

Life Sciences

The UK: Collaboration for Success



Office for
Life Sciences

UK
TRADE &
INVESTMENT



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The UK – A world leader in Life Sciences

The United Kingdom is a global centre of excellence in Life Sciences. Here, innovation flourishes and is easy to commercialise; industry collaborates with academia and the health service; people are highly-skilled and motivated; the Government is supportive and businesses thrive.

The UK is the third most popular investment location in the world and is acknowledged as the number one gateway to Europe, the largest market in the world with 27 member states and a population of nearly 500 million. Strong trading links exist between the UK and the rest of the world and our strategic location, as well as excellent communication links, make this country an ideal base for global business.

In this global Life Sciences marketplace, the UK is not complacent and recognises that it continually needs to evolve and innovate to remain a world leader in Life Sciences. The Office for Life Sciences (OLS) was established in January 2009, bringing together industry, Government and academia to develop initiatives that strengthen the position of the UK as a global centre of excellence in Life Sciences.

In a year of action for Life Sciences, the OLS has made significant progress on a set of Government actions to further enhance the operating environment for Life Sciences companies in the UK. Industry and the Government are working together to ensure that the benefits of this enhanced environment are conveyed to investors and partners throughout the world.

The UK Life Sciences Industry UK Life Sciences (pharmaceuticals, medical technology and medical biotechnology) is a world leading, high-tech industry investing over £5 billion in R&D in the UK.

- The UK medical technology sector has nearly 3,000 companies generating £10.6 billion of turnover. It employs 52,000 people. 43% of companies are less than 10 years old.
- The UK medical biotechnology sector consists of over 750 companies with a combined turnover of £4.2 billion, representing an estimated 30% of European turnover in the sector. It employs 24,000 people. Medical biotechnology is driven by innovation with 86% of all companies engaged in research and development. The UK has one of the most developed sectors in Europe with a balance of young and established businesses.
- The UK pharmaceutical sector employs some 67,000 people working in around 600 companies with combined annual sales of around £15.6 billion.

Five key factors make the UK a world leader in Life Sciences and set this country apart as the location of choice for investors:

1 World-class science, innovation and skills

The UK is home to some of the world's leading Life Sciences companies, public sector research institutions, universities and the NHS, all of which are engaged in groundbreaking research and translational science delivered by some of the top scientists in the world. This drives the development of innovative medicines and technologies, delivering healthcare benefits and economic prosperity on a global scale.

2 A culture of collaboration between industry, academia, the NHS and the UK Government

The partnership between the UK's Life Sciences industry, its universities, the NHS and the Government is a role model for the world. The links forged between these different organisations have created a unique environment where innovation thrives, businesses are supported and healthcare outcomes improve year-on-year.

3 The NHS – A unique opportunity for investors

The NHS is unique, delivering “cradle to grave” care for the UK's 61 million residents. Not only is it one of the largest purchasers of Life Sciences products in the world, spending around £15 billion a year on goods and services, but the NHS is also a proven research partner for developing and evaluating new medicines and technologies.

4 Clinical trials – An evolving environment

The UK has discovered and developed as many leading medicines as the rest of Europe combined. The unique potential offered by the NHS is a major contributory factor. Recognising the increasingly competitive market place for clinical trials, the NHS has recently introduced a range of measures to streamline the clinical trials process and make it easier for Life Sciences companies to access the unique potential of the NHS in this vital area.

5 A supportive business and regulatory environment

The UK Government is pro-business and regards Life Sciences as a priority industry for driving economic growth and meeting future healthcare challenges. Via the OLS, it has recently introduced a range of initiatives that strengthen the UK still further as a global centre of excellence in Life Sciences. These include providing a new route into the NHS for innovations, increasing access to finance and rewarding innovation through a supportive fiscal environment.

“The UK offers us exactly what we are looking for in developing our business. There is a highly-skilled workforce and the opportunity to collaborate with some of the best academic institutions in the world. We are delighted that the Government is taking such a proactive approach to supporting the Life Sciences industry.”

Mark WJ Ferguson, CEO, Renovo Group plc

World-class science, innovation and skills

The UK is a world leader in science and innovation in Life Sciences with some of the world's leading universities and scientists.

The UK has the world's most productive research base. Around 40% of European biotechnology companies are based here and 35% of European biopharmaceutical clinical trials take place in one of our centres of excellence. Patients throughout the world benefit from the UK's exceptional culture of collaboration between industry, academia, the NHS and Government.

The UK is the most popular location in Europe for investing in pharmaceutical and biotechnology R&D. The UK attracts almost 10% of the world's pharmaceutical R&D funding.

We have a Higher Education system that is recognised worldwide for excellence and an NHS system that has a reputation for delivering high-quality education and training. Both also have a strong track-record in translating research into commercial application, such that many Life Sciences companies are built on the exploitation of this cutting-edge research and development.

Four of the top six universities in the world are located here: Cambridge, University College London, Imperial College and Oxford. The UK has the most productive research base in the G8. We produce more publications and citations per researcher and per pound of public funding than any of our major competitors. We are responsible for 8% of world publications, and we have increased our global share of the most cited papers to 14%.

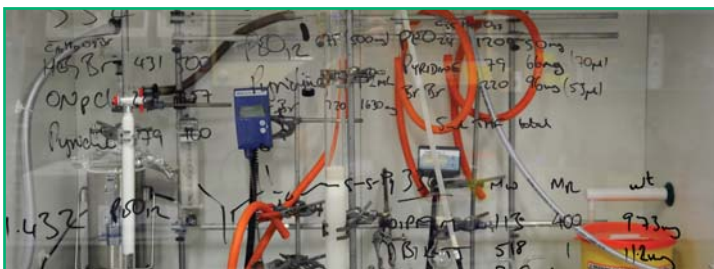
UK scientists have been awarded more than 20 Nobel Prizes in Life Sciences-related disciplines and the University of Cambridge has been awarded more Nobel Prizes than any other institution in the world.

In 2007–08 university spin-out companies employed nearly 14,000 people and had a combined turnover of over £1.1 billion. Over the last 10 years, university bioscience departments alone have generated over 200 spin-out companies.

Our reputation as a world leader in research therefore creates a strong pull to attract and retain Life Sciences business in the UK. But we have the potential to go further to augment the vibrant, highly-skilled and innovative research base.

In 2009, the Office for Life Sciences worked with Life Sciences businesses and academia to establish the Industry and Higher Education Forum for Life Sciences. This Forum will help ensure that graduates leave with the core high-level skills and critical disciplines required to pursue a career in Life Sciences research and development.

Key to this is the formation of the Society of Biology, which represents the views of over 80,000 biologists, and their development of an accreditation system that will recognise academic rigour, experience and expertise within the biological sciences.





Funding for Health and Biomedical Research

Increased Government investment for health and biomedical research in the UK will bring funding above £1.7 billion in 2010-11, mainly through the Medical Research Council (MRC) and the National Institute for Health Research (NIHR). In addition the UK has an active charitable sector of over £1 billion per year supporting biomedical research through charities such as the Wellcome Trust, Cancer Research UK and the British Heart Foundation. The Wellcome Trust is the largest charity in the UK, and one of the largest worldwide, funding innovative biomedical research, both in the UK and internationally and spending around £600 million each year.

A World-Class Regenerative Medicine Community

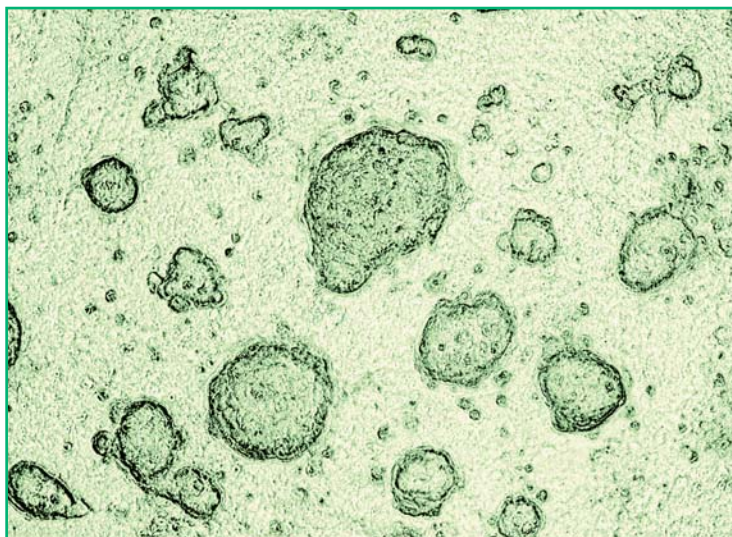
The UK is a world leader in regenerative medicine. It is building a connected regenerative medicine community to enable businesses in this country to provide leading-edge solutions for the global market. To help with this the Government has launched, through its funding agencies, a "RegenMed" programme, consisting of a total investment of £21.5 million. The Technology Strategy Board administers this programme and to date, over 40 companies have been approved to receive more than £4.5 million to support research and development into regenerative medicines. The programme will continue to grow in 2010.

The PISCES (Preliminary Investigation of Stem Cells for Stroke) stem cell trial – ReNeuron Group plc.

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

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

TEAMSS will address a key challenge to sustaining regenerative cell products through clinical trials to approval. It will identify critical points in the product development path based on 'just-in-time' delivery of a candidate human ES cell (HES) therapy for age-related macular degeneration (AMD) and prescribe alternative, regulatory compliant approaches to product supply. The project will be performed in partnership with The Weinberg Group and Angel Biotechnology plc who will be providing consultation and expertise.



A culture of collaboration

The Government support pledged to the UK Life Sciences industry was strengthened in January 2009 by the formation of the Office for Life Sciences (OLS). The aim of the OLS was to signal to the world the vital role that Life Sciences play in driving economic growth and bringing about patient benefit, and to develop a package of actions to transform the operating environment for UK Life Sciences. In July 2009, the OLS published these actions in the *Life Sciences Blueprint*, committing Government to an ambitious and comprehensive programme of delivery. Significant progress has been made since July 2009; this progress was reported in *Life Sciences 2010: Delivering the Blueprint*, published in January 2010.

In 2010, the UK will begin a new era of collaboration between industry and the public sector through the establishment of the UK Life Sciences Super Cluster. At the heart of the UK Life Sciences Super Cluster will be the creation of Therapeutic Capability Clusters.

The creation of Therapeutic Capability Clusters is a novel approach to building strong industry, academia and NHS collaboration in the early clinical development of new drugs and interventions (early phase human clinical trials). Led by the Office for Strategic Coordination of Health Research, and capturing the strengths and expertise of the academic and NHS research community, Therapeutic Capability Clusters will bring together the UK's leading researchers and clinicians and drive forward the development of innovative medicine and technologies in critical therapeutic areas. Therapeutic Capability Clusters will act as a single point of contact between academic/NHS researchers and industry, thus providing a focus for collaboration, coordination and communication with industry.

The first Therapeutic Capability Cluster will target research in immunology and inflammation, focusing on diseases such as asthma and rheumatoid arthritis. In the longer-term, the aim is to build a series of Therapeutic Capability Clusters in other major therapeutic areas and by doing so enable the UK to function as a single Life Sciences Super Cluster.

The **UK Life Sciences Super Cluster** is a unique opportunity for the UK to drive forward translational research in critical areas of high disease burden which will, in turn, improve patient care and drive economic growth. No existing cluster, national or international, has focused on early clinical development and experimental medicine in areas of medical need.



Cross Sector Collaboration: Translational Medicine Research Collaboration

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

Investment of £37 million in a New Bioscience Campus

A unique £37 million Bioscience Campus is being developed on the Stevenage site of GSK, funded by a partnership of the Government, GlaxoSmithKline, The Wellcome Trust, Technology Strategy Board and the East of England Development Agency. The project will create a world leading hub for biotech companies.

“The Stevenage Campus will affirm the UK as a global hub for the Life Sciences industry. It will bring together scientists from around the world, providing them with new access to leading research and development facilities. This will foster innovation and accelerate the discovery and development of new medicines.”

Andrew Witty, CEO, GlaxoSmithKline



Collaboration to Develop a New Translational Medicine Unit at a purpose-built Hospital Facility in Manchester

ICON plc, a global service provider to the pharmaceutical, biotechnology and medical device industries, recently announced that it has signed a collaborative agreement with the Central Manchester University Hospitals NHS Foundation Trust (CMFT) to develop a purpose-built translational medicine facility.

“We are delighted to be collaborating with the CMFT and the Manchester Academic Health Centre to continue to develop the region as an international centre of excellence in translational medicine. Moving to a hospital-based setting also meets the needs of our customers who are increasingly looking to run their first-in-human studies in hospital environments.”

Dr Thomas Frey, President, ICON Development Solutions

“Our aim is to build upon our investments in facilities and high-calibre clinical academic staff to consolidate our reputation as a leading international research hospital. This exciting new collaboration with ICON is a major step for the Trust and will accelerate the translation of research discoveries into new medicines.”

Mike Deegan, Chief Executive, CMFT

“This is an example of the type of collaboration between industry, academia and the NHS that the ABPI is seeking to encourage and which we believe will help drive forward translational medicine, building on the strength of the pharmaceutical, science and clinical base in the UK.”

Dr Allison Jeynes-Ellis, Medical and Innovation Director, Association of the British Pharmaceutical Industry (ABPI)



The NHS – A unique opportunity for investors

The UK has a unique health system – the NHS. It is the largest publicly-funded health services in the world, offering “cradle to grave” care for the UK’s 61 million residents.

The NHS is one of the largest purchasers of Life Sciences products in the world, spending around £15 billion each year on goods and services. It has a workforce of more than 1.3 million, giving companies and investors access to an important resource of clinicians, patients, clinical trials, research and different specialisms. NHS clinicians carry out leading-edge research into almost every major disease area and the innovative technologies and services developed by the NHS are having an impact on healthcare across the world.

Both NHS and industry recognise the potential for building a better business-to-business relationship and a number of initiatives are progressing this for mutual benefit.

The **NHS Life Sciences Innovation Delivery Board** has been established with a key objective of improving the strategic relationship between the NHS and the Life Sciences industry including working together to meet the quality and productivity challenge in the NHS. It also has a role in accelerating the uptake of cost-effective drugs and innovations in medical technologies.

The **Innovation Pass** is a three year initiative that will make it easier for the NHS to pioneer new treatments. The scheme will give patients with rare diseases access to highly innovative drugs that have not yet been appraised by the National Institute for Health and Clinical Excellence (NICE), the organisation that appraises new drugs in the UK. The Pass will enable valuable information to be collected and used towards a future NICE appraisal.

“The introduction of the Innovation Pass will allow patients with unmet medical needs to gain early access to the innovative technologies being developed by Life Sciences companies. It also signals to the investment community that the Government understands and supports the innovative Life Science industry in the UK.”

Clive Dix, Chairman BioIndustry Association (BIA)

NHS at the forefront of driving innovation

People with diabetes will be able to simply look into a Glucose Meter to measure their glucose level. Similar in appearance to a mobile phone, device will eliminate the need for the traditional ‘finger stick’ procedure that many users find painful and cumbersome.

Healthcare company, Lein Applied Diagnostics, have developed a non-invasive way of measuring glucose levels by shining a low-power laser beam into the eye. The device promises to alleviate both the pain and the cost of the traditional way of obtaining a glucose-level test, i.e. drawing blood several times a day using a disposable testing finger-stick. Lein are currently undertaking clinical trials and are developing a hand-held device that will be around the size of a mobile phone with support from the National Innovation Centre.

Clinical trials: An evolving environment

The UK has discovered and developed as many leading medicines as the rest of Europe combined.

The NHS is a proven research partner for developing and evaluating new medicines and technologies. It gives companies access to a diverse and characterised patient population, eminent clinicians and researchers across most disease areas. The **National Institute for Health Research (NIHR)** has had a pivotal role in implementing a range of initiatives to streamline and improve the clinical trial process and enable organisations to capitalise on the NHS' unique potential. These initiatives are starting to deliver real benefits by shortening set-up times and accelerating patient recruitment.

In addition, the NHS, working in partnership with research councils and medical charities, has developed internationally leading infrastructure to host and support experimental medicine studies to the highest standards of safety and efficiency. This networked infrastructure is forging strong links with industry partners.

Improvements to UK Clinical Trial Processes

- **The UK Clinical Research Network (UKCRN)** helps to support and deliver high quality later-phase clinical research studies, including clinical trials of interventions in prevention, diagnosis, treatment and care. As a key part of this, the NIHR Clinical Research Network recruited over 330,000 patients to clinical studies in England in 2008-09 and projections indicate that this figure will continue to rise.
- **The Industry Costing Template** has been developed by NIHR to speed up the initiation of industry contract trials in the NHS by reducing the need for site-by-site negotiations. It provides transparency, greater consistency and predictability on costing for companies and, although not compulsory, 90% of nearly 200 NHS Trusts now use the Costing Template for industry-sponsored studies.
- **Integrated Research Application System (IRAS)** is a single online system used to apply for permissions and approvals from ethics committees, the NHS and regulators. All the data required to make a clinical trial application can now be submitted via IRAS, making the system faster and minimising bureaucracy.
- **Nationally approved standard Agreements** have been introduced to speed up the contracting process for industry-sponsored trials carried out in the NHS by removing the need for site-by-site reviews and local legal agreements to be drawn up. They enable trials to start earlier, improving the speed of industry-sponsored clinical trials and giving NHS patients faster access to innovative treatments. For example, the **model Clinical Trial Agreement (mCTA)** removes the needs for sponsors and the requirement for hospitals to draft and review contracts for each trial site. It has halved the average start-up time to 64 days. The **model Clinical Investigation Agreement (mCIA)** is a similar Agreement which has been drawn up for use in medical technology company sponsored clinical trials.
- **NIHR** has introduced a new Coordinated System for gaining NHS Permission (CSP). The CSP replaces a system where 400 NHS Trusts each managed their own approvals. It is used for all NIHR Clinical Research Network studies.
- **The National Research Ethics Service** provides a UK-wide system for ethical review on the principle of one decision for the whole of the UK. Ethics applications now take 35-40 days, on average.

A supportive business and regulatory environment

The UK business environment is consistently ranked among the best in the world, with pro-business policies, a consultative approach to formulating regulations and an internationally competitive tax environment for foreign investors.

An important criterion for Life Sciences investors is access to funding and a fiscal environment that supports innovation and translational science.

The Government will introduce a **Patent Box** from April 2013, reducing the rate of corporation tax from 28% to 10% on income from patents. This will strengthen the incentives to invest in innovative industries and ensure the UK remains an attractive location for innovation. All businesses that develop patents can benefit.

“We welcome this groundbreaking initiative, which has the potential to make the UK one of the most attractive places for business to invest in developing new medicines.”

David Brennan, CEO, AstraZeneca

The **UK Innovation Investment Fund** has been set-up to invest in technology-based businesses with high-growth potential. The Government has now appointed two Fund-of-Fund managers, Hermes Private Equity and the European Investment Fund. Venture capital will be available early in 2010 to invest in innovative UK businesses. The Government investment of £150 million has already leveraged £175 million in additional money. Further private investments will be secured before the Fund closes for investment in 2011 and the ambition is to create a £1 billion 15-year fund.



UK Life Sciences Key Facts

- Two of the top five global pharmaceutical companies have their headquarters in the UK and many others site their European headquarters here.
- Five of the top twenty medicines in terms of global sales were developed in the UK.
- 35% of European biopharmaceutical clinical trials take place in UK centres of excellence.
- The UK attracts almost 10% of the world's pharmaceutical R&D funding.
- Four of the world's top six universities are located in the UK: Cambridge, University College London, Imperial College and Oxford.
- UK scientists have been awarded more than 20 Nobel Prizes in Life Sciences-related disciplines and the Medical Research Council Laboratory of Molecular Biology alone has supported the work of 14 Nobel prizewinning scientists.
- In the last 10 years Life Sciences departments within UK universities have generated over 200 spin-out companies, now employing over 1,000 people.

There has never been a better time for Life Sciences organisations to invest in the UK and to become a part of our dynamic and successful Life Sciences industry.

Collaboration for success

A defining characteristic of the UK is that industry, academia, the NHS and Government work together to create an environment where UK Life Sciences can grow and be globally successful, as well as meeting the healthcare challenges of the 21st Century.

The Government will continue to work to maintain the UK's leading position in the Life Sciences.

Action has been taken at all stages of the innovation cycle from early collaborative work to translate cutting edge science into effective treatments and medical technologies; through providing a new route into the NHS for selected innovations; to increasing access to finance and rewarding innovation through a supportive fiscal environment; to helping companies commercialise for business success.

The UK Life Sciences Super Cluster will bring together the UK's leading researchers and clinicians to drive forward the development of innovative medicines and technologies in critical therapeutic areas.

The Innovation Pass is a scheme that will give patients with rarer diseases access to highly innovative drugs that have not yet been appraised by the National Institute for Health and Clinical Excellence (NICE).

The NHS Life Sciences Innovation Delivery Board has been established with a key objective of improving the strategic relationship between the NHS and the Life Sciences industry including working together to meet the quality and productivity challenge in the NHS.

The Industry and Higher Education Forum is seeing employers, academia and public sector funders working together to equip graduates with the skills and knowledge needed for a prosperous career in Life Sciences.

The Patent Box will apply a 10% rate of corporation tax to income from patents from April 2013. This strengthens the incentives to invest in innovative industries.

The UK Innovation Investment Fund will invest in technology-based businesses with high-growth potential.

For more information about the UK Life Sciences industry and for details of how UK Trade & Investment could support you to invest in the UK, please contact us.

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UK Trade & Investment is the Government organisation that helps UK-based companies succeed in the global economy and assists overseas companies to bring their high-quality investment to the UK.

For further information, please visit
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Published January 2010 by UK Trade & Investment
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URN 10/579 – The UK: collaboration for success.

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Scanning electron micrograph of Purkinje neurons. 2008.



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