HM Government

Industrial Strategy: government and industry in partnership

Strategy for UK Life Sciences

One Year On

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Prime Minister's foreword

In December 2011 I launched the Government's ten-year *Strategy for UK Life Sciences*, setting out a long-term vision to re-establish the UK's global leadership in life sciences, and support the growth of British life science small and medium-sized enterprises.

The life science industry is truly a jewel in the crown of our economy. There are around 380 pharmaceutical companies based in the UK, employing nearly 70,000 people, with an annual turnover of £30bn. In addition, the medical technology and medical biotechnology sectors together employ over 96,000 people with a combined annual turnover of around £20bn.

However, we recognise that in order to win the global race, we need to do more to make the most of the UK's strengths in the life sciences sector: our universities, clinical research base, industry and the NHS. By more closely integrating the UK's unique advantages, we can attract new investment to our shores, and create new jobs and economic opportunities in an increasingly competitive industry.

I am pleased with the progress that we have made over the last year on this important agenda, and I would like to thank everyone involved in implementation and delivery over the past 12 months. Thanks in large part to this work, the UK has received over £1bn of new private life science investment over the last year, and we are now ready to move to the next level of ambition by setting out a world-leading policy framework on genomics.

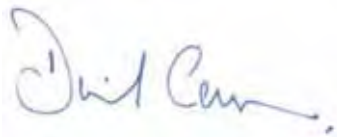
Genetic science has the potential to transform healthcare systems around the world, and support the emergence of British companies creating new jobs and revenues for the UK. My ambition is nothing less than for the UK to become the world leader in this emerging industrial sector, and this strategy document sets out the direction for how we will meet this global ambition. In the coming years, we will start to harness the power of genomic data in the UK to improve patient care, develop innovative new drugs and bioinformatics technologies, and create world-class genomic platforms for innovation that will drive global investment to the UK.

Investors, researchers and entrepreneurs around the world recognise that large-scale genomic platforms will support the growth of new British – and global – start-ups. The key characteristic of technology platforms is that they serve as a catalyst for further innovation. Hundreds of thousands of businesses, for example, are built on top of the Apple App Store, and we want to see the emergence of genomic platforms in the UK that similarly support the emergence of new companies and innovations.

There is a significant global opportunity ahead. While the UK represents less than 1% of the global population, our diverse society and commercial expertise mean that if we can create the right framework for genomics, we will develop valuable new products that are sold around the world.

The UK has a world-class research base and NHS. Thanks to this Government's policies, we are fast developing a world-class environment for life science research and investment. Our vision for genomics will help the UK win the global race for life science investment. We will not rest until we have achieved our goal.

Rt Hon David Cameron MP
Prime Minister



Ministerial foreword

Twelve months ago the Prime Minister set out the *Strategy for UK Life Sciences*, making clear the level of our commitment to a sector we see as vital to the UK's long-term economic prospects. We set out our vision of an integrated healthcare economy in which the different elements of the UK sector (fundamental research, clinical research, industry and the National Health Service (NHS)) are able to work much more closely together to accelerate healthcare innovation. We believe that by integrating the UK's unique strengths in the NHS and basic science we can ensure that patients gain the most benefit from an innovative NHS. Our ambition is that the UK remains a location of choice for investment in an increasingly competitive and globalised health life sciences sector.

We were clear that whilst some measures were immediate, the plan sets out a ten-year vision and will require ongoing development. The Strategy introduced a range of measures across the UK healthcare ecosystem to reduce barriers and improve incentives for the quicker development and adoption of healthcare innovation in the UK.

This year we have made substantial progress in implementing these measures. In order to strengthen networks between academia, industry and the NHS, we are investing £1bn per annum through the National Institute for Health Research, which includes £500m in our translational research infrastructure in the NHS. The Biomedical Catalyst was introduced to bridge the 'valley of death' between the bench

and the clinic, and the early response from industry is that this funding is already having the intended impact of stimulating innovative research. We are also committed to exploring the unique possibilities presented by the NHS, which is a key asset to the UK health life sciences sector. Already the Clinical Practice Research Datalink, in conjunction with NHS Information Centre, is making NHS clinical data available to support translational research.

We have started to implement key measures in the NHS Chief Executive's report *Innovation, Health and Wealth*. The Comply or Explain regime to support the funding direction attached to National Institute for Health and Clinical Excellence Technology Appraisals has been embedded in the NHS. The Academic Health Science Networks will be established in early 2013 and will provide a unique opportunity to align education, clinical research, informatics, innovation, training and education and healthcare delivery. They will improve patient and population outcomes by translating research into practice and developing and implementing integrated healthcare services. The NHS is implementing each of the *Innovation, Health and Wealth* High Impact Innovations, which have the potential to drive significant improvements in quality and value and will also deliver long-term sustainable improvements in key services.

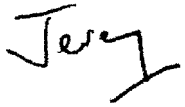
We work closely with companies across the sector to ensure these measures are making a real difference to their work and their decisions to invest and remain in the UK. UKTI have now set up the Life Science Investment Organisation, which is led by experienced professionals from industry to ensure we continue to promote the UK as the partner of choice for overseas companies. In June 2012 we sent a UK delegation to the BIO international convention to promote the UK as a destination for businesses. At the conference David Willetts was awarded the BIO International Leadership Award in direct recognition of the Government's work to support the life sciences industry.

In the coming year we plan to take this further by capitalising on the UK's strengths in genomics, and the potential to make the UK a world leader in the fast emerging fields of genomic and stratified medicine, through closer integration of our genomic and clinical data sets. From Darwin to Nobel Laureate Fredrick Sanger, a British biochemist who developed the method used to first sequence the human genome, the UK has led the world in genetics and genomics. We now need to retain that leadership in the application and exploitation of genomics and population-based health research. We want to ensure the UK remains at the forefront of developing the increasingly targeted drugs, devices, diagnostics and innovative healthcare services that modern patients and healthcare demand.

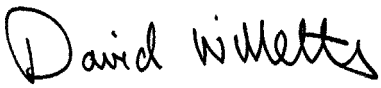
As the cost of genome sequencing reduces and new opportunities in diagnosis and treatment based on genomics studies are rapidly emerging, the UK is uniquely well placed to play a world-leading role in this next phase of the biomedical revolution. We believe this initiative has the potential to keep the UK at the forefront of innovations in molecular diagnostics, stratified, targeted and increasingly 'personalised' medicines, preventative therapies, health informatics and digital healthcare.

The health life sciences sector is changing rapidly to adapt to the latest scientific breakthroughs, technologies and new models of disease diagnosis and treatment. We are determined to do all we can to ensure that the UK develops an integrated healthcare economy in which our world class universities, NHS and commercial life sciences sector can work together in the interests of patients and the wider economy.

Rt Hon Jeremy Hunt MP
Secretary of State for Health



Rt Hon David Willetts MP
Minister for Universities and Science



Update from the Life Science Champions

In December 2011 the Government set out in the *Strategy for UK Life Sciences* a bold vision to strengthen the health life sciences sector of the UK economy based on closer collaboration between academia, the NHS and industry. As well as a clear vision, the Strategy set out a range of specific measures from the Department for Business, Innovation and Skills and the Department of Health across the fields of translational research, venture investment, industry and the NHS to help the UK develop an 'integrated healthcare economy' to accelerate medical innovation. The various measures are set out in the two reports, but cover five key areas:

- Translational Research Infrastructure
- Venture Investment
- Industrial Inward Investment
- NHS Adoption of Innovation
- Global Promotion of the UK through UKTI

As the UK's Life Science 'Champions' we were charged with monitoring the implementation of the Strategy, through reports to the Prime Minister and close working with officials in the relevant departments responsible for disseminating and delivering the Strategy commitments.

It is clear from the interactions we have with industry, academia and investors that the clarity of the Government's commitment to the life sciences demonstrated by the Strategy has contributed to a real buoyancy and return of confidence in the sector. There has been considerable international interest in what the UK is doing.



In the last 12 months we have seen significant new inflows of venture capital and inward investment. Anecdotally we hear that over £1bn has been raised in a number of new UK life sciences venture funds. Several major inward investments have been announced, not least GSK's announcement of a £500m investment in a new advanced manufacturing plant, as a direct result of the measures announced. The last 12 months have also seen a renewed spirit of collaboration between industry, the NHS, and university partnerships, with explicit commitments from the NHS to support an innovation agenda widely recognised and welcomed by industry.

There are some clear early success stories emerging from the Strategy such as the establishment of the Biomedical Catalyst to accelerate clinical proof of concept studies and facilitate NHS adoption of innovation. The first round of funding has attracted significant new risk capital co-investments and much enthusiasm from the small and medium enterprise sector. New partnerships and infrastructure have emerged including the Medical Research Council-National Institute for Health Research Phenome Centre and the National Institute for Health Research Translational Research Partnerships facilitated by National Institute for Health Research Office for Clinical Research Infrastructure.

The fiscal incentives, due to be phased in from April 2013, will improve the R&D environment – the Patent Box has for example already resulted in a major investment decision. The establishment of UKTI's Life Science Investment Organisation led by experienced industry professionals should finally bring a coherent approach to the global marketing of the UK life sciences.

Patient engagement and recruitment into clinical trials continues to improve while contract research organisations report that the UK is again increasing its share of global commercial clinical trials. Support for the science base is safeguarding the future of health life sciences.

We are particularly pleased to see the ministerial support that has led to much progress on adaptive licensing. This is a particularly important regulatory reform for small and medium sized enterprises, which could potentially transform the life cycle of small companies and provide earlier access for patients to transformative new medicines.

The Strategy was announced alongside the NHS's *Innovation, Health and Wealth report* from the NHS Chief Executive, which will provide a mechanism for the NHS to adopt and benefit from innovations in healthcare more effectively than in the past. This is a crucially important programme and although it will take time, progress is clearly being made and welcomed by industry.

We want to make Britain the best place in the world to develop medicines and devices, particularly those that can be better targeted at the patients most likely to respond. Long term we aim to see a fundamental change in the way the NHS and industry approach value-adding innovation, as partners in an integrated healthcare economy where patients, the NHS, UK plc and industry all benefit from a common commitment to accelerate its adoption.

For medicines, a value-based pricing approach can put the UK in the vanguard of countries basing reimbursement of innovative medicines on payment by performance – through a discrete value assessment model, based on well-founded health economics around demonstrable patient and societal benefit.

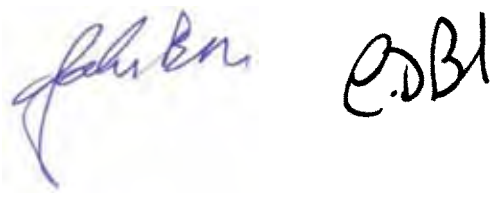
NHS clinical data is another unique selling point for the UK in developing the health life sciences sector. We are in danger of failing to fully capitalise on this opportunity if we do not move quickly to grow the access to more information held by the NHS (i.e. hospital prescribing data) in support of the work of the Clinical Practice Research Datalink working in cooperation with the Health and Social Care Information Centre.

This objective becomes even more important given the investment in a new framework on genomics, which capitalises on our leading position in this field. The UK must move swiftly and at scale to be in the first wave of countries capable of generating, handling and analysing whole genome sequences. Genome sequencing provides an exciting new future for aspects of healthcare; enhancing diagnosis, improving our understanding of disease mechanism and identifying effective therapies. Not only will health outcomes be improved and NHS resources spent more effectively, but also the commercial opportunities for exploiting this data are significant.

This is a long-term Strategy and the government departments involved still have much to do, but the outcomes to date show early promise and we anticipate an acceleration of the programme as it moves into its second year.

We are greatly indebted to George Freeman MP, Government Adviser on Life Sciences, for his ongoing contribution to our work and to the continued promotion of the *Strategy for UK Life Sciences*.

Professor Sir John Bell, Chris Brinsmead



1 Strategy for UK Life Sciences: One Year On





In the 2011 *Strategy for UK Life Sciences*, the Government set out a clear strategic response to the global market challenges and underlying pressures driving the rapid evolution of today's health life sciences sector in the UK. We introduced an ambitious long-term programme, outlining a range of practical measures that the Government will take to improve the environment for large and small health life science companies in the UK, providing support from discovery right through to the commercialisation of medicines, diagnostics and devices.

The *Strategy for UK Life Sciences* was designed around three key principles:

1. **Building a life sciences ecosystem**

   We committed to 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 acknowledged the need to nurture highly skilled researchers, clinicians and technicians, assisting 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 agreed to 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 *Strategy for UK Life Sciences* very clearly signals the Government's commitment to a sector we see as vital to the UK's long-term economic prospects. This is part of our wider Industrial Strategy, in which Government is working in partnership with industry in key sectors of particular importance to the UK's long-term global competitiveness. As part of this approach, in 2013 the Government will publish an Agricultural Technology Life Sciences Strategy.

Minister for Universities and Science, the Rt Hon David Willetts MP, Parliamentary Under-Secretary of State for Quality, Earl Howe, and Minister of State for Trade and Investment, Lord Green have been leading engagement with health life sciences industry representatives, continuing to underline the importance that Government places on our relationship with this sector.

Embracing innovation has to be at the heart of changes to the NHS, from patient pathways to new treatments and devices. *Innovation, Health and Wealth* was launched alongside the *Strategy for UK Life Sciences*, and set out a challenging vision for the NHS to deliver improved care and services for patients against

the backdrop of fiscal restraint. The new NHS Commissioning Board will be charged with delivering this ambitious agenda and will focus on the uptake of cost effective medicines and technologies, continuing to give innovation a central priority through the system. The Coalition Agreement, *Our Programme for Government*, set out the Government's intention to introduce a value-based pricing system. The Government has said that the new system will be introduced in January 2014 when the current Pharmaceutical Price Regulation Scheme comes to an end in 2013. Negotiations between the Department of Health and the Association for the British Pharmaceutical Industry on the new pricing arrangements are now getting under way.

As the Champions have highlighted in their earlier remarks, this is a ten-year strategy and a number of initiatives will take time to have an impact. Nonetheless, by working across government and promoting new partnerships with industry, research charities, patient groups and other stakeholders, good progress has been made during this first year in implementing a large number of the measures set out in the Strategy.

In addition to progressing the measures set out in the Strategy last year, the Government has committed to a range of additional initiatives that will enhance health life sciences in the UK:

- **UK Research Partnership Investment Fund:** In October a further £200m was announced for the UK Research Partnership Investment Fund, adding to £100m provided at Budget 2012. Nine of the 14 projects announced in the first round, securing £146.5m of Government funding, are relevant to life sciences.
- **Regional Growth Fund:** £42m has been allocated to the life sciences sector through the third round of the Regional Growth Fund.
- **Dementia Research:** which builds on the existing National Dementia Strategy, commits the Medical Research Council (MRC), National Institute for Health Research (NIHR) and Economic and Social Research Council to increase funding for research into dementia from £26.6m in 2009/10 to an estimated £66.3m in 2014/15. The NIHR has also committed £36m over the next five years in a new NIHR Dementia Translational Research Collaboration.
- **Biobank:** The expansion of the UK Biobank, with an additional £9.6m for undertaking a programme of imaging.

However, we cannot afford to be complacent. The pace of change in this most fast moving of sectors creates a challenging environment. This is fuelled not least by continued breakthroughs in genetic and computing sciences here in the UK, and by the changing nature and structure of the industry. We have to focus on implementing the measures we announced last year, and on monitoring the evolving landscape to look for new ways to promote the UK as a global life sciences hub. To help us towards these aims, we will work with industry to agree how best to facilitate our ongoing conversations with the sector. We will consider how we can take full advantage of our existing arrangements, whilst ensuring they are fit for purpose within the changing environment.

Today we are announcing a new focus on unlocking the potential of the UK's strengths in genomics. We have set out a UK strategy for the development of an enterprise framework to harness the potential of genomic technologies. The field of genomics is set to revolutionise the way we practise medicine, changing fundamentally the way we diagnose, prevent and treat disease. The UK has led the world in genetic and genomic science, and the Government is determined to provide a supportive environment, to ensure that the UK remains at the forefront of new innovations in this field, capitalising on this leadership for the benefit of UK patients, the NHS, and the UK economy.

Strategy for UK Life Sciences: 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.

2012: Implementing the *Strategy for UK Life Sciences*

1. Building a life sciences ecosystem

- The **Biomedical Catalyst** committed £49m to 64 projects, which will leverage at least £25m of private sector funding.
- The **Synthetic Biology Roadmap** for the UK was published in July.
- In December, the MRC will announce its first awards under the **Stratified Medicine Initiative**.
- The **Clinical Practice Research Datalink** was launched in March.
- The Health and Social Care Information Centre launched its new **Data Linkage Service** in September.
- Interviews for **Academic Health Science Networks** will take place from December this year.
- The **High Impact Innovations** website was launched in August, and CQUIN payments will be conditional on compliance from April 2013.
- The **Life Sciences Investment Organisation** was set up in August.

2. Attracting, developing and rewarding the best talent

- The first eight NIHR **Research Professorships** were announced in February.
- The Society of Biology **Degree Accreditation Programme** successfully completed its pilot in March.
- 31 learners are undertaking Cogent **higher level apprenticeships** for life science and chemical science professionals.
- The **Technical Apprenticeship Service** was launched in January and has to date placed 31 apprentices with 13 life science companies.

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

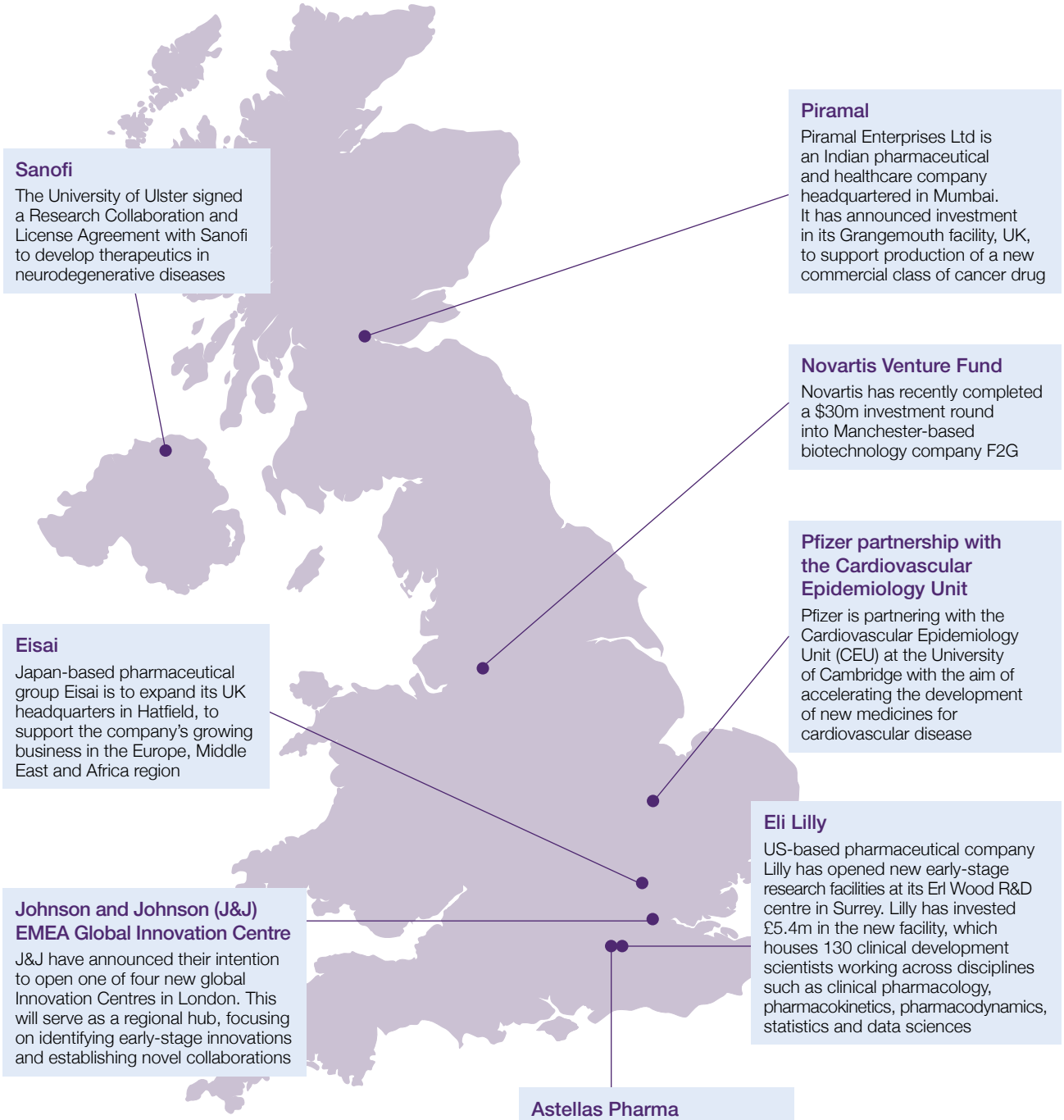
- The **Seed Enterprise Investment Scheme** was launched in April 2012.
- The Finance Act gained Royal Assent on 17 July 2012, and as a result a new **cost-sharing VAT exemption** was introduced in the UK.
- The MHRA established an expert group which is generating proposals for regulatory innovation, including the development of an **adaptive licensing** project.
- From July to October 2012 the MHRA held a public consultation on introducing an **early access scheme**.

2012: Investment in life sciences

Inward investment successes over the past year have spanned the full spectrum of the health life sciences sector, including biomedical discovery and research, clinical and product development, manufacturing, and commercial operations.

"Pfizer benefits from the CEU's access to internationally outstanding data and sample resources and the expertise necessary to achieve our shared objectives."

Tim Rolph, Chief Scientific Officer, Cardiovascular and Metabolic Diseases Research Unit, Pfizer



Sanofi
The University of Ulster signed a Research Collaboration and License Agreement with Sanofi to develop therapeutics in neurodegenerative diseases

Piramal
Piramal Enterprises Ltd is an Indian pharmaceutical and healthcare company headquartered in Mumbai. It has announced investment in its Grangemouth facility, UK, to support production of a new commercial class of cancer drug

Novartis Venture Fund
Novartis has recently completed a $30m investment round into Manchester-based biotechnology company F2G

Pfizer partnership with the Cardiovascular Epidemiology Unit
Pfizer is partnering with the Cardiovascular Epidemiology Unit (CEU) at the University of Cambridge with the aim of accelerating the development of new medicines for cardiovascular disease

Eisai
Japan-based pharmaceutical group Eisai is to expand its UK headquarters in Hatfield, to support the company's growing business in the Europe, Middle East and Africa region

Eli Lilly
US-based pharmaceutical company Lilly has opened new early-stage research facilities at its Erl Wood R&D centre in Surrey. Lilly has invested £5.4m in the new facility, which houses 130 clinical development scientists working across disciplines such as clinical pharmacology, pharmacokinetics, pharmacodynamics, statistics and data sciences

Johnson and Johnson (J&J) EMEA Global Innovation Centre
J&J have announced their intention to open one of four new global Innovation Centres in London. This will serve as a regional hub, focusing on identifying early-stage innovations and establishing novel collaborations

Astellas Pharma
Astellas Pharma opened a new European headquarters in Surrey

2012: Government investing in growth

Whilst life science companies and "hot spots" for various life science segments are located throughout the UK, several internationally significant major health life sciences clusters have grown around leading research base centres of excellence. In 2012 the Government has demonstrated its commitment to build on previous investment, both private and public, to support the further growth of these clusters. The following are examples of awards which will strengthen the major clusters:

UK Research Partnership Investment Fund – The £300m UK Research Partnership Investment Fund (UK RPIF), managed by the Higher Education Funding Council for England, will provide investment in higher education research facilities and strategic research partnerships. The following projects, announced in 2012, which will all support collaboration between academia, charities and industry, are relevant to life sciences:

- A **£32m partnership (£10m from RPIF)** between the University of Oxford and a consortium including UCB Pharma, Ludwig Institute for Cancer Research, Janssen Pharmaceutica NV, Boehringer Ingelheim and Takeda for a new centre for drug target discovery and for research based on medical data sets.
- A **£138m partnership (£35m from RPIF)** between the University of Oxford and a consortium including Synergy Health, Cancer Research UK, Roche Diagnostics, GE Healthcare and the Oxford University Hospitals NHS Trust to establish a new world-leading centre for targeted cancer research.
- A **£38m project (£11.9m from RPIF)** at the University of Dundee, with co-investment from the Wellcome Trust and others, contributing to a new centre to increase scope for translating life sciences research into global healthcare solutions in areas such as cancer, infectious diseases, eczema and diabetes.
- A **£38m partnership (£12.8m from RPIF)** between the University of Manchester, the Christie Hospital and Cancer Research UK to develop the Manchester Cancer Research Centre.
- An **£85m partnership (£10m from RPIF)** between University College London and the Great Ormond Street Hospital for a Centre for Children's Rare Disease Research.
- A **£32m partnership (£10.5m from RPIF)** between Queen's University Belfast, the Atlantic Philanthropies, a Wellcome-Wolfson Capital Award, the Sir Jules Thorn Charitable Trust and the Insight Trust for the Visually Impaired to deliver the next phase of the Institute of Health Sciences.
- A **£34m partnership (£10.35m from RPIF)** between the University of Nottingham, GlaxoSmithKline (GSK) and other co-investors to support the Centre in Sustainable Chemistry.
- A **£150m partnership (£35m from RPIF)** between Imperial College London and Voreda to develop a Research & Translation Hub at Imperial West Technology Campus.
- A **£33m partnership (£11m from RPIF)** between the University of Liverpool and Unilever to develop a state-of-the-art materials chemistry research hub, the 'Materials Innovation Factory', providing an unparalleled suite of open-access facilities.

Regional Growth Fund – The Regional Growth Fund (RGF) is helping to rebalance the economy by supporting those areas and communities currently dependent on the public sector. RGF co-investment will help generate additional job opportunities in the life sciences sector across England. The third round of the fund is £1bn, of which £42m has been allocated to the life science sector. Selected bidders include:

- **Lilly:** an animal health biotech manufacturing facility at Lilly's Speke manufacturing site in Liverpool.
- **Redx Pharma:** A five-year project to create a Liverpool-based pharmaceutical R&D centre focused on new anti-infective drugs, targeting microbial infection, influenza, hepatitis C and HIV.
- **Liverpool School of Tropical Medicine**: A research, development and innovation space for the new Centre for Maternal and Child Health, focusing on the investigation and treatment of infectious diseases.
- **SCM Pharma:** expanding manufacturing capacity to address the changing needs of the pharmaceutical industry in Newcastle.
- **AstraZeneca:** A Biopharmaceutical Science Park and Open Innovation Centre at their Alderley Park pharmaceutical R&D site.
- **DePuy Synthes:** A Centre of Excellence for New Product Development in Leeds, which will provide a facility for industry leading research, design, development, and testing of innovative solutions for the orthopaedics health care market.
- **BCM:** A project to bring manufacturing facilities in a Grade 1 Listed building in Nottingham up to modern standards.
- **Porton Down:** A science park that will provide research and accommodation facilities for science and research based industries to work alongside Defence Science and Technology Laboratory facility and the Health Protection Agency.

N.B. – All funding awards are subject to further due diligence being conducted satisfactorily.

The **new £24m Birmingham Institute of Translational Medicine, funded in part through the Greater Birmingham and Solihull City Deal** will rapidly accelerate the development of new therapies, providing capacity for high quality clinical trial design and delivery, and bringing together clinicians, academics, small and medium-sized enterprises (SMEs) and large pharmaceutical firms under one roof.

2012: Life sciences in the UK

Through the *Strategy for UK Life Sciences*, the Government acknowledged the changing nature of the health life sciences sector, with a growing number of SMEs playing a leading role in driving growth. In 2012, over 380 pharmaceutical companies are based in the UK, employing nearly 70,000 people, with an annual turnover of £30bn. The medical technology and medical biotechnology sectors represent over 4,100 companies employing over 96,000 people with an annual turnover of around £20bn. The range of activities of these companies is broad: in addition to life science manufacturing (e.g. production of medicines and medical devices), the sector includes companies whose main activity is R&D, and others offering services and expertise to assist manufacturing and R&D-focused companies to bring products to market and commercialise their research.

- Pharmaceuticals and medical devices share of manufacturing exports was 11% in 2011.
- The pharmaceuticals sector in particular makes an important contribution to the UK's trade balance. Exports grew by 11% a year between 2000 and 2011.
- Life sciences sectors remained resilient during the recession (e.g. export growth of 31% between 2008 and 2011 for pharmaceuticals).
- The pharmaceutical sector accounted for almost 39% of total manufacturing business R&D spend in 2011, higher than any other manufacturing sector.
- Pharmaceutical R&D spend has shown robust growth, increasing by 70% between 2000 and 2011.

2 Building a life sciences ecosystem

The *Strategy for UK Life Sciences* set out a clear case for the need to strengthen the UK life sciences ecosystem by making it easier for researchers to commercialise academic research, placing clinical research at the heart of the NHS and empowering patients to participate in research. Aiming to promote further collaboration between academia, the NHS and industry, the long-term goal of the Strategy is to encourage innovative responses to some of the most acute healthcare challenges in the UK today. The Government will continue to value and support the vital research taking place, ensuring that the UK can maintain its position as a world leader in biomedical research.

One year on, the impact of the Strategy is starting to materialise, with those funding commitments set out in the Strategy already being channelled to cutting-edge collaborative research projects through the Biomedical Catalyst, MRC funding for Experimental and Stratified Medicine, and NIHR research infrastructure to support experimental medicine and clinical research in the NHS. Initial feedback indicates that these programmes are helping to address the barriers to successful commercialisation of innovative research ideas that were identified in the Strategy, however we are yet to see the full impact of these measures and will monitor ongoing progress with interest. Government will continue to support the emergence of successful clusters in the life sciences landscape. The new Cell Therapy Catapult, construction of which is underway in the centre of London, will provide a model of the flourishing life sciences ecosystem. The Catapult will encourage growth in the life sciences industry, taking products into clinical trial and de-risking them for further investment.

The Welsh Government's National Institute for Social Care and Health Research (NISCHR) recognises the significant contribution the life science sector makes to the health and wealth of Wales. The recently published *Industry Engagement in Wales* emphasises the importance of academia, industry and the NHS forging new, collaborative ways of working. The policy also outlines the importance of translational research to deliver effective interventions and therapies to benefit human health.

In December 2012 the Government announced the development of the National Biologics Industry Innovation Centre, a large scale open access facility for the manufacture of biologic medicines such as antibodies and vaccines. This £38m project will be managed by the Centre for Process Innovation as part of the High Value Manufacturing Catapult.

The Department of Health plans a capital award of £25m over the next two years to fund a new robotic bio-sample repository in the south of England. This will enhance England's capacity to support research into disease mechanisms, diagnosis and treatments, working closely with the NIHR's experimental medicine infrastructure.

i. Making it easier to commercialise academic research

Biomedical Catalyst

In the *Strategy for UK Life Sciences,* the MRC and the Technology Strategy Board (TSB) each committed £90m over three years to the Biomedical Catalyst, an integrated £180m funding programme to support the development of innovative solutions to healthcare challenges by both SMEs and academics across the UK, including projects which have been outside the scope of existing TSB and MRC schemes. Initial projects supported are in areas including stratified healthcare, regenerative medicine, diagnostics, eHealth solutions and break-through medical technologies and devices. The Biomedical Catalyst was created in response to feedback from academics and SMEs about the difficulty of securing funding to support the process of taking research from concept to commercialisation. From a situation where

"The Biomedical Catalyst has been a hugely welcome advance in UK Government support for the medical industry."

Jim Rowland, Xiros Ltd

Universal flu vaccine that could protect against pandemic: Scientists at the University of Oxford have been awarded nearly £800,000 to test a universal flu jab that could protect against all known strains of the illness, including the more serious bird and swine flu. If successful, it could eventually replace the annual flu jabs offered to vulnerable groups with a one-off vaccination.

A vaccine for hospital-acquired infection C. difficile: Researchers at Royal Holloway, University of London have been awarded £500,000 to develop a promising new vaccine for C. difficile, a bacterial infection that kills around 3,000 people a year. The vaccine could be given orally in a solution or tablet, making it straightforward to administer and without the need for injection.

A mobile app to help manage mental health in the community: A team of scientists at the University of Manchester has been awarded almost £900,000 to develop a mobile phone app that helps patients with serious mental illness, such as schizophrenia and bipolar disorder, to manage their own condition and care more effectively at home. The ClinTouch app is a personalised electronic tool that records information on an individual's symptoms several times a day and uploads this data wirelessly to a database, which allows doctors to monitor fluctuations indicating a deterioration in their condition.

Immunocore an Oxford based SME is developing a new class of biologic drug targeting prostate cancer: ImmTACs are highly novel because they recognise intracellular changes in cancerous cells and can therefore be used to treat diseases, such as prostate cancer, that are not currently amenable to targeted biological therapies. Targeted therapies represent a significant advance over traditional chemotherapy because they selectively attack the cancer and not the rest of the body.

"The Biomedical Catalyst is the single most successful intervention in stimulating innovation among emerging life science R&D companies since the introduction of R&D tax credits"

Jon Rees CEO, OBN (UK) Ltd

some of the most promising research ideas were failing at an early stage, the Biomedical Catalyst is now supporting researchers and emerging SMEs, creating a system where patients in the UK are more likely to have access to new treatments.

Further commitments from the first round of the programme were announced in November 2012. This brings a total so far of **£49m committed to 64 projects, which will leverage at least £25m of private sector funding**. 40 projects will be led by SMEs, and 24 are University-led. Of the more advanced funded projects more than 20% were collaborative, involving both academia and industry. Panels will meet in January and February 2013 to consider proposals in the next round of funding.

"The Biomedical Catalyst has truly lived up to its name: it has catalysed our thinking, altered our behaviour, and given us much more credibility in our global ambitions."

Derek Hill CEO, IXICO

Innovative Neuromodulation device:
One of the most effective treatments for late-stage Parkinson's disease is Deep Brain Stimulation, which involves routing electrodes to targets in the brain through which a small electrical current is supplied from an implanted stimulator. Bristol based medical technology company Bioinduction Ltd has developed an innovative stimulator which aims to significantly reduce the time taken in surgery, with the additional benefits of safer procedures and lower cost.

Synthetic biology

The Strategy included a commitment to commission an independent panel to develop a technology roadmap, proposing actions required to establish a world leading synthetic biology industry. Synthetic Biology is the design and engineering of biologically based parts, novel devices and systems as well as the redesign of existing, natural biological systems. The *Synthetic Biology Roadmap* for the UK was published in July, and a Synthetic Biology Leadership Council has been established. The first meeting of the Council will take place in December 2012. **An additional £50m was allocated in December 2012, to enable a network of new multidisciplinary research and training centres, including for gene synthesis, to be established as a foundation for commercial success.**

New sets of genes (encoded in DNA sequence) often need to be introduced and assembled in specified positions within a long DNA sequence. The genetic techniques currently available for this 'assembly' task are quite primitive and considered to be a serious bottleneck in synthetic biology. A new **£4m programme at the University of Glasgow** will establish a sophisticated new methodology for this gene assembly process which will achieve a step-change in the speed and efficiency of creating useful biological systems.

MRC/ABPI STratification and Extreme Response Mechanism INDiabetes – MASTERMIND is a five-year partnership programme between academia and industry to examine stratification in Type 2 diabetes, sponsored by the MRC and the Association for the British Pharmaceutical Industry (ABPI). The partnership, which has initially been awarded £2m, with a further £4m to follow, aims to define the clinical characteristics and mechanism for extreme response to different classes of diabetes treatment, to establish a large bioresource for genetic and non-genetic biomarker discovery, to identify key factors in determining an individual's likely response to a given drug, and to develop the appropriate models to assess the effectiveness and cost effectiveness of a stratified approach. The MASTERMIND consortium involves over 20 partners, including academic institutions across the UK, UK health care providers and pharmaceutical companies GSK, Pfizer, AstraZeneca, Takeda and Bristol Myers Squibb.

Stratified medicine

In the *Strategy for UK Life Sciences*, the MRC committed to invest up to £60m over four years to advance the development of targeted treatments for specific groups of patients who may suffer from the same broad disease. This is a new way of working for many academics and pharmaceutical partners, with an emphasis on collaborative working at the earliest phases of research. Programmes must build on the existing UK clinical research infrastructure and involve patient groups. The MRC has also invested £9.5m in two pilot consortia, focusing on chronic obstructive pulmonary disease (COPD), rheumatoid arthritis and **in April 2012 announced a £2m initial investment in a third pilot consortia to stratify type 2 diabetes – the MASTERMIND consortia.** 15 pharmaceutical companies have committed to supporting this scheme.

In December 2012 the MRC announced an investment of £10.6m in three large-scale collaborative awards under its Stratified Medicine initiative. These will tackle diseases which have a huge impact on patient's lives – rheumatoid arthritis, hepatitis C and a rare disease called Gaucher's. The programme focused on arthritis will be delivered in partnership with Arthritis Research UK who will also contribute £1m.

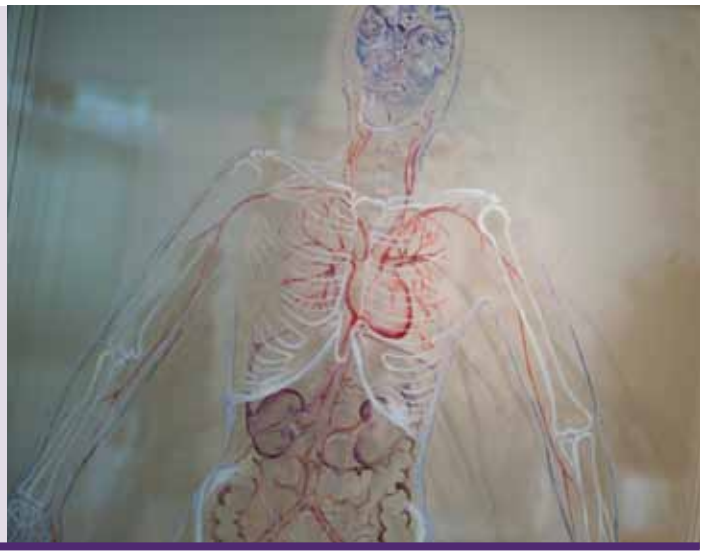
Each award will enable the development of a large consortium of scientists, patients, charities and industry partners from across the country and internationally, who will work in collaboration to improve our understanding of why groups of people with these diseases respond differently to treatments. The research will span universities, hospitals, and pharmaceutical, biotechnology and diagnostics companies. Taken together, the programmes combine 34 academic groups, working with 20 industry partners. Only a mix of skills and expertise on this scale can deliver a deeper understanding of these different illnesses and enable doctors and health professionals to select the right drug, for the right patient, at the right time. These consortia not only have the potential to improve patient care and save money for the NHS, but will also facilitate more effective drug development and enhance the UK's reputation as a location of choice for trials of new therapies.

Experimental medicine

As set out in the Strategy, the MRC is investing £60m over three years through MRC Experimental Medicine Challenge Grants. These grants will support ambitious, challenge-led UK programmes of research into disease mechanisms in humans.

The **MRC-NIHR Phenome Centre**, which will analyse thousands of samples of blood, urine and tissue to discover how our genes interact with our environment to cause and affect the course of disease, will open at Imperial College London in 2013. This will support the development of improved diagnosis and treatments for patients.

The Centre is a partnership between the Medical Research Council, the National Institute for Health Research, analytical technology companies Bruker and Waters, King's College London and Imperial College London.



A large number of outline applications were received from which 30 full-stage applications were invited and are now being assessed through rigorous international peer review. This initiative benefits from substantial industry engagement, with a third of applications featuring a formal industrial partner. The first round of funding decisions will be made in March 2013.

The MRC also agreed to invest up to £10m in a collaboration with AstraZeneca, who made 22 compounds available to academic researchers. This partnership is providing academic researchers with access to high quality clinical and pre-clinical compounds, the building blocks of new drugs, in order to help better understand a spectrum of human diseases through exploring new treatments. This initiative is a world-leading open innovation collaboration, with the potential to stimulate new relationships between academia and industry. Over 100 outlines were received, on the basis of which 23 full applications were submitted. 15 awards were made with a total funding amount of approximately £7m. A formal announcement of the awards was made in October 2012. **In November 2012, this ground-breaking collaboration won the 'Best Partnership Alliance' award at the annual SCRIP Awards event in London.**

In March, the Government announced that over **£100m will be invested in 19 NIHR Clinical Research Facilities (CRFs)** around England to develop new treatments to benefit thousands of patients. CRFs are purpose-built, cutting-edge facilities, with specialist clinical, research and support staff, in locations where universities and NHS Trusts work together on dedicated programmes of patient-orientated experimental medicine research. The NIHR Moorfields CRF has a long standing collaboration with Pfizer on glaucoma studies, and more recently on the development of human embryonic stem cell therapy for patients with macular degeneration, and the NIHR/Wellcome Trust University College London Hospitals CRF has been working with Siemens to develop a diagnostic test for liver fibrosis bringing it to market and validating its use in the NHS through the CRF.

The NIHR is also working in partnership with Cancer Research UK to fund Experimental Cancer Medicine Centres (ECMCs) in England by jointly investing £35m funding over the next five years. ECMCs play a leading role in speeding up the process of cancer drug development and the search for cancer biomarkers – molecules present in blood or tissue – that can be used to diagnose cancer, predict the aggressiveness of the disease, or show whether a drug will be

effective in a specific patient and at what dose. ECMCs are supporting industry engagement through the ECMC combinations alliance. The alliance supports off critical pathway studies utilising industry novel agents in a shared risk reward business model. Trial performance is managed by Cancer Research UK's Drug Development office (who also provide additional funds if required). AstraZeneca is the first partner in this initiative and high level talks with additional major pharmaceutical companies are in progress.

Regenerative medicine

The *Strategy for UK Life Sciences* announced that the TSB would provide up to £50m over the next five years to fund a Cell Therapy Catapult. **The Cell Therapy Catapult has now been established with the appointment of Keith Thompson as CEO. It is currently located in the Tower Wing of Guy's Hospital and will move into state of the art laboratories there at the end of 2013**. Situated at the heart of a cluster of hospitals, clinical research centres and universities, the Catapult will encourage growth in the UK life sciences industry, taking products into clinical trial and de-risking them for further investment. It will also be a source of regulatory expertise to ensure that products can get to the clinic safely in the shortest time, so that commercially viable products are progressed and investable propositions generated. The Catapult will aim to raise £20m a year additional funding through grant sources and private sector contracts.

The MRC, Engineering and Physical Sciences Research Council (EPSRC) and Biotechnology and Biological Sciences Research Council (BBSRC) also made a commitment in the Strategy to jointly invest £25m over five years to maximise the potential of the Cell Therapy Catapult. £20m will fund a UK Regenerative Medicine Platform, with up to five interdisciplinary research hubs. These hubs will have the expertise and critical mass to address the key technical and scientific challenges associated with translating promising scientific discoveries. Up to £5m will be invested in disease-focussed programmes, working in collaboration with charities and other funding partners to address specific areas. **In support of the UK Regenerative Medicine Platform, £20m of new funding was allocated in December 2012 to allow for a top-up fund to provide imaging and cell manufacture technologies as well as a clean room.**

ELIXIR

As agreed in the Strategy, £75m funding has been provided to support a new facility for biological data-storage at the European Bioinformatics Institute in Cambridge and to deliver a new technical hub. This is part of the European ELIXIR programme, which aims to enable rapid and effective utilisation of publicly funded genomic and other molecular biological data. **Discussions are underway with industry collaborators (including GSK, AstraZeneca, Pfizer, Unilever and Syngenta) to identify six potential partnership projects at the hub. The hub will be officially opened in 2013.**

Major support for the new building comes from the BBSRC, the MRC, the Natural Environment Research Council and the Wellcome Trust. The project is expected to leverage further European funding, with 13 countries now members of the ELIXIR Interim Board.

ii. Putting clinical research at the heart of innovation in the NHS

The *Strategy for UK Life Sciences* recognised the centrality of the NHS to a high-performing UK health life sciences ecosystem. One year on, the Government is keen to reiterate its commitment to exploring how best to unlock the vast potential represented by the NHS's unique data resource, whilst retaining the strong principles relating to patient rights and confidentiality that have always been at the heart of the NHS.

In 2012, the Clinical Practice Research Datalink (CPRD) was successfully launched, and new initiatives such as the NIHR BioResource and NIHR Translational Research Partnerships will strengthen and develop clinical research. In 2011/12 99% of NHS Trusts recruited patients to studies being run via the NIHR Clinical Research Network (CRN). 60% of NHS Trusts participated in commercial studies supported by the NIHR CRN, and overall 595,540 participants were recruited to NIHR CRN studies. As of 2013, performance against the 70-day benchmark from receipt of a valid research application to the recruitment of the first patient for trials will affect NIHR funding to providers of NHS services.

By facilitating collaboration between the NHS and research organisations, the Strategy has paved the way for a new partnership model. Patients are increasingly better informed and empowered to access new treatments in the shortest possible time, alongside an infrastructure that provides researchers with access to necessary tools and resources. Again, we acknowledge that progress is still to be made, and will continue to work with stakeholders to understand whether the changes to the NHS infrastructure are having the intended impacts of supporting innovative research and ensuring that patients are informed about how best to access new treatments.

The Trials Acceleration Programme (TAP) by Leukaemia & Lymphoma Research is designed to give haematological oncology patients accelerated and wider access to early stage trials. Working within the existing NIHR Cancer Research Network, TAP's dedicated centralised management at the University of Birmingham minimises the 'red tape' to establish trials and deliver accelerated results via disseminated patient recruitment across 13 UK centres. Early results from Novartis Pharmaceuticals UK Ltd show a 50% reduction in set-up time and significant reduction in costs per patient. In its first year of operation TAP has ratified nine new trials that would not otherwise have taken place in the UK including collaborations with eight pharmaceutical companies.

Clinical Practice Research Datalink

The CPRD was launched in March 2012. As agreed in the *Strategy for UK Life Sciences*, the CPRD is the result of a £60m investment by the NIHR and Medicines and Healthcare products Regulatory Authority (MHRA) and will provide access to data that supports clinical trials and population observational studies on an unprecedented scale.

The CPRD operates across England, connecting patient information from GPs and hospitals to other records, such as disease registries, and holds the resultant information in anonymised form to protect patients' privacy. The combined datasets can be used to answer medical research questions, and the results shared via peer reviewed publications. Future

projects include the addition of air pollution data, social care records and potential for working with UK Biobank. CPRD also aims to link with similar systems that cover populations in Scotland and Wales. Governance approval is sought for all new data linkages.

Since the service was launched in March 2012, 16 global pharmaceutical companies have been granted CPRD data licences, over 100 research studies have been submitted and 623 researchers have registered on the CPRD website. We will build on this early platform to provide an invaluable resource for the research community.

Professor Dame Sally C. Davies, Chief Medical Officer for England has said that CPRD has

"the potential to revolutionise research, make a real difference for patients, and allow us to become world leaders in the field"

Health and Social Care Information Centre Data Linkage Service

"The HSCIC has helped us to solve one of the fundamental challenges facing researchers today – how to protect patient confidentiality at the same time as conducting the research required to improve health services in the UK."

The Nuffield Trust

The Health and Social Care Information Centre (HSCIC) launched its new 'Data Linkage Service' on 17 September 2012, in line with commitments set out in the *Strategy for UK Life Sciences*. The data linkage service adds significant value to individual sets of data by combining and matching them at an anonymised individual record level in a secure environment. From April 2013 the service will begin to offer anonymised extracts of linked data on a routine (i.e. monthly) basis. The

Improving the efficiency of Randomised Clinical Trials (RCTs): RCTs are the key means of demonstrating the efficacy and safety of new medicines. Assessing feasibility of RCTs is a critical early step. Unlocking the potential of large electronic healthcare databases to improve feasibility studies and patient recruitment significantly reduces time and cost for research organisations planning clinical trials. CPRD has with partners developed a RCT feasibility assessment tool, TrialViz as part of its ongoing initiative of a whole series of IT tools aimed at clinical trial efficiency. Innovative searching algorithms and optimisation techniques incorporating data quality metrics allow location of GP practices and patients matching the study selection criteria in real time.

Devices: In certain therapeutic areas, such as cardiovascular, joint replacement and wound care, CPRD is already making available data that can be used to undertake the required research to assess the benefits and risks of the use of devices, particularly devices to be implanted in a patient.

Improvements in clinical trial performance: Scottish Health Research Register (SHARE), a register of pre-consented patients who have indicated their willingness to be approached to take part in research, is being progressed in Scotland. Individuals who have agreed to join the register will have their eligibility for participation in specific studies determined using electronic health record linkage. The register is being developed as a federated system across NHS Research Scotland and a range of recruitment methods are being tested.

Development of National Advisory Group: Health Informatics Research Advisory Group
A Health Informatics Research Advisory Group has been established in Scotland to identify obstacles to electronic records research and propose solutions, provide advice to the Scottish Government on strategies for e-health records research and consider what investment would best enhance Scotland's e-health research capability.

volume of extracts available will grow as the datasets within the HSCIC increase. HSCIC is working with the CPRD and ABPI to identify priority areas for linkage.

The HSCIC can provide linkage services across a range of datasets including: hospital episodes statistics, patient reported outcome measures, mental health minimum dataset and primary care data. For the first time users of health and social care data in England will be able to examine a joined-up journey of patient care to drive improvements in treatment and outcomes.

The HSCIC has signed a memorandum of understanding with AstraZeneca to develop understanding about the role medicines play in helping patients with chronic diseases. This is the first collaboration of its kind and is intended to develop the intelligent use of data in healthcare decision-making. Adhering to strict information governance principles that ensure patient confidentiality, the first initiative will focus on diabetes, looking at how anonymised, integrated health data can be used to identify unmet clinical need.

E-health informatics

A consortium of 10 UK government and charity research funders led by the MRC[1] has awarded £19m to four E-health Research Centres based in London, Manchester, Dundee and Swansea. The centres will study conditions including cardiovascular disease, diabetes and children's health. In addition the centres will train the next generation of researchers to have the skills to analyse and link large and complex data. The aim is to develop more effective treatments, improve drug safety, identify risks to public health and gain insight into the cause and development of diseases by linking anonymised patient records and health research data.

1. 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 NISCHR (Welsh Government), the Chief Scientist Office (Scottish Government Health Directorates) and the Wellcome Trust.

Building on the success of the Swansea-led E-Health centre of excellence, NISCHR Welsh Government is launching a new strategy to maximise the use of routine data for research in Wales. NISCHR intends to broaden support for approaches to utilise routine data for research. The strategy will be published in March 2013.

NHS Constitution

The NHS Constitution sets out in one place what patients, staff and the public can expect from the NHS in England. In July 2012, the Secretary of State for Health reported to Parliament on the effect of the NHS Constitution since its launch in January 2009. Subsequently, following engagement with a wide range of stakeholders over the summer, the NHS Future Forum put forward a series of proposals about how to strengthen the NHS Constitution. The Government accepted the Forum's recommendations in full and **a public consultation on strengthening the Constitution was launched by the Department of Health on 5 November 2012.** The consultation proposes a number of changes to improve the Constitution, including issues relating to the protection of patient privacy and confidentiality, access to patient data, and responsibilities regarding informing patients about the use of data.

Review of Information governance

The Government has commissioned a **review of the current information governance rules and their application**, to ensure that there is an appropriate balance between protecting confidential and identifiable information within health and care records and using and sharing information to improve the quality and safety of care. This independent review is being led by Dame Fiona Caldicott and is expected to report early in 2013.

The **Nuffield Trust** is a charitable trust undertaking research into health services and health policy. It uses the data linkage service to link cohort data to hospital episode statistics (HES) in order to assess a wide variety of health interventions.

The **Department for Transport** has successfully linked road traffic injury data to HES. Researchers have used this information to model demand on the NHS from traffic accidents. Future developments will link to HES accident & emergency data.

Use of HSCIC for the Million Women Study: The Million Women Study is the largest study of women's health worldwide, including 1.3 million women in England and Scotland. Because of the unique and excellent data linkage services available in the UK, data on the cohort is updated annually, for example on cancer incidence and hospital admission. One example of the use which has been made of the linked data is a study which was able to document for the first time the full effects of smoking and of stopping smoking in women. In October 2012 a study was published in the Lancet which showed that two out of every three deaths in smokers were due to smoking, and that stopping was more beneficial than previously thought. This work was widely reported in the media.

The NISCHR in Wales has invested over £7m over three years in one Biomedical Research Centre and three Biomedical Research Units. The Haemostasis Biomedical Research Unit in Swansea is investigating a new biomarker which has the potential to give the clinician an improved method of determining blood coagulation. Early studies have been promising and could help to identify which patients are likely to respond to anti coagulant therapy.

NIHR BioResource

The Strategy outlined existing commitments to develop clinical research, including £800m NIHR funding over five years from April 2012 for new NIHR Biomedical Research Centres and Units. Linked to this, progress has been made in developing the NIHR BioResource announced in the Strategy by the participating NIHR Biomedical Research Centres in Cambridge, Oxford and London and NIHR Leicester Cardiovascular Biomedical Research Unit, and **the BioResource is due to be launched in April 2014. It 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. 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.

NIHR Translational Research Partnerships

The two NIHR Translational Research Partnerships (TRPs), launched on 6 October 2011 in Joint and Related Inflammatory Diseases and Inflammatory Lung Disease, continue to progress. The TRPs bring together 36 universities and NHS organisations across the UK, and are co-ordinated by a dedicated team within the NIHR Office for Clinical Research Infrastructure (NOCRI). **Three research agreements have been signed with companies, two with the joint and related inflammatory diseases partnership and one with the inflammatory respiratory partnership. The NOCRI team are currently in discussions with 24 companies, large and small, about future collaborative projects.**

The **Cambridge BioResource** (part of the NIHR Cambridge BRC and precursor to the NIHR National BioResource) was set up in 2005 and continues to support research studies investigating the links between genes, the environment, health and disease. For example, the project "Effects of Brain Derived Neurotrophic Factor (BDNF) gene polymorphism on brain imaging and behavioural biomarkers of plasticity" led by Professor Pradeep Nathan at the University of Cambridge in collaboration with GSK aims to identify biomakers that could be applied to future clinical studies of plasticity modifying drugs with a BDNF-related mechanism of action. Approximately 60 subjects, identified through the Cambridge BioResource, will undergo assessment using functional and structural brain imaging, brain stimulation, electrophysiological and behavioural biomarkers of learning and plasticity.

Proximagen, a UK Biotechnology company, has been engaging with the Joint and Related Inflammatory Diseases Partnership through NOCRI. The company was exploring early development of a new drug and obtained expert scientific input and advice from the researchers within the TRP. As a result of this advice the company amended its original clinical development plans to include an additional inflammatory disease with significant unmet clinical need as a new therapeutic target. A new research study is now underway to validate this target in patient samples via the TRP. Proximagen and the TRP used the NIHR/MRC model Industry Collaborative Research Agreement which facilitated fast study set up.

NIHR Healthcare Technology Co-operatives

NIHR has committed **£6.4m to fund eight new NIHR Healthcare Technology Co-operatives (HTCs) within the NHS as centres of expertise in developing new concepts, demonstrating proof of principle and devising research protocols for new medical devices, healthcare technologies or technology-dependent interventions**. The new NIHR HTCs will address clinical areas and themes such as chronic gastrointestinal disease, brain injury, heart disease, wound management and mental health. These are all conditions of high morbidity and unmet need for NHS patients and healthcare technology users, which have not to date benefited from a high degree of innovation. HTCs will work collaboratively with industry, patients and patient groups, charities, industry and academics to develop new medical devices, healthcare technologies or technology-dependent interventions, which will improve treatment and quality of life for patients.

NIHR Diagnostic Evidence Co-operatives

NIHR has announced that it will fund up to **five new NIHR Diagnostic Evidence Co-operatives (DECs)**. DECs will focus on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness

Imanova is a unique joint venture between the MRC and three leading London universities – Imperial College, King's College London and University College London. The business has been operating for one year following the transfer of facilities and staff from GSK's renowned Clinical Imaging Centre at Hammersmith. Imanova is the first company to have been approved for eligibility for direct grant funding from Research Councils UK in line with the Strategy commitment to state of the art research facilities. Imanova possesses world leading capabilities in molecular imaging sciences, coupled with magnetic resonance imaging.

This year Imanova researchers have dramatically increased the number of clinical and preclinical imaging studies at the centre, with over 30 in various stages of implementation and a further 30 in preparation. Areas of activity include mental health, neurodegeneration, oncology, cardiovascular, respiratory and infectious disease. Imanova is ideally placed to support translation across the innovation pipeline and has developed relationships in both academia and industry. To date, Imanova has established collaborations with nearly 100 researchers from across its partner organisations and is already involved in numerous commercial projects with pharmaceutical and biotech companies. The MRC has committed substantial funding to the partnership in addition to programme funding for imaging projects in the future. GSK has played a key role in transferring the facility to public sector partners and remains a key commercial customer.

Building on its existing reputation, Imanova intends to extend its activities in research and early-stage drug development with increased focus on imaging biomarker development.

The **Structural Genomics Consortium** (SGC), established in 2004, is a public-private partnership that supports the discovery of new medicines through basic research and has an open access ethos by promptly placing results, reagents and know-how in the public domain. A 200-strong team operates across sites in Oxford and Toronto, with a focus on the structural and chemical biology of human proteins. Since 2011 the SGC has attracted £21m worth of inward investment from partners including GSK, Novartis, Pfizer, Lilly, Abbott, Takeda, Boehringer Ingelheim and Janssen.

and care pathway benefits of in vitro diagnostic medical devices has the potential to lead to improvements in healthcare services and the quality of life of NHS patients.

"I believe what is happening in Oxford at the moment is quite remarkable…I think we are creating a new way of working with industry"

Professor Chas Bountra, Professor of Translational Medicine, Head of Structural Genomics Consortium (SGC), University of Oxford

In Wales, NISCHR has recently published the NHS R&D allocations Delivery Framework 2012/13. This document outlines the new R&D performance management arrangements for NHS organisations and sets a national objective 'to create a research environment which promotes and encourages commercially funded research activity within the NHS'.

NHS Research Scotland (NRS) is a partnership between the Scottish Government's Chief Scientist Office and the NHS Boards in Scotland. Designed to deliver greater efficiency and effectiveness to the NHS R&D and research ethics functions, it works collaboratively with industry through the NHS Research Partnership Forum. NRS achievements to date include the adoption of single contract and cost negotiations across Scotland. As a consequence, NRS has significantly reduced R&D approval times and is attracting considerable interest from industry, having recently entered into strategic collaborations with PPD Ltd and Quintiles.

Framework for collaborative funding bids

Research Councils UK has published a new principles-based framework for treatment and submission of multi-institutional funding bids. The *Principles for Funding Multi-Institutional Collaboration in Innovation and Research* can be found at: www.rcuk.ac.uk/research/Pages/principles.aspx

UK Clinical Trials Gateway

The UK Clinical Trials Gateway provides the public with authoritative and accessible information about clinical trials in the UK. In April 2012 the NIHR launched an update which builds on the original version but increases the amount of easily accessible summary information describing what each trial is doing. Versions of the Gateway are also now available for the iPhone, iPad and Android devices. **Since the Gateway was initially launched in March 2011 there have been over 211,000 page views by more than 91,800 unique visitors.**

Clinical trials – 70-day benchmark

In December 2011 the NIHR made the 70-day benchmark from receipt of a valid research application to the recruitment of the first patient for trials a condition of new contracts with providers of NHS services with the aim of improving timelines for getting clinical studies up and running. **Performance against this benchmark will affect NIHR funding to providers of NHS services from 2013**.

UK Biobank

The MRC has provided £9.6m for expansion of UK Biobank. This expansion will include 8,000 brain scans where one of the applications will be to help scientists discover why some people develop dementia and others do not. The UK Biobank is a unique research resource of data and samples from half a million participants that will enable researchers to determine the role of nature and nurture in health and disease. On 30 March 2012, the UK Biobank opened for use by researchers in academia and industry working on health related research in the public interest. UK Biobank has been funded by the MRC the Wellcome Trust, the Department of Health, the British Heart Foundation and the Scottish and Welsh Governments.

Dr Wendy Ewart, the MRC's Deputy Chief Executive and Director of Strategy, said:

"UK Biobank opening its doors to researchers represents a huge step forward in our efforts to understand the role that genes, environment and lifestyle play in the development of disease. The success of this major partnership project is testament to the strength of UK biomedical research in the global science scene."

iii. Encouraging adoption and diffusion of innovation in the NHS

Innovation Health and Wealth, accelerating adoption and diffusion in the NHS (IHW) set out a delivery agenda for spreading innovation at pace and scale throughout the NHS. It included a number of actions that aimed to deliver significant improvements in the quality and value of care delivered in the NHS. They were designed as an integrated set of measures that together will support the NHS to achieve a systematic and profound change in the way in which services are delivered.

Like many other health economies, the NHS is facing a tougher financial climate. This means that simply doing more of the same is no longer an option. We need to do things differently. IHW is an essential tool in helping address the challenges of an ageing population, chronic disease, health inequalities and rising public expectations – especially when resources are constrained. IHW is on track to deliver all of its milestones. Much has been achieved but there is always more that can be done.

The strategic alliance between Almac Group and Queen's University, Belfast with £4.4m support from Almac, Invest Northern Ireland and the McClay Foundation, combines industrial and academic expertise with state of the art technology and access to patient samples through the Northern Ireland Biobank. Since 2011, a test has been developed and commercialised to predict patients with colon cancer who need chemotherapy, a test to predict the risk of dying from prostate cancer is undergoing validation and novel drug targets for breast and ovarian cancer have been identified.

IHW Call to Action

Now, more than ever, innovation has a vital role to play in delivering higher quality care and value for money while at the same time driving economic growth. The innovation landscape before the publication of IHW lacked transparency and accountability, there was variable compliance with NICE Technology Appraisals, and it was confused and cluttered with layers of organisations seeking to serve as gateways for interaction between the NHS, academia and industry partners. The value for money for patients, the NHS, UK plc and healthcare partners was doubtful and innovation was not a central priority throughout the system.

IHW seeks to solve a problem that has built up over decades, we need long-term sustainable changes to be embedded right at the heart of the NHS. We need not only to change structures and processes, but also a change in culture and behaviour – that takes time. Implementation of IHW is in the NHS Operating Framework and the new Clinical Commissioning Groups have a Legal Duty to demonstrate their commitment to innovation. To support this **IHW is working with the NHS new Improvement Body to launch an IHW Call to Action, ensuring that innovation is at the heart of the way the NHS operates and that it becomes an integral part of the daily work of every member of staff, influencing and driving culture change.**

Given that the NHS is a very large, disaggregated organisation, with some 1.4 million employees the early impact of IHW one year on is palpable.

NICE Technology Appraisals

The Comply or Explain regime set out in IHW is underpinned by the funding direction attached to NICE Technology Appraisals. **Work is well advanced to ensure that all NICE Technology Appraisals are automatically included on local formularies and by April 2013, all local formularies will be publicly available**. All partners have agreed the NICE Implementation Collaborative (NIC) concordat and the NIC is currently identifying the barriers to uptake of innovation in the system across four pilot areas in medicines, medical technology and diagnostics to identify the barriers to and solutions for increasing rapid uptake.

In addition, **the NHS will publish information on compliance locally through the Innovation Scorecard**. We anticipate this will show that compliance is variable with the NHS being very good at uptake of older technologies but less good at uptake at pace of the newest innovations. Critical to the success of the

Wider considerations for the uptake of new innovations are currently being evaluated through a number of initiatives across the Welsh Government. A Health and Wellbeing Good Practice and Innovation Board has been established to enable evaluation of the potential impact of innovations and facilitate and accelerate their adoption by the NHS, social services and third sector organisations in Wales. The National Assembly for Wales' Health and Social Care Committee will be reviewing the uptake of medical technology in Wales and the possible barriers to effective new technologies being more accessible to patients.

transparency agenda is the collection and common definitions of the data sets in the NHS.

The Comply or Explain regime is reducing variation and assures patients of their access to the cost-effective technologies and medicines their doctors believe they need. **Following a Strategic Health Authority assurance exercise, the NHS South of England is now moving towards full compliance with all NICE Technology Appraisals on local formularies, and the rest of the country will shortly follow.**

Academic Health Science Networks (AHSNs)

To make the NHS a better place to do business with, AHSNs are being created, to develop a systematic approach to ensure diffusion of innovation happens and do more of what we already know works.

15 AHSN applications have been received and designation panel interviews will take place between December 2012 and February 2013 with the expectation that AHSNs will be in place Q1 2013/14 in line with the time lines published in IHW.

Each AHSN application will set out its plan for their first 100 days including those aspects bespoke to their application and incorporating what they will do to support the Comply or Explain regime and work with SMEs on medical technology projects and research participation. **IHW is working with the Association of British Healthcare Industries to ensure that in every AHSN there is an understanding of the medical technology development process and that AHSNs maximise the potential of partnering with medical technology companies to facilitate knowledge of emerging innovations.**

Northern Ireland's small population and integrated health and social care services provide an excellent test-bed for the deployment and evaluation of innovative healthcare technologies. Implementation of the new Memorandum of Understanding on Connected Health & Prosperity between the Northern Ireland Assembly Health Department and Invest Northern Ireland has created new opportunities for academic and business R&D to focus on solutions to healthcare problems.

In June 2012 the Scottish Government launched its *Health And Wealth In Scotland: A Statement Of Intent For Innovation In Health*. At the heart of the Statement is partnership working between Government, NHS Scotland, industry and the research community to identify and develop innovative solutions to the challenges facing health and healthcare. Work is already underway to establish partnerships to create solutions in the areas of medicines, medical technologies and digital health.

In August 2012 **the Wellcome Trust and EPSRC announced the launch of a joint £30m initiative to find biomedical engineering solutions to challenging healthcare problems**. The 'Innovative Engineering for Health' initiative will provide funding for a limited number of ground-breaking, long-term projects designed to address a specific healthcare need for which current solutions are inadequate. Up to £10m is available for each project, providing the resources to conduct high quality basic research and to enable its adoption into clinical or public health practice. Applications were invited for projects that will address the problems of the highest priority in healthcare or public health for which solutions are not obvious with the current state of technology.

Establishing organisations of this size and scope and ensuring they are all of high quality within nine months would be a significant undertaking at any time. Given the level of change the NHS is experiencing, it is testament to the commitment of the NHS and its academic, industry and research partners to deliver IHW that such substantial progress has been made.

Specialised Services Commissioning Innovation Fund (SSCIF)

The NHS Commissioning Board (NHS CB) will have responsibility for specialised services commissioning. In line with the IHW commitment it has established the SSCIF to rapidly test and evaluate innovations that have the potential to deliver high impact changes for specialised services throughout the NHS. **This will make innovations available to NHS patients much earlier than is currently possible.**

SSCIF evaluation projects will enable NHS CB specialised services to generate a better understanding of the cost and quality impact of innovations and create a robust evidence base for use in national commissioning decisions. Generating better evidence will result in better, more robust commissioning decisions and more rapid, widespread adoption of proven innovations in the NHS. This will mean that patients will have earlier access to innovative care, the value for money to the NHS will improve and the drive to support wealth creation will be achieved.

As a result, it will transform the way that new innovations are identified, tested and adopted by the NHS.

High Impact Innovations (HIIs)

IHW set out that from April 2013, compliance with six HIIs will become a pre-qualification requirement for CQUIN payments. In this way, **IHW for the first time introduced an innovation 'gateway' to CQUIN whereby providers will need to comply with 50% or more of the HIIs that apply to them in order to unlock 2013/2014 CQUIN funding. They will need to explain to commissioners why compliance is not 100%**.

The six HIIs are:

- 3 million lives
- intra-operative fluid management
- child in a chair in a day
- international and commercial activity
- digital first
- carers for people with dementia

Minimum requirements for providers to comply with each HII will be set nationally and providers will need to work with local commissioners to ensure that plans are aligned with local commissioning strategies. The NHS CB Local Area Teams will seek assurance from local commissioners that CQUIN prequalification has formed part of their planning process for 2013/14.

The website www.innovation.nhs.uk provides online support for the NHS to assist in the implementation of each High Impact Innovation and enables the sharing of best practice, case studies and discussion forums to generate a community of innovators delivering IHW locally.

The latest data from the National Technology Adoption Centre suggests already an increased uptake of 23% year on year in the intra-operative fluid management market. The 3millionlives initiative is yielding strong relationships within the industry that has seen a new model of delivery offered to the NHS. This has resulted in the identification of a number of Pathfinder sites that are **working with industry to deliver a telehealth supported service to the first 100,000 patients in 2013, a 20 fold increase on the existing telehealth use in England.**

IHW is not a single solution fix but a long-term and large-scale change programme for the NHS. For more information about the implementation of IHW, see the NHS CB report *Creating Change: Innovation Health and Wealth Update*.

The creation of the NICE Implementation Collaborative (NIC) will harness the skills, experience and dedication of organisations and individuals from across the healthcare system to improve patient outcomes for all. The NIC is a unique partnership whose members are committed to working together to support a system where patients have faster and more consistent access to NICE-recommended medicines, treatments and technologies. This independent partnership between the NHS, the life sciences industry, healthcare professional bodies, key health organisations and the public is transformational and heralds a collaborative approach that will be critical in achieving improved outcomes for the whole population. The signing of the NIC concordat by all its partners will be the very first time that the NHS and its stakeholders have come together to work in this way and completely re-draws the landscape. Rather than the traditional model, industry will now work with academia, clinical groups, the NHS Commissioning Board, NICE and representative bodies to drive compliance with NICE recommendations.

Edinburgh BioQuarter

The BioQuarter in Edinburgh is a flagship life sciences site which brings together a growing cluster of industry, scientists and clinicians to accelerate the growth of Scotland's burgeoning bio-science cluster. It is benefiting from being one of four life sciences Enterprise Area sites created by the Scottish Government which offers incentives to support and stimulate investment in some of Scotland's most dynamic industries. The BioQuarter houses a growing community of tenants including Swedish healthcare firm Mölnlycke AB, spin-out i2eye Diagnostics Ltd, creators of the world's first visual field analyser for young children and other patient groups; Roslin Cells, providers of stem cells for research and therapeutic use, and Calcivis Limited, a company undertaking research into the early detection of active tooth decay.

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

The *Strategy for UK Life Sciences* emphasised just how important it is, not only to pave the way for the UK to become the global hub for life sciences, but to communicate this message globally. UK Trade and Investment (UKTI) works with UK-based business to ensure their success in international markets and encourage the best overseas companies to look to the UK as their global partner of choice.

One year on, **UKTI has signalled the importance of the life sciences sector to the UK economy by establishing a dedicated unit which will focus on catalysing inward investment in UK life sciences**.

The **Life Science Investment Organisation (LSIO)** aims to:

- Create unified messaging explaining the UK offer to businesses for use by UKTI's overseas network and partners.
- Undertake proactive, targeted business development in areas of UK strength, highlighting the business implications of the on-going improvements to the UK life sciences ecosystem and the wider commercial environment.
- Build a community of supporters and advocates across the wider UK life sciences ecosystem to promote and deliver on inward investment opportunities in life sciences.

To ensure consistent, maximum impact overseas promotion of the Strategy and the updated UK offer for inward investment, UKTI is adopting a new global communication approach and have produced the *UKTI Life Science Prospectus* – a document that outlines how the Strategy will unlock opportunities for global industry to invest in the UK.

In addition, UKTI **LSIO will focus targeted business development campaigns on the following four themes: Dementia, Stratified Medicine, Experimental Medicine and Clinical Trials and Medical Technologies**, launching the Stratified Medicine campaign first, with others to closely follow. UKTI is also working in partnership with NOCRI to develop and sell the UK offer for Experimental Medicine and Clinical Trials.

Over the last year, UKTI has undertaken an ambitious programme of engagement with senior industry leaders from global pharmaceutical, biotechnology, and medical technology companies. High-profile events were held during the Olympic and Paralympic Games which brought together global life sciences business leaders, clinicians and researchers, policy makers, influencers and decision

makers. UKTI has also led on engagement in key overseas markets, promoting the UK life sciences sector at major international events such as the 2012 BIO International Convention (biotechnology and pharmaceuticals), and 2012 AdvaMed Conference (medical technologies and diagnostics).

"Britain is at its greatest when it works with its partners."

Dr. Oliver Harrison, Director of Strategy, Health Authority of Abu Dhabi

Sandbox Healthcare: Sandbox Industries recently announced the launch of Healthbox Europe, which invested £50,000 in seven selected healthcare start-ups, providing seed capital, access to a mentor network, collaborative workspace, educational modules specifically for healthcare entrepreneurs and the opportunity to pitch their businesses to investors.

Cancer Research Technology Pioneer Fund: The Cancer Research Technology Pioneer Fund has been established in London with Cancer Research Technology and the European Investment Fund to create a £50m investment fund to bridge the investment gap between cancer drug discovery and early development. It will take potential cancer drugs, primarily discovered by Cancer Research UK, from discovery through to entry to Phase II clinical trials before partnering with pharmaceutical and biotechnology companies.

The opening of Watchmoor Park: The new Novartis office at Watchmoor Park was officially opened on 2 November 2012 and represents a multi-million pound investment by Novartis in the site and local area. It is also the site of the Alcon academy healthcare professional training facility, which expects to educate over 800 healthcare professionals in the latest eye surgery techniques.

3 Attracting, developing and rewarding talent

The success of the *Strategy for UK Life Sciences* relies on a world-class supply of highly motivated, innovative and skilled scientists, clinicians and technologists, with the skills and knowledge required to deliver cutting-edge products and services. In order to create the right environment for this to happen, Cogent, the Sector Skills Council for life sciences and the Society of Biology were tasked with delivering a number of actions to nurture a skills pipeline that meets the needs of employers, with a focus on building talent and providing new training opportunities.

Cogent has set up an SME Skills Group that will focus on designing targeted industry-led training standards and encouraging skills and training activity amongst life sciences SMEs. It has also developed the Life Science Skills Awards, which will reward apprentices, individuals, educators and employers who have excelled in their contribution to skills in the life sciences sector. The inaugural awards ceremony will take place on 16 May 2013. It is an exciting stage in the delivery of the Strategy skills commitments, with many of the programmes still at an early phase. The Government will work with Cogent, the Society of Biology, industry and those participating in schemes to understand how the programmes are progressing and the impact that these initiatives are having on individual career development.

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

NIHR Research Professorships

NIHR Research Professorships were developed to support selected leaders capable of making a real difference to the effective translation of research in England. **Appointees from the first competition have now been announced, with funding of £1.5m over five years for each of the eight professors. Professors based in Keele, Leeds, Newcastle, Oxford and London, with research areas including ophthalmology, oncology, musculoskeletal and mental health were successful in the first round**.

The second annual competition was launched in February 2012, and the new research professorships will be announced shortly.

Life Sciences Skills Gateway

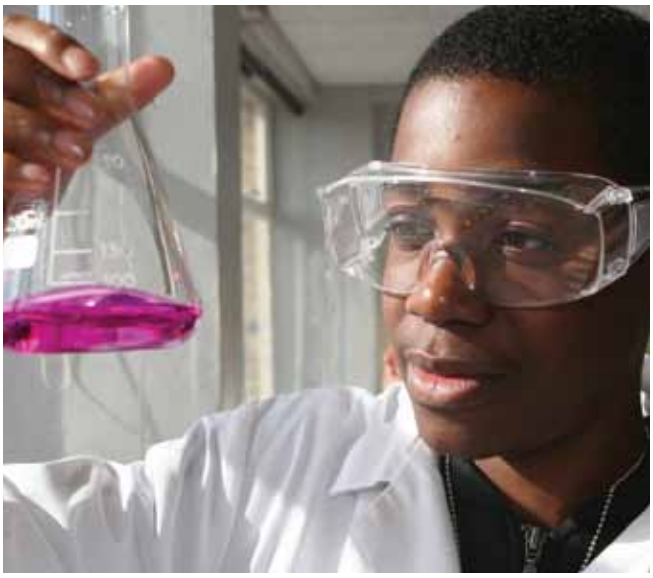
Cogent is developing a web-based Life Sciences Skills Gateway that will be a comprehensive careers resource to help individuals plan their careers in the life sciences. It will be the first dedicated life sciences careers resource detailing pathways by which individuals progress from an Apprenticeship/Higher Apprenticeship to an undergraduate degree programme and beyond. **A prototype is currently in development and will be launched in early 2013**.

Degree Accreditation Programme

The Society of Biology Degree Accreditation Programme successfully completed its pilot in March 2012, resulting in four accredited Biochemistry programmes. The Society has since secured funding from the UK Commission for Employment and Skills (UKCES) to expand the programme to cover molecular aspects of biology, whole organism biology and ecological and environmental science. The funding will also allow for the promotion and support of the accreditation programme and ongoing careers support for students and graduates of accredited courses. By the end of next year the Society aims to have at least ten degree programmes fully accredited, increasing to around 50 in 2014.

"The Higher Apprenticeship in Life Sciences provides a fantastic opportunity to study in higher education as well as learning a range of laboratory based practical skills in a real life working environment. I have already had hands on experience with compound screening in assay development, cell transfections, cloning, cell culture and DNA purification. I have enjoyed every minute so far at Takeda Cambridge and I'm confident I will continue to feel this way throughout the duration of my placement here."

Natalie, Takeda Higher Apprentice



ii. Developing scientific excellence alongside commercial rigour

Higher Level Apprenticeships

There are currently 31 learners undertaking the Higher Apprenticeship for Life Science and Chemical Science Professionals. This is running ahead of schedule – Cogent was tasked with delivering nine places for the pilot in February and a further 20 in September. The Apprenticeship Framework has been expanded to incorporate more disciplines within the life sciences industry, including packaging development, process development, food science and chemical science. Currently, it covers England and Scotland. From April 2013, a healthcare science apprenticeship offer will become available in the NHS following the launch of the Modernising Scientific Careers programme.

Technical Apprenticeship Service

The Technical Apprenticeship Service (TAS) was launched in January 2012 and has to date placed 31 apprentices with 13 life sciences companies. TAS supports employers in England in the recruitment, selection and training of apprentices to meet the skills and growth needs of life science employers.

"As a university that took part in the pilot and as a leading research-intensive institution, we recognise the value this brings to the whole scientific ecosystem – including higher education, individual researchers, industry and society in general".

Professor Eric Thomas, Vice-Chancellor, University of Bristol

Placements and mentoring: *Developing tomorrow's scientists today*

Subject to contract, Cogent has been awarded funding from UKCES to deliver *Developing tomorrow's scientists today – transforming Life Sciences through placements and mentoring*. The project will deliver a sector-specific placements and mentoring service in England. This will reverse the decline in student placement numbers across the sector, increase the number of placements offered by SMEs, increase the three-year success rate for SMEs through company mentoring and encourage interaction between business, commerce and the NHS.

120 new placements will be delivered over the first two years, increasing to 100 placements a year from the third year. The service will also provide 50 new life sciences company mentors, 30 new inter-company mentoring relationships and 70 trained intra-company mentors for placements and students.

"Takeda Cambridge is very pleased to be supporting the important work of Cogent in developing training frameworks for SMEs and identifying skills gaps in the biosciences industry. We are delighted to be participating in the Higher Apprenticeship life sciences pilot scheme and to have our first apprentice start work in our in vitro pharmacology department. What we have found is that, whilst some first class graduates can struggle with the transfer to the workplace, our apprentice has added value very quickly and is already developing and contributing to our drug discovery projects"

Linda Millett, Head of Human Resources, Takeda

NHS Research Scotland Career Researcher Award

These awards are specifically targeted at clinicians in the early stages of their careers and are designed to build a new cohort of research active clinicians. 34 awards were announced in 2011 and a further round of NHS Research Scotland Career Researcher Fellowships was recently announced; bringing total investment in new researchers to £6m over four years.

MSD Scottish Life Sciences Fund

Launched in May 2012 the MSD Scottish Life Sciences Fund will provide over £3m over the next three years to support life sciences training in drug discovery and the next generation of life scientists at six Scottish Universities: Aberdeen, Dundee, Edinburgh, Glasgow, St Andrews and Strathclyde. The fund will provide high-quality research and training opportunities for outstanding candidates, including 36 undergraduate student placements, 18 PhD studentships across a range of disciplines and six Research Fellowships in drug discovery. Fund partners include MSD UK, who is investing £3.1m, the Scottish Universities Life Sciences Alliance who are allocating £350,000 and the Scottish Funding Council who are contributing £300,000 of funding.

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

Whilst part of the approach set out in the *Strategy for UK Life Sciences* involves connecting actors within the health life sciences ecosystem to maximise the potential gains from the UK's excellent research environment, equally the Strategy recognised the central role that the Government has to play in providing the best environment for growth. This aspect of the Strategy reflects the importance that the Government places on listening and responding to those at the forefront of the life sciences sector, and learning from their experiences about the aspects of the UK system that can hinder progress. The Strategy laid the foundations for a more open and reactive environment, reducing the time and cost of bringing new products to market.

One year on, we are pleased to report that some good progress has been made towards alleviating these barriers, although we are aware of the work still needed to make the process of commercialisation of innovation more straightforward. As initiatives such as the Patent Box and above the line R&D tax credits come into force in 2013, we want to continue to work with industry, ensuring that the UK truly becomes the location of choice for investment.

i. Tax changes to incentivise investment in R&D

The Patent Box

The Patent Box is a key initiative to make the UK tax regime competitive for innovative high-tech companies. **It will provide a 10% corporation tax rate on profits attributed to patents, phasing in from April 2013**. The regime will apply to UK, European Patent Office and certain other patents. Profits from licensing, patented products and services are included.

R&D Tax Credit

In 2013 the Government will introduce an above the line (ATL) R&D tax credit, to improve the visibility and certainty of R&D tax relief to attract large scale investment in innovation.

Sir Andrew Witty, the GSK chief executive, said:

"The introduction of the Patent Box has transformed the way in which we view the UK as a location for new investments, ensuring that the medicines of the future will not only be discovered, but can also continue to be made here in Britain."

R&D tax credits are a tax relief designed to incentivise companies to carry out more research and to induce multinational companies to carry out more research in the UK. **In consultation with business, both the SME and large company schemes have been developed over the last eighteen months to make them more competitive, simple and effective**.

Enterprise Investment Scheme

The Seed Enterprise Investment Scheme (SEIS) was launched in April 2012 to provide generous tax incentives for individuals making investments in new small businesses. SEIS offers tax relief at 50% of the cost of shares in qualifying companies, up to a maximum annual investment limit of £100,000. **To raise awareness about this initiative, a series of country-wide roadshows were run and a website was launched in October 2012.**

Cost-sharing VAT exemption

The Finance Act gained Royal Assent on 17 July 2012, and as a result a new VAT exemption was introduced in the UK. It applies when businesses and organisations that have exempt or non-business activities come together as a cost sharing group to share services. This new exemption reduces one of the barriers to achieving efficiencies through cooperation and collaboration by businesses and organisations that would otherwise be unable to recover VAT that they incur.

ii. Regulation

Medicines Red Tape Challenge

Following a Medicines Red Tape Challenge the MHRA has committed to a review of guidance. This will build on the MHRA's work in producing the Human Medicines Regulations 2012, which replaced nearly all UK medicines legislation, including most of the Medicines Act 1968 and over 200 statutory instruments. This will be completed by March 2014, alongside the transfer of all content from the MHRA website to Gov.UK.

The MHRA will also consider if regulatory guidance over five years old can be archived and ask industry which areas should be reviewed first. Other measures include a new reclassification procedure which could halve the MHRA approval time of the reclassified product, a review of MHRA sanctions and penalties, and taking the UK's risk-adapted approach to clinical trials into Europe in the EU regulation negotiations.

In March 2012 GSK announced that it would build its first new manufacturing plant in almost 40 years at Ulverston in Cumbria and invest more in its two sites at Montrose and Irvine in Scotland. GSK's decision was in direct response to the introduction of the Patent Box.

Regulation of clinical trials

The UK has been pressing for the EU to introduce a risk proportionate approach to clinical trial approvals and a mechanism for harmonising applications for multi-state clinical trials. Revised EU legislation has now been issued by the European Commission for negotiation. This legislation, once agreed, will reduce scope for differing interpretations of the legislation across the EU. It will also set out tighter timescales for the various processes included in clinical trial approvals.

The MHRA already approves applications for clinical trials in the UK faster than most Member States. We are committed to maintaining our position as a leading Member State in this area to encourage companies to see the UK as an attractive place to conduct clinical trials. **Guidance to demonstrate how proportionate trial management can be conducted has been developed by MHRA in collaboration with representatives from commercial and non-commercial researchers**.

Navigating the regulatory landscape

The MHRA published a summary document on its website in February 2012, highlighting to SMEs the existing regulatory tools to support patient access to innovative breakthrough products. It has also developed a programme of work to communicate this information, include referencing it at conferences, and in articles in the trade press.

MHRA has acknowledged that, although there are EU and other regulators' standards for good manufacturing practice (GMP) that govern the way medicines are manufactured, these do not specify the precise details of developments in manufacturing technology that can be adopted. To adopt innovative manufacturing technology, companies should work with regulators such as MHRA to ensure that their new manufacturing practices will be accepted as meeting the required standards. The MHRA is making a commitment to continue to have an 'open door' policy in working on such initiatives with industry and where appropriate to champion them in Europe and internationally, encouraging wider adoption of this approach.

Adaptive licensing

As agreed in the *Strategy for UK Life Sciences*, a group of experts drawn from government, regulators, the NHS, industry, and the academic and third sector communities was set up this year by the MHRA and has been meeting regularly to discuss healthcare regulation issues. The work of the Expert Group picks up the challenge set in the Strategy to generate 'next step' proposals for regulatory innovation which led to the development of the adaptive licensing project. The Expert Group and its supporting working groups have met regularly to coordinate the different workstreams coming out of the project, agreed on a tripartite programme of work and are committed to meeting the Prime Minister's request to set up a pilot by the end of the year.

A key aspect of the proposed pilot is to **advance and maximise the potential of existing drug licensing processes by encouraging collaborative and pro-active use of support mechanisms, to improve public health and to stimulate innovative drug development.**

This comprehensive tripartite programme will draw together:

- Work at the EU level on how the existing flexibilities in EU regulation can be used to bring forward innovative products, including a discussion about the most efficient use of data-gathering methods and its implications for drug licensing and safety monitoring procedures.
- Work at the national level, conducted by the MHRA and the Expert Group, exploring options to help companies maximise the potential of existing drug licensing processes. A retrospective analysis of licensed medicines is planned to consider whether alternative pathways could have been used, with a view to informing and influencing debate nationally and at EU level.
- Work at arms-length from the MHRA and the Government. The co-ordination of some other activities required for the pilot will have to be undertaken at arms-length from government and industry by the Centre for the Advancement of Sustainable Medical Innovation. This will include the exploration of suitable candidate products.

Early access

In July 2012 the MHRA launched a public consultation on the feasibility and desirability of introducing a scheme in the UK to make certain new and promising medicines available to patients before they are formally licensed. The consultation closed in October 2012 and MHRA received 52 responses which are being assessed. Although there was support for consideration of such a scheme, respondents expressed a range of views in response to the questions posed on pricing and cost effective NHS funding, and consideration of options

A European company has developed a process for using adult stem cells in poor prognosis heart disease. Before introduction at the clinical site, the frozen cells were thawed, their preservative (which has toxic side effects) was removed, and they we re-suspended in fresh medium. The need for a GMP facility to complete these manufacturing steps had huge costs and availability implications. Advice provided by the MHRA on the use of alternative manufacturing strategies opened the way to the development of alternatives (including the use of different preservative), thus reducing the cost and improving the likely availability of the product to substantially larger populations of patients.

continues in conjunction with the Department of Health. If introduced, this scheme would provide a scientific opinion from the MHRA on the benefits and risks of a new medicine around a year before the licensing process is completed. This would provide additional information for clinicians and patients to assist in treatment decisions in areas of unmet need. The scheme would be voluntary and companies would decide whether to apply.

The Health Research Authority (HRA)

The Health Research Authority (HRA) was established as a Special Health Authority on 1 December 2011. The recently published draft Care and Support Bill contains clauses to establish the HRA as an executive non-departmental public body operating across the UK. The HRA promotes and protects the interests of patients and the public in health research, with the National Research Ethics Service as its core.

The HRA has announced it will run a feasibility study aiming to simplify and streamline approvals for research in the NHS by combining NHS study-wide review and elements of the Research Ethics Committee review into a single quality -assured assessment.

Use of animals in research

The Government recognises that the carefully regulated use of animals plays an essential role in scientific research, particularly in ensuring new medicines are safe and effective. The UK benefits from the most effective regulatory regimes in the world, and very much in line with the coalition commitment the UK is also seen as the world leader in the 3R's (the replacement, refinement and reduction of the use of animals in scientific research). The Government and the Police (led by the Metropolitan Police) remain committed to working closely and collaboratively with the life sciences community and their supply chain to manage any risk, and any perceived risk, from the activities of animal rights campaigners.

5 Making the UK a world leader in genomics and bioinformatics

One year on from the *Strategy for UK Life Sciences*, the Government is pleased to announce a new framework to support the development of genomics and bioinformatics technologies, which have the potential to improve patient care and generate significant economic value in the UK. The Government's approach builds on the successful aspects of the *Strategy for UK Life Sciences* such as building collaboration between the NHS, academia and industry for the benefit of patients.

Genomics is transforming healthcare

Since the Human Genome Project was completed the advances in genomic technology have been more rapid and more successful than we could ever have imagined. The cost of sequencing a human genome has decreased 100,000 fold over the past decade, and over the same period the time taken to sequence a genome has fallen from ten years to a single day. We will soon be able to sequence a human genome for under £1,000, and the cost is likely to fall further in the coming years.

With this ability to interrogate human genomes rapidly and cheaply comes the prospect that many aspects of medicine will be revolutionised. We are already beginning to use genomics in important areas of patient care, for example:

- Knowledge of genomics has been applied to diagnose many patients who suffer from rare genetic abnormalities.
- In cancer we know that the genetic changes that arise in tumours are major factors in determining disease progression and response to therapy. Understanding the genetics of both the tumour and the patient are increasingly important in managing the disease. We can use genetic information to define different types of disease, as well as to target the use of certain types of cancer medicines to the patients who will most benefit. Treating patients earlier with more targeted therapy has the potential to create longer remissions and more cures. The Cancer Research UK Stratified Medicine Programme has been leading the way in preparing the NHS for routine genetic testing for cancer.
- Screening is becoming more efficient; for example, genetic disease can be diagnosed prenatally using a blood sample from the mother.
- Microbiology has been transformed by this technology. Doctors can now use genome sequencing to construct family trees of bacteria or viruses from infected patients, pinpointing the source of an outbreak to close it down more quickly.

In the future, we can expect genomics to help spur similar advances in other disease areas, enabling clinicians to tailor treatments to an individual's needs. For example, research using large groups of patients has revealed that there are thousands of links between variants in an individual's DNA sequence and complex diseases such as heart disease and diabetes. These types of studies should enable researchers to identify the underlying mechanisms of a patient's disease, narrowing down the diagnostic categories and allowing doctors to choose the best therapy for that individual. As this new 'stratified medicine' approach to health evolves it is also likely that we can expect major changes in our approach to public health. Linking genomic data with information about a patient's health and environment through health records or research cohorts, such as the UK Biobank, means the complex interactions between genes and environment can be unpicked.

This is the world that the UK government and the NHS have started to plan for. Building on the wider *Strategy for UK Life Sciences* we want to ensure that we are forward looking and well placed to take the opportunities for patients and industry. We must make sure that patients in the UK are among the first in the world to benefit from this paradigm shift in how genomics is used.

"We believe that the UK is well placed to lead the global adoption of genomic technologies within mainstream clinical practice and to support public health. The foundations lie in our world-class research, our existing use of genetics and the increasing partnerships between the NHS, academia and industry, making it possible, with the right motivation, to embrace innovation at every level."

Human Genomics Strategy Group report, January 2012

The UK's Historic strength in Genomics

Discovery of DNA

Professor James Watson and Dr Francis Crick, working in the MRC's unit at the Cavendish Laboratory in Cambridge, famously described the structure of DNA in the scientific journal Nature in April 1953. The work owed a substantial debt to Dr Rosalind Franklin and Professor Maurice Wilkins at the MRC Biophysics Unit at King's College London. The discovery transformed scientists' understanding of human diseases and treatments and triggered the development of new DNA technologies with enormous economic and health benefits. Professors Watson and Wilkins and Dr Crick won the 1962 Nobel Prize in Physiology or Medicine for this work; Dr Franklin had died four years previously.

Southern Blotting

Supported by the MRC throughout his career, Professor Ed Southern developed an approach in the 1970s in Edinburgh to label nucleic acids to interrogate genetic material and explore sequence variation – globally known as the 'Southern Blot', this technique continues to underpin research in an enormous range of fields in biology and medicine, including genetic mapping, disease diagnosis and DNA fingerprinting as developed by Professor Alec Jeffreys. In the 1990s in Oxford he developed methods for synthesising DNA on glass (so-called microarrays) which has had enormous impact in understanding the interplay between genes and health and disease.

Technological advances in DNA sequencing

Professor Balasubramanian from the University of Cambridge invented Solexa Sequencing, an ultrafast way to sequence DNA. Balasubramanian's invention has revolutionised bioscience. By exploiting the fluorescence specific to each of the four base chemicals in DNA and building the system onto a microchip that can handle millions of DNA fragments at the same time, Solexa Sequencing has decreased the time it takes to read a genome by up to 10,000 times, compared to previous technologies. Prof Balasubramanian and colleagues founded Solexa Ltd in 1998 and following several rounds of fundraising and the launch of its core product The Genome Analyser, the company was sold to Illumina for $600m in 2007.

The UK is a world leader in genomics

Throughout the last 60 years UK scientists have made many of the most significant contributions to the field. The structure of DNA was discovered by James Watson and Frances Crick in Cambridge in 1950, and one of the first DNA sequencing methods was invented by Frederick Sanger at the Medical Research Council's laboratories in Cambridge in 1977. The dramatic drop in the cost of DNA sequencing seen over the last two decades has been largely driven by advances in sequencing technology from Cambridge, Oxford and Imperial College, demonstrating our unique strength in this field.

The UK's world-leading expertise in genomics is widely recognised. Pharmaceutical and biotechnology companies seek out the clinical and scientific expertise of UK doctors and academic researchers to help develop new

treatments and technologies. The European Bioinformatics Institute, providing genomics and bioinformatics services to 20 countries in Europe and beyond, is located near Cambridge, and the Wellcome Trust Sanger Institute has played a leading role in the world's largest genome sequencing projects.

The Human Genomics Strategy Group (HGSG) was an expert group established as part of the Government's response to the 2009 House of Lords Inquiry into genomic medicine, with the remit to:

- monitor advances in genetic and genomics research, both basic and translational, to evaluate their benefit to healthcare services in the NHS; and
- develop, in partnership with other stakeholders, a vision for genomics in the NHS.

Its report, published in January 2012, included recommendations for:

- ensuring the successful translation of laboratory and academic research into quality assured care pathways;
- developing a service delivery infrastructure that will enable equitable and affordable access to high quality genomic and genetic testing services, from commissioning the initial test through to counselling patients and their families;
- putting in place the bioinformatics platform needed to underpin genomic and genetic testing and facilitate ongoing research;
- training the NHS and public health workforce of today and tomorrow;
- recognising the legal and ethical issues around the use of genomic data, and developing appropriate safeguards and processes to protect individuals; and
- raising public awareness of genomic technology and how it can be used to benefit the care of patients across the NHS and indeed the world.

These recommendations have provided the foundations for developing a vision for genomic technology for healthcare.

The role of the NHS as a national healthcare provider which serves a large and diverse population means that it is ideally placed to support the development of large-scale genomic information for health research. The Government's commitment to place the NHS at the heart of innovative research is transforming how we link the best possible patient care with research in hospitals, universities or industry. Serving 60 million people, the NHS has the opportunity to access a wealth of genetic data through routine clinical care that can help us increase the knowledge of disease and harness genomic technologies to improve treatment. The ability to study groups of patients with similar clinical and genetic make-up will be hugely valuable for health researchers – both academic institutions and the biosciences industry, often working in collaboration – giving them the tools they need to develop better, more targeted treatments for the future. The UK is uniquely placed to utilise this wealth of information.

The proposal

By combining NHS clinical information with new genomic sequences there is real opportunity to capitalise on past investments in the NHS and medical research.

To fully realise this potential, the Government has three key objectives:

- To harness the potential of genomic technology by the NHS to improve patient outcomes and healthcare;
- To maximise the opportunities for research and translation of research findings into health and economic benefits for the UK; and

Large data sets are already improving the quality of care

In the UK, over 300,000 patients are diagnosed with cancer each year. Work is currently underway to implement a single cancer registration system for England (ENCORE). ENCORE will bring together information from a range of IT systems: clinical, pathology, radiology, radiotherapy and administrative datasets. This linkage is already contributing to our current knowledge on cancer. For example, linkage between routinely collected data and that from clinical trials databases has already been shown to provide a highly cost effective approach to long term follow up of clinical trials. Similarly, a Systemic Anti Cancer Treatment (SACT) dataset has been developed and approved to collect information on chemotherapy delivered in this country. No other large country will have information on this scale or a system of similar sophistication that will allow monitoring of the quality of cancer care given to the whole population. We will make the SACT Dataset available by April 2014.

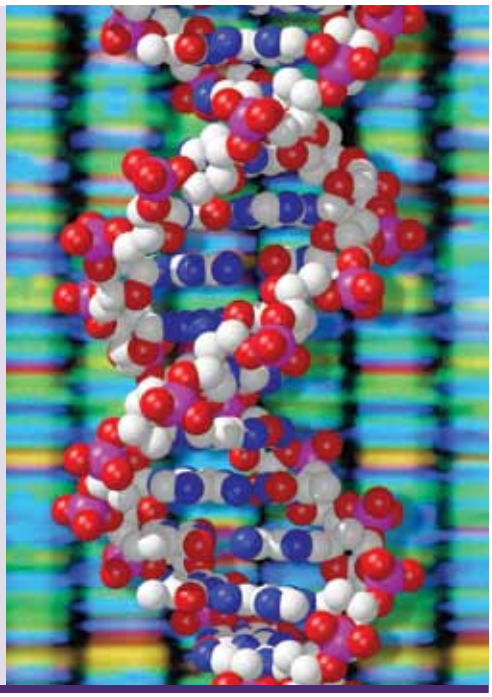
In clinical diagnostic settings, there are a number of disease specific databases, for example the Diagnostic Mutation Database (DMuDB), which whilst useful in a diagnostic capacity would benefit from better interoperability of their software platforms and agreed, shared standards and protocols for data access.

The NHS Commissioning Board has established a strategic programme, Care.Data, which will deliver the information architecture capable of receiving clinically rich data from across the NHS backed by the commitment to protect patient confidentiality from start to finish. Care.Data will be in service from April 2013 and will - from that date - provide access to existing anonymised flows of secondary care data and new flows of anonymised interoperable primary care data in the NHS in England, including clinical and prescribing information. In itself this constitutes a globally unprecedented commitment to improve patient outcomes and empower researchers. From April 2014, the service will extend to include richer secondary care data and within three years routine interoperable data from all care contexts.

Care.Data will therefore enable us to move from the current position of separate flow with few linkages, to capturing outcomes for known conditions, comparative prescribing data, understanding pathway benefits and ultimately allowing patients to access their hospital records.

Genomic technologies are revolutionising cancer treatment

In April 2012 the Department of Health consulted on new arrangements to ensure that all appropriate patients can benefit from targeted treatments as soon as they are available by providing access to high quality, accurate genetic testing of tumour samples. Genetic testing has been available for several years, for example to test for a specific chromosome change in chronic myelogenous leukaemia, the BCR/ABL translocation, which is targeted by the drug imatinib. More recently, DNA sequencing of patients with non-small cell lung cancer for the EGFR gene mutation has been used to identify patients who are most likely to benefit from the drug gefitinib, and tested patients with metastatic colorectal cancer for the KRAS mutation to identify those most likely to benefit from the drug cetuximab. Combined with early diagnosis and commitment to providing the most up-to-date therapies, genomic advances have the potential to substantially reduce cancer mortality.



- To support the growth of UK genomics and bioinformatics companies, including SMEs by enabling the creation of genomic platforms for innovation.

The UK also has significant advantages:

- The structure and scale of the NHS;
- Relatively centralised and standardised data collection and increasing use of electronic health records;
- A well developed network of NHS Regional Genetics Centres supported by molecular genetics and pathology laboratories;
- An extremely strong genomics research base comprising medical schools, universities and research institutions such as the Wellcome Trust Sanger Institute and the MRC Institute of Genetics and Molecular Medicine; and
- World-leading research cohorts that offer unparalleled opportunities to explore the determinants of health throughout the life course. The breadth and depth of data available through UK Biobank make this a unique resource for researchers around the world.

Rare diseases are often the result of genetic changes that can be readily detected by whole genome sequencing. Finding the root cause of diseases that cause problems in young children can prove very beneficial for children with these disorders and their parents, preventing protracted, usually unsuccessful attempts to define the disease using other diagnostic tests. As many as 30,000 such patients born every year and many could benefit from this type of genetic analysis. The DDD project (Deciphering Developmental Disorders) based at the Wellcome Trust Sanger Institute in Cambridge is linking clinical geneticists and their patients from across the UK with researchers and bioinformatics experts to use advanced sequencing techniques to provide diagnoses for children with developmental disorders and identify areas for further research.

To support the development of this activity, the Government will:

1. Develop the capability to undertake whole genome sequencing at scale for the benefit of patients in the NHS

The Government will ensure that NHS patients are amongst the first in the world to benefit from the application of genome sequencing technology applied in a healthcare setting. There is now evidence that treatment of both cancer and rare diseases would quickly benefit from this genome sequencing and it is likely that many other indications will follow. **Focussing initially on cancer, rare diseases and infectious diseases, we will efficiently sequence 100,000 whole genomes at diagnostic quality.**

The Department of Health has committed up to £100m to this initiative that will be used:

- to develop the necessary skills to support delivering the best patient outcomes;
- to support the linking of data and treatment outcomes which is essential for optimal patient care and future public and private research; and
- to pump-prime the sequencing of 100,000 genomes from NHS patients.

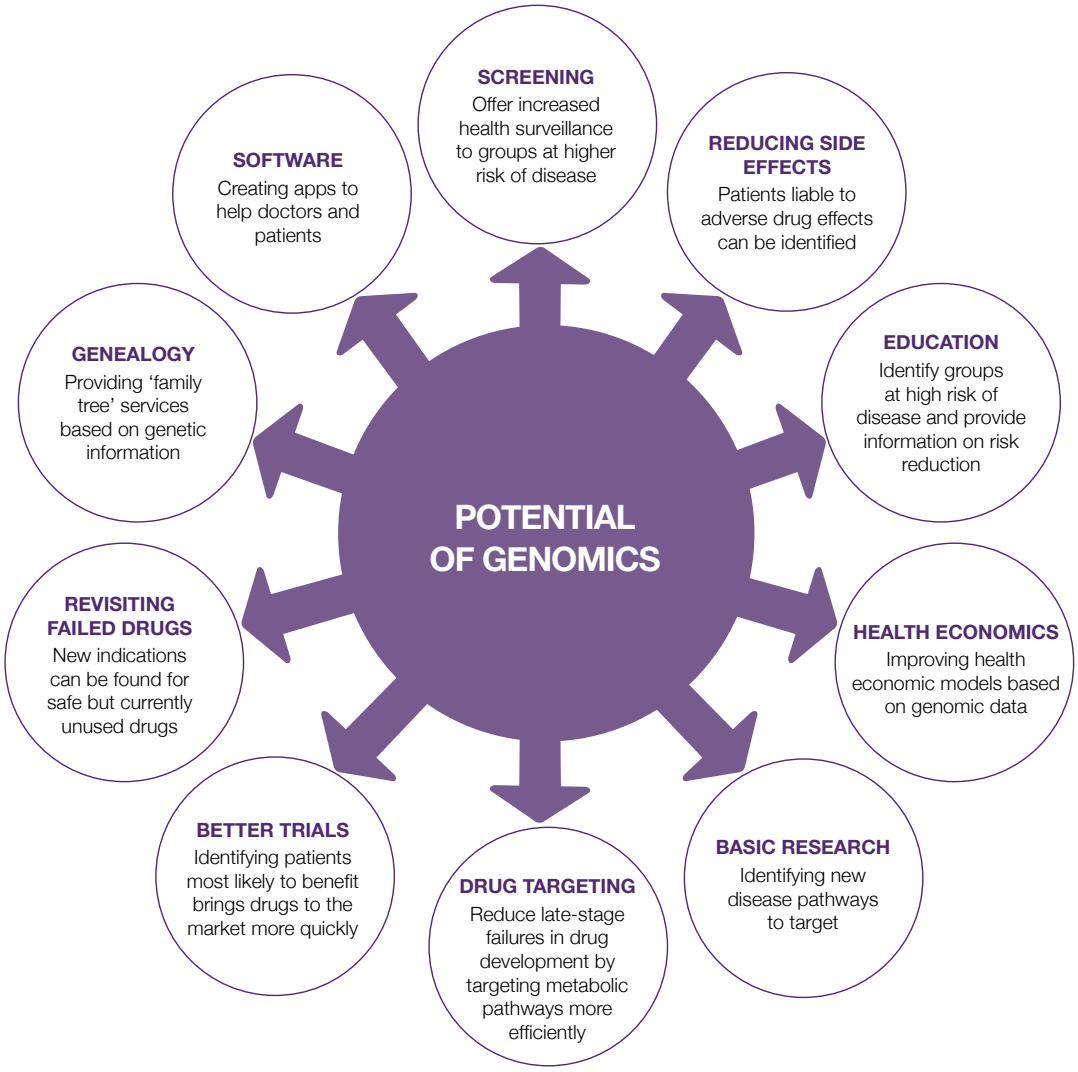
Sir David Nicholson, NHS Chief Executive and Chief Executive of the NHS Commissioning Board, will lead on delivering the NHS vision for genomics, starting with a process to ensure that by April 2014 at the latest, a small number of contracts will be in place for whole genome sequences for NHS patients starting with cancer and rare disease. This initiative represents a major paradigm shift for how the NHS approaches the diagnosis of disease. The NHS will prioritise sequencing for cancer and rare (inherited) diseases where, along with infectious diseases, the technology is already showing patient benefit.

The initial service design work will be completed by June 2013 and will lay the framework for the procurement of capacity to sequence 100,000 whole genomes of NHS patient at diagnostic quality over the next three to five years.

Patients will be asked to give full and explicit consent to have their genetic data analysed and stored. To ensure public confidence in matters of confidentiality and access, this work will be monitored by the Chief Medical Officer for England. The information from patients will be strictly controlled within existing NHS arrangements, and managed in a way that protects patient confidentiality.

2. Develop the genomic platforms to make the UK the destination of choice for life sciences

Sequencing an individual's DNA is an impressive demonstration of scientific innovation, but the real potential comes from being able to analyse aggregated data from large population genomic datasets, link them anonymously to clinical information, and reveal insights into susceptibility, causality, and progression of human disease. Whilst individual clinical trials may gather sequence data, there is currently no routine capture of this data to make it conveniently available for broader research purposes.



The UK has world leading cohorts that provide a vital resource for understanding genetic, environmental and social influences on health and disease (e.g. Avon Longitudinal Study of Parents and Children (ALSPAC), TwinsUK and DDD). To date, the latest genotypic techniques and whole genome sequencing have only been applied on a small scale of a few thousand samples, with systematic sequencing analysis limited by costs and technologies.

Researchers in academia and industry are interested in opportunities to generate genomic data on a significant scale within the UK, and in the future benefits to human health. 100,000 whole genome sequences will provide a valuable data source and the beginnings of a hub for genomic research. This promises to provide a rich source of information for researchers looking to discover new determinants of health and disease, develop new diagnostic tools and treatments, and further our understanding of the basic mechanisms of disease.

Now is the time to move faster. In addition to the sequencing described above, MRC will, with other funders, accelerate this agenda and exploit new technologies. UK Biobank offers the most powerful and important opportunity, with 500,000 participants, and within the next few weeks, **the MRC will start with the assessment of plans for a £10m genome analysis of a first subset of UK Biobank participants**. This will serve to pump-prime a longer-term strategy for genomic analysis of UK Biobank.

To complement the advances in health services, and the strengths of European Bioinformatics Institute, **we will create an exciting new biomedical informatics capability in our universities**. This – using capital funds announced in the autumn statement – will ensure they can lead in developing and applying new informatics and computational approaches, and can quickly engage the new data-heavy research fields, alongside major research hubs worldwide.

As part of the framework we will ensure good alignment with health services' informatics and the new e-Health Informatics Research Centres (e-HIRCs) co-funded with charities. Interoperability and a culture of cooperation will be priorities, as will new investment in skills that academic and industry research need in future.

In addition, the TSB has identified commercial applications of sequencing technologies and approaches in interpreting biological data as key focus areas in biosciences, and will support collaborative proposals in these areas as part of both the £10m Technology Inspired Innovation competition which is currently open, and the £180m Biomedical Catalyst announced in the *Strategy for UK Life Sciences*.

3. Investments in skills

Developing the capability and capacity to maximise the UK's use of this data takes time. Whilst we have a strong research base to start from, **the Government is investing to ensure the UK has the necessary genomic and bioinformatic skills amongst researchers and NHS staff** and to prepare for the increased use of genomics in public health so we remain at the forefront of genomic science and its translation into healthcare benefits.

Investing to improve bioinformatics skills in the NHS

The NHS CB and Health Education England (HEE) will build on the existing NHS science skills to increase biomedical informatics support in the healthcare system, as well as to provide resources for NHS staff at all levels to develop their genetic and genomic knowledge base. We will build and expand current arrangements to:

- Deliver a pipeline of specialist clinical bioinformatician knowledge and skills at all levels through the Modernising Science Careers framework from undergraduate through to higher specialist scientist training and including academic career development. This will include the use of anonymised patient data to bring together bioinformatics training with a clinical pathway focus. Integral to this will be the delivery and development of up to 40 postgraduate scientists and a new Masters level programme in Clinical Bioinformatics.
- Through HEE Government will develop the capacity and capability in the existing specialist genetics and pathology workforce to work more broadly and support the wider clinical team. This will ensure that molecular pathology and genomics are integral to future service delivery and support all clinical pathways and targeted treatment. This will include a specific programme of learning and skill development working with the Royal College of Pathology and others in the development of resources such as e-learning modules and an accredited learning resource framework.
- Develop skills for non-specialist healthcare professionals: specifically to develop a suite of tools and resources (including flexible and transferable modules of learning, such as e-learning, and a competency framework for quality and development purposes) and commissioned continuing professional development programmes at a range of academic levels, working with the NHS and HEE to roll out and implement.

National Bioinformatics Framework for career development

The Research Councils already invest strongly in skills development in the fields of bioinformatics, biostatistics and computational biology at the PhD and junior investigator

level, including through strong partnerships with industry (e.g. in stratified medicine). The Research Councils recognise the need to further strengthen UK capability, by developing skills and careers to deliver the 'science of the future' – integrating biology, physical sciences (mathematics, physics, computation etc.) and other disciplines. The MRC is considering proposals for a step-change in investment, aligned with other Research Council's key investments, to build capacity, establish a national framework of skills that will further enhance the UK's international position in biomedical informatics and provide new opportunities to transform healthcare and stimulate private sector growth.

The Framework will address the pressing needs for both data and methodology technologists and provide career development awards for the next generation of research leaders. This will build on existing PhD and post-doctoral programmes and develop new and deeper partnerships with industry – both pharmaceutical and biotech – and with new partners such as sequencing and informatics businesses. The MRC will work with the pharmaceutical and biotechnology industries to increase the proportion of collaborative PhDs in biomedical informatics.

4. Public communication and dialogue

Going forward we will implement a public communication and engagement plan which addresses the aspirations and concerns of the public. We will begin a dialogue with patients and partners to establish the correct approach within the NHS to capitalise on the creation of a health care system able to generate and use large amounts of genetic data to improve the health of patients.

Progress in implementing the *Strategy for UK Life Sciences*

Strategy measure	Update
1. 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.	**Stratified Medicine** In December 2012 the MRC announced an investment of £10.6m in three large-scale collaborative awards under its Stratified Medicine initiative. These will tackle diseases which have a huge impact on patient's lives – rheumatoid arthritis, hepatitis C and a rare disease called Gaucher's. **Experimental Medicine** As set out in the Strategy, the MRC is investing £60m over three years through MRC Experimental Medicine Challenge Grants. These grants will support ambitious, challenge-led UK programmes of research into disease mechanisms in humans. A large number of outline applications were received from which 30 full-stage applications were invited and are now being assessed through rigorous international peer review. The MRC also agreed to invest £10m in a collaboration with AstraZeneca, who made 22 compounds available to academic researchers to develop medicines. **Biomedical Catalyst** The Biomedical Catalyst is a £180m funding programme jointly operated by the MRC and TSB. This year, £49m has been committed to 64 projects led by universities and SMEs, which will leverage at least £25m of private sector funding.
2. We will commission an independent panel to develop a technology roadmap that will propose actions required to establish a world leading synthetic biology industry.	A Synthetic Biology roadmap was published in July 2012, and a Synthetic Biology Leadership Council has been established. The first meeting of the council will take place in December 2012.
3. Through the TSB, we will invest up to £10m per annum in a Cell Therapy Technology and Innovation Centre (TIC), based in London.	The TIC became the Cell Therapy Catapult centre, and became operational this year with the appointment of Keith Thompson as the CEO and premises established at Guy's Hospital.
4. 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.	As part of the strategy, the Research Councils have established a £25m UK Regenerative Medicine Platform. The Platform will comprise several interdisciplinary research hubs, providing a programme to promote the development of regenerative therapies and to address the key technical and scientific challenges associated with translating promising scientific discoveries.

Strategy measure	Update
5. 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.	**ELIXIR** The new facility for biological data-storage will be called ELIXIR. Plans for ELIXIR are progressing on time and on or below budget. **Technical Hub** Plans for the new technical hub are also progressing to schedule. The formal opening of the Hub is being planned for 2013.
6. We will enable small state-of-the-art research facilities to secure recognition and apply for Research Council funding.	This measure was completed in February 2012. The first organisation to benefit from this change is Imanova – an innovative alliance between the UK's Medical Research Council and three world-class London Universities: Imperial College, Kings College and University College.
7. 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.	Early in 2012 RCUK published new principles in support of collaboration in research and related activities.
8. As announced in the Autumn Statement 2011, we will introduce the EU VAT cost-sharing exemption in the Finance Bill 2012.	From Royal Assent of the Finance Act on 17 July 2012 a new VAT exemption was introduced in the UK. It applies when businesses and organisations that have exempt or non-business activities come together as a cost sharing group to share services.
9. 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), the latter of which is an investment of £60 million investment by NIHR and MHRA.	The HSCIC launched its new 'Data Linkage Service' on 17 September 2012. This service adds significant value to individual sets of data by combining and matching them at an individual record level in a secure environment. The CPRD was launched on 28 March 2012.
10. 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.	Coordination between London's three Academic Health Science Centres became embedded this year. This has provided extended reach to the centres.
11. 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.	The appointment of Chris Brinsmead and Professor Sir John Bell as Life Science Champions was made in December 2011.

Strategy measure	Update
12. 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 update to the Clinical Trials Gateway was launched by NIHR on 25 April 2012. The update significantly increases and improves the amount of information available to patients, clinicians and the public about clinical trials.
13. 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.	The national BioResource is on target to be delivered by April 2014. It will provide a national cohort of healthy volunteers, patients and their families, who wish to participate in experimental medicine research.
14. 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.	As part of its package of proposals for strengthening the NHS Constitution, the Government is consulting on including new patient rights and pledges and staff responsibilities that clarify how patients' data is protected and used. The Government has commissioned a review of the current information governance rules and their application, to ensure that there is an appropriate balance between protecting confidential and identifiable information within health and care records and using and sharing information to improve the quality and safety of care. This independent review is being led by Dame Fiona Caldicott and is expected to report early in 2013.
15. 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.	The Life Science Investment Organisation (LSIO) was established in August 2012 to deliver a rapid increase in life science investment into the UK.
16. 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.	Four high-profile events were held during the Olympic and Paralympic Games which attracted senior delegates representing global life sciences business leaders, clinicians, researchers and policy makers.
17. We will create new partnerships in translational medicine and biopharmaceuticals, underpinned by the Memorandum of Understanding between the UK and China.	A biopharma trade mission visited China in October 2012, building on the successful mission of September 2011. The mission focussed on developing partnerships in this area and generated a number of potential collaborations between UK and Chinese companies.
18. Through Cogent we will provide information on careers in life sciences, for students, employers and educators.	Cogent is developing a web-based Life Sciences Skills Gateway that will be a comprehensive careers resource to help individuals plan their careers in the life sciences. It will be the first dedicated life science careers resource detailing pathways by which individuals progress from an Apprenticeship/Higher Apprenticeship to an Undergraduate Degree programme and beyond. A prototype is currently in development.

Strategy measure	Update
19. Through the Society of Biology, we will improve practical teaching standards, by expanding the accreditation programme for undergraduate biology degrees.	The Society of Biology successfully completed its pilot degree accreditation programme in March 2012, which accredited a total of four biochemistry courses. The Society has since secured funding from the UK Commission for Employment and Skills via the Growth and Innovation Fund to expand the programme to cover molecular aspects of biology, whole organism biology and ecological and environmental science.
20. Together with Cogent and others, we will develop a process to kite-mark FE and HE programmes. This will be piloted in 2012.	It has now been agreed that an alternative approach to kitemarking would be preferable. Where professional accreditation exists, Sector Skills Councils will not now be expected to facilitate the kite-marking of individual courses, but to work with professional bodies to enhance the employer involvement through the professional accreditation processes. Where there is no professional accreditation, are leading further work to establish the optimum way forward.
21. Through Cogent, we will develop a strategy to increase the uptake of industry placements in the UK.	Cogent has undertaken extensive research on placements in the UK and published an evidence report in June. On the basis of this evidence, Cogent is looking to develop a not for profit service for industrial placements and mentoring called *Developing Tomorrow's Scientists Today*.
22. 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.	There are currently 31 learners undertaking Higher Level Apprenticeships in Life Sciences. This is slightly ahead of schedule – Cogent were tasked with delivering nine places for the pilot in February and a further 20 in September. The Apprenticeship Framework been has been expanded to allow more disciplines within the life sciences industry including packaging development, process development, healthcare science, food science and chemical science.
23. 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.	The Technical Apprenticeship Service (TAS) was launched in January 2012 and has to date has placed 31 apprentices with 13 life sciences companies. The TAS supports employers in the recruitment, selection and training of apprentices to meet the skills and growth needs of life science employers.
24. 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.	Subject to contract, Cogent has been awarded funding from UKCES for *Developing tomorrow's scientists today – transforming Life Sciences through placements and mentoring*. The project will deliver a sector-specific placements and mentoring service which will reverse the decline in student placement numbers across the sector, increase the number of placements offered by SMEs, increase the three-year success rate for SMEs through company mentoring and encourage interaction between business, commerce and the NHS.

Strategy measure	Update
25. • 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.	**Seed Enterprise Investment Scheme (SEIS)** The SEIS was launched in April 2012 to provide generous tax incentives for individuals making investments in new small businesses. SEIS offers income tax relief at 50% of the cost of shares in qualifying companies, up to a maximum annual investment limit of £100,000. SEIS has been positively received by Angel investors, but there are concerns that it is not widely known about outside of the existing community of investors. To address this, a number of communication initiatives have been implemented: • nine educational events ("Windows of Opportunity" roadshow) that demonstrated financing options, including SEIS, for small young businesses. By the end of November over 3,000 businesses and entrepreneurs will have attended. • New SEIS information website (www.seiswindow.org.uk) launched, particularly targeting the entrepreneur, new investor and experienced investor. **Above the line (ATL) R&D tax credit** In 2013 the Government will introduce an above the line (ATL) R&D tax credit, to improve the visibility and certainty of R&D tax relief to attract large scale investment in innovation. **Relief to Contract Research Organisations** In a June 2011 consultation, the Government proposed two possible solutions. 1. Certification: The customer would provide the subcontractor with a certificate to confirm that the work they were undertaking was part of an R&D project. 2. Joint election – The subcontractor and the customer would state that for the purposes of determining whether work was R&D they would be treated as part of the same group, and allow HMRC to request or disclose information as necessary for determining this. Responses to the consultation, published in December 2011, suggested that neither certification nor joint election provide a universally workable solution. The Government is continuing to explore possible solutions to this issue in the context of the announced changes to the large-company R&D tax credit scheme. **Pre-clearance system** A pilot has been run, and a report is being prepared on the findings of the pilot and whether the scheme should be made permanent.
26. Through the MHRA, we will launch a regulatory audit and Red Tape Challenge in March 2012.	Following a Medicines Red Tape Challenge the MHRA has committed to a review of guidance. This will build on the MHRA's work in producing the Human Medicines Regulations 2012, which replaced nearly all UK medicines legislation, including most of the Medicines Act 1968 and over 200 statutory instruments. This will be completed by March 2014, alongside the transfer of all content from the MHRA website to Gov.UK.

Strategy measure	Update
27. 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.	Whilst there are strict EU and international standards for good manufacturing practice (GMP) that govern the way medicines are manufactured, these do not – and need not – specify the precise details of developments in manufacturing technology that can be adopted. To obtain agreement to adopt new practices, companies can work with regulators such as MHRA to ensure their new practices will be accepted as meeting the required standards. The MHRA is making a commitment to continue to have an 'open door' policy in working on such initiatives with industry, to make this more visible, and where appropriate championing them in Europe and internationally to help ensure they are recognised and adopted.
28. 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.	NICE Scientific Advice has devised a one day training workshop targeted to help the developers of medical technologies and members of the investment community understand how NICE defines value, enabling them to develop a value proposition for their product.
29. 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.	The MHRA published a summary document on its website in February 2012, and has developed a programme of work to include reference at conferences, articles in trade press. The MHRA is monitoring the impact of this advice.
30. In addition, early in 2012 the MHRA will bring forward for consultation proposals for an 'Early Access Scheme'.	The MHRA consulted on this scheme from 17 July to 5 October 2012. Some 50 responses are being analysed before the end of 2012.
31. 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.	A group of experts has been established, and its initial meeting was held on 27 June 2012, and its second meeting was held on 9 October 2012.

Glossary of abbreviations

AHSN	Academic Health Science Network
ABPI	Association for the British Pharmaceutical Industry
BBSRC	Biotechnology and Biological Sciences Research Council
CPRD	Clinical Practice Research Datalink
ECMCs	Experimental Cancer Research Medical Centres
EPSRC	Engineering and Physical Sciences Research Council
HEE	Health Education England
HES	Hospital Episode Statistics
HII	High Impact Innovations
HRA	Health Research Authority
HSCIC	Health and Social Care Information Centre
LSIO	Life Science Investment Organisation
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NHS CB	NHS Commissioning Board
NIC	NICE Implementation Collaborative
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NIHR CRN	NIHR Clinical Research Network
NIHR CRFs	NIHR Clinical Research Facilities
NISCHR	National Institute for Social Care and Health Research
NOCRI	NIHR Office for Clinical Research Infrastructure
NRS	NHS Research Scotland
RGF	Regional Growth Fund
SEIS	Seed Enterprise Investment Scheme
SMEs	Small and Medium-sized Enterprises
SSCIF	Specialised Services Commissioning Innovation Fund
STEM	Science, Technology, Engineering and Maths
TAS	Technical Apprenticeship Service
TRP	NIHR Translational Research Partnership
TSB	Technology Strategy Board
UKCES	UK Commission for Employment and Skills
UK RPIF	UK Research Partnership Investment Fund
UKTI	UK Trade and Investment

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Any enquiries regarding this publication should be sent to us at: officeforlifesciences@bis.gsi.gov.uk

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