmacies will increase uptake of a confirmatory test conducted at the GP surgery compared to screening with a risk score alone.



A world-leading environment for investment and growth in life sciences

The UK is investing in innovation and growth directly

- > The Government recognises the need to invest in innovation and health care which is why we have protected the £4.6bn science budget, increased the Department of Health research budget and committed to real terms increases in annual health spending.
- > **More than £1bn is being invested in 2011/12 by our sector research councils, the Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC). And almost £1bn is being invested annually in the health research and NHS research infrastructure through the National Institute for Health Research (NIHR).**



We are making it more attractive for companies to invest in UK innovation

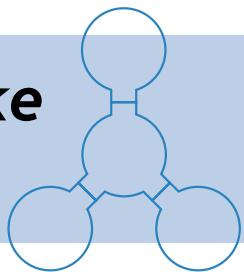
i We are strengthening the tax system to make innovation pay

- > The UK is becoming even more attractive to companies investing in innovation. **We are introducing the Patent Box in 2013**, to reduce the corporation tax on profits from patents to 10%. This will provide tax relief of at least £200m annually to the life science sector.
- > **R&D tax credits are being improved even further:** we have increased the superdeduction relief available to SMEs to 200% (raising to 225% by April 2012) and removed the minimum spend requirement.
- > A series of additional tax measures have been designed to make the UK a globally competitive environment for investment. **We have cut the main rate of corporation tax**, doubled the lifetime limit for entrepreneurs' relief for serial investors, and enhanced the relief available under the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCT).

ii We are addressing the financing and regulatory barriers that slow innovations reaching patients

- > To make sure that the best innovations don't get stuck in the 'valley of death' **a new £180m Biomedical Catalyst Fund will be introduced**. It will support the development of promising novel technologies emerging from the partnership between clinicians, academics and industry.
- > To increase the speed and efficiency of regulatory and health technology assessment pathways for drug development, **we will publish for consultation a new 'Early Access Scheme'**. The Medicines and Healthcare products Regulatory Agency (MHRA) will also work with industry to support greater use of the existing pathways of conditional authorisation, accelerated assessment, and early licensing under exceptional circumstances. Working with the NHS, industry, academia and charities such as Cancer Research UK, **the MHRA will ensure that the UK takes a lead in the ongoing debate to develop better ways of regulating in a world of increasingly targeted therapies**.
- > **A more enabling regulatory environment for innovative manufacturing technology will also be supported**. Government, through the MHRA, will work with the industry and other international regulators to develop a set of actions, by the second quarter of 2012.

Examples of the attributes that make the UK the place to invest



Setting up in the UK

The UK is the easiest place to set up and run a business in Europe (World Bank: 'Doing Business 2011'). It ranks first in Europe and fourth in the world for ease of doing business.

UK Tax and regulatory environment

The UK is an internationally competitive location for tax. Advantages include one of the lowest main corporate tax rates in the EU, generous tax allowances and competitive personal rates, the most extensive network of double taxation treaties in the world and low social welfare contributions.

The UK is joint first with the USA in the world for Product Market Regulation (PMR). It has the least barriers to entrepreneurship in the world and has the third fewest barriers to trade and investment in the world.

Springboard UK

The UK is the number one gateway to Europe, giving easy access to the 27 member states of the European Union, the world's largest single market. It offers world-class transport links – with Heathrow's new Terminal 5, and more expansion planned for international airports, sea containers and the rail network.

UK labour market

The UK's labour market is one of the world's most flexible. This factor combined with the strong skills base in the UK is reflected in our excellent record of attracting major foreign investors from all over the world.

The UK is the sixth largest economy in the world with a GDP of US \$2,174 billion

Making it happen

In addition to the game-changing investments and policy changes set out above, the full range of policies that support the Government's strategy are described in detail in the two accompanying documents: *The Strategy for UK Life Sciences*, and the NHS Chief Executive's review *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*. These reviews have been launched together to demonstrate the importance of driving a change of culture across the research base and the NHS.



We recognise that delivering on the commitments in both reviews is vital to achieving our vision of the UK as the global hub for life sciences. **That is why we are making sure that the implementation is as strong as the ambition:** in addition to the departmental implementation plans, we will appoint two independent Life Sciences Champions to support delivery.

The first of these champions will act as chair of an independent Life Sciences Advisory Board comprising of 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 Skills) and Rt. Hon. Andrew Lansley CBE MP (Secretary of State for Health). The report will be submitted to the Prime Minister and made available publicly. This governance process will not alter the existing accountability arrangements within departments or implementation arrangements for the NHS Chief Executive's Review. The second Life Sciences Champion will act as a collaboration champion to foster partnership across the UK clusters and within government.

Delivering on these commitments will position the UK as a global leader in life sciences. It will provide the nurturing environment needed to generate and attract research, development, and manufacturing, and to create the systems and behaviours needed to drive fast adoption of effective technologies in the NHS.

This document, and the strategies underpinning it, represents the start of a journey working with industry to make the UK a world-leading centre for discovery, development, manufacture and adoption. It shows that we are investing in the UK life sciences so that the most innovative companies can too.

If you would like any more details please contact –
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