Technology Strategy Board
Driving Innovation

Medicines and Healthcare

Strategy 2009-2012

MEDICINES AND HEALTHCARE APPLICATION AREA

The vision of the Technology Strategy Board is for the UK to be a global leader in innovation and a magnet for innovative businesses, where technology is applied rapidly, effectively and sustainably to create wealth and enhance quality of life.

Our three-year organisational strategy is to drive innovation by **connecting** and **catalysing**. To achieve this we are focusing on three themes: challenge-led innovation, technology-inspired innovation and the innovation climate.

For more information on the overall strategy see **www.innovateuk.org.**

We have identified a number of application areas and technology areas on which to focus, and for which we are developing specific area strategies. This document presents the strategy for the **Medicines and Healthcare** Application Area.

Foreword

The Technology Strategy Board aims to make the UK a global leader in innovation. Our job is to ensure that the UK is in the forefront of innovation enabled by technology.

Our task at the Technology Strategy Board is to *Connect and Catalyse*. As part of our challenge-led approach to innovation, we treat societal and economic challenges of the future not just as threats but also as opportunities for innovative solutions that enhance the quality of life and increase wealth.

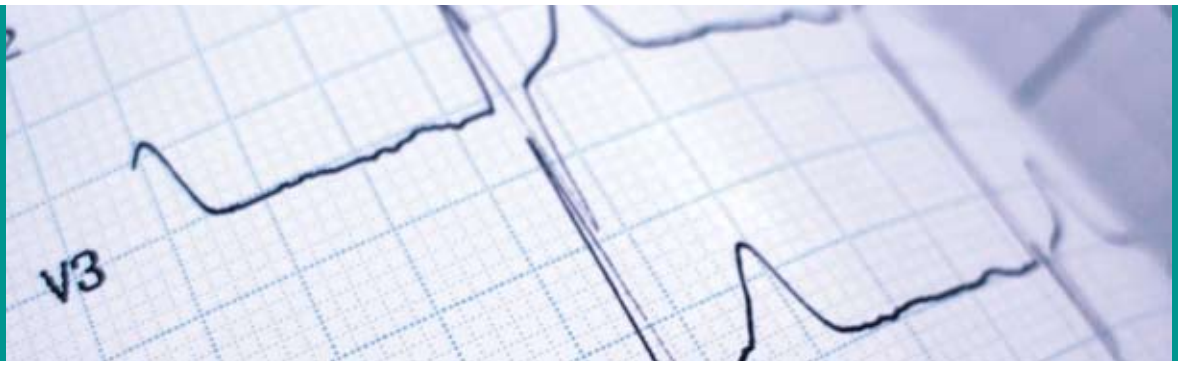
The world is changing. Globalisation, digital communications and the growth of emerging economies present profound challenges to UK business sectors. Yet where there are challenges there are also opportunities. Open access to global supply networks and emerging markets is easier than ever before; the highly skilled workforce, world-class creative industries and science bases, and open-market philosophy also put us in a strong position.

The UK is a powerhouse in the medicines and healthcare technology sectors; this is an industry where we are truly world-class. The industry has developed products and services which have had a significant impact on global healthcare, while Government investment in health research means that the UK has built the foundations to ensure the industry can maintain and improve its potential for innovation. The formation of the Office for Life Sciences has highlighted the importance of the UK medicines and healthcare technology sectors, and will ensure that they are well placed to become a major growth industry.

This strategy provides the context for our investments in the area for 2009-12. It identifies opportunities for the industry in disease prevention and management, diagnosis and treatment, as various trends and drivers make an impact on the way healthcare will be provided in the future. The industry faces a number of challenges in developing solutions to exploit these opportunities, and we will work with key players to enable UK businesses to make full and effective use of the wealth of knowledge and technological development.

Increasing convergence in a wide range of underpinning technologies could lead to innovative solutions to future healthcare challenges. Bringing together the key players and enabling cross-disciplinary collaboration to create innovative solutions is a major strand in this strategy. As a national overarching organisation, the Technology Strategy Board is in a good position to enable collaborations by working with key partners. We have developed close working relationships with the Office for Life Sciences, the Department of Health, the research councils, the regional development agencies and the devolved administrations. We are looking forward to building on these and developing new partnerships with the key businesses in the medicines and healthcare technology sectors, to help implement this strategy and contribute to wealth creation in the UK.

Iain Gray
Chief Executive, Technology Strategy Board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Executive summary

There is no doubt that the UK is a powerhouse in the medicines and health technologies industry. The UK excels in developing medicines and healthcare technologies and has played a major role in establishing the industry on a global stage. The UK medicines industry discovered and/or developed more than 20% of the world's 100 top selling medicines, more than any country apart from the US, and more than the rest of Europe combined. The pharmaceuticals and biotechnology industries contributed 4% of total UK value added in 2008 at £30.1bn, while the healthcare equipment and services sector contributed 0.5% at £3.7bn.

However, the industry is facing key changes and challenges which could dramatically affect healthcare provision (see table below). Many companies acknowledge that there will be serious consequences for the industry unless they embrace new business and innovation models that overcome the development hurdles to the types of products and services that are needed to fulfil the needs of healthcare providers and patients.

This Medicines and Healthcare Strategy provides a business-led vision for the UK medicines and healthcare sector to drive innovation forward in the development of the next generation of disease prevention, diagnosis and treatment. Through this strategy we will work to ensure that the UK remains a dominant player in the global arena.

Addressing healthcare challenges

Current healthcare models are facing greater challenges, both physically and financially, in providing for a growing, ageing population with an increasing burden of disease. For companies to devise solutions to these challenges, they must recognise the drivers behind the healthcare challenges and look at models of:

- disease prevention and proactive management of chronic disease
- earlier and better detection and diagnosis of disease leading to marked improvements in patient outcomes
- highly effective treatments that are tailored to patients' needs and either modify the underlying disease or offer potential cures.

The UK Government has recognised the importance of the industry in meeting these challenges. For example, it has created the Office for Life Sciences, to address key issues affecting the pharmaceutical, medical biotech and devices sectors, and to make a real difference to the operating environment for life sciences companies. It is also boosting the level of investment underpinning health research from £1.4bn a year in 2007-08 to around £1.7bn per annum by 2010-11.

We have built on government priorities, support and investment in developing our strategy for medicines and healthcare to promote business-led innovation aimed at creating wealth and enhancing quality of life.

Global healthcare trends	
Global economics	Increasing affluence in emerging economies sees increasing demand for integrated healthcare provision. The E7 countries (India, China, Brazil, Russia, Turkey, Indonesia and Mexico) are projected to triple their GDPs from $5.1trn in 2004 to $15.7trn by 2020.
Demographics	The proportion of people aged over 65 will increase from 7.3% to 9.4% of the overall population by 2020. The demands of age-specific ailments will place increasingly difficult demands on healthcare services.
Epidemiological trends	Genetics, diet and environmental factors all impinge on the prevalence and severity of disease affecting different populations. Increasing affluence in developing countries will see increases in chronic diseases associated with environment, age and lifestyle. For example, the World Health Organisation estimates that the number of obese people worldwide will increase from 400 million in 2005 to over 700 million by 2015.
Pharmacogenomics	Genetic variations also affect the way individuals respond to drug treatments. The responses can have varying consequences, ranging from poor responses to therapy to quite severe side effects. There is an increased need to understand the basis of these variations in order to improve the development of new treatments as well as patient care.
Environmental change	The impact of climate change on human health is difficult to predict; however, an increase in prevalence or geographical reach of vector-borne diseases (eg malaria and sleeping sickness) is highly likely. Large health effects are also likely from food supply changes, environmental degradation and population movements.
Clinical advances versus financial constraints	Governments, health providers and insurers are under increasing pressure to balance the delivery of healthcare against growing demand and increasing costs for provision. The OECD countries spent nearly $3.5trn in 2005 which could rise to $10trn per year by 2020.

Our strategy

Our UK strategy for medicines and healthcare is challenge-led with a focus on the healthcare market. We have selected some focus areas for investments which we believe are key to addressing market needs and opportunities. Our focus areas are:

- commercial translational research
- uptake of innovation
- facilitating collaboration.

We selected these areas on the basis of the Technology Strategy Board criteria for investment (see our corporate strategy *Connect and Catalyse* for further information).

- Does the UK have the capability?
- Is there a large market opportunity?
- Is the idea ready?
- Can the Technology Strategy Board make a difference?

UK businesses in the medicines and healthcare technologies sectors face both business and technological challenges in translating promising ideas and concepts into products and services that meet healthcare providers' and patients' needs. Furthermore, there is the requirement to closely align those articulated needs and the research and development programmes, not only to ensure the right products and services are designed and built but also to facilitate their adoption and uptake.

The pace of change in technology development means that it will be 'innovation supply chains' that compete in the future and not individual companies. Developing and nurturing this network of innovative players is key to continued success for this sector through encouraging collaborative working and knowledge exchange to overcome the technological and business challenges and hence create a robust commercial R&D base, stimulate economic growth and return wider benefits to the UK.

Our focus areas

Commercial translational research

Translational research refers to the process of taking the findings from basic or clinical research and using them to produce innovation in healthcare settings, or the process of converting basic and clinical research into ideas and products and introducing those products into clinical practice.

Medical translational research is multidisciplinary in nature, involving basic, applied and clinical scientists focused with one end in mind, that of delivering real and cost-effective benefits to patients. However, reports have identified gaps in, or a lack of co-ordination of, funding and other support mechanisms for taking ideas from the lab to a stage at which a commercial partner might take them on, or to a stage where a small or medium-sized enterprise developing such ideas might be able to access commercial financing or partnership opportunities to bring products to market.

The Technology Strategy Board will:

- work with industry to identify and articulate key challenges faced by medicines and healthcare technologies companies in translating ideas into products and services that have the potential to lead to step changes in disease prevention and management, diagnosis and treatment
- focus our investments and support to address the business challenges, through engaging the technical and knowledge base in academia, in clinical research and industry to enable the development of the best solutions.

Uptake of innovation

A significant challenge facing innovators is the uptake of the products by healthcare providers. The provision of healthcare can be an emotive issue and payers have to try to make objective decisions on whether a new diagnostic, device or treatment should be used, occasionally based on limited usage information available at the time of product launch. It is incumbent on the innovators to provide the relevant information and demonstrate the value of their products in the context of how they will help address the healthcare providers' challenges.

Furthermore, poor uptake of innovation is not allowing companies to carry out critical post-marketing surveillance for novel drugs and devices, and hence delays their ability to carry out incremental improvements to their products.

For businesses – particularly small and medium-sized enterprises – failing to appreciate the needs and drivers of end-users and patients can lead to some of the problems relating to the implementation of innovation.

The Technology Strategy Board will:

- work with industry to identify the need for knowledge exchange, between key players at the early stages of product development, with the aim of developing new tools to demonstrate the value of innovative treatments and interventions and new business models for the industry
- work with the Department of Health, the devolved health departments and the NHS National innovation Centre to understand and clearly articulate the problems and needs of end-users and patients so that businesses can design and build the best solutions.

Facilitating collaboration

The medicines and healthcare environment in the UK presents significant opportunities for collaborative working between the large pharmaceutical companies, small and medium-sized enterprises and the academic and clinical base, to address challenges in healthcare together. However, cultural, institutional and financial barriers have been identified around collaborative working, which ultimately affect the translational process. Addressing these barriers is a key challenge to ensuring continued success for the UK-based sector.

The Technology Strategy Board will:

- work with the newly created Health Tech and Medicines Knowledge Transfer Network and existing collaborative programmes and networks to engage industry in building 'innovation supply chains' to create an integrated approach to collaborative working.

How are we going to do it?

Working in partnership

All of our work will require a partnership approach involving the different technology and application areas within the Technology Strategy Board along with collaboration with key government departments, the Office for Life Sciences and Office for Strategic Coordination of Health Research, research councils, and the regional development agencies and devolved administrations. Involvement in international activities (in collaboration with UK Trade and Investment) will be essential to ensure that we take a global perspective when positioning interventions in innovation in the UK as well as to ensure international markets are accessible to companies investing in innovation in the UK.

We aim to maximise the impact of joint working – using the Technology Strategy Board's position to bridge the gap between the public and private sectors. We will also increase the focus on developments within the EU and the Framework programmes since the opportunities for increased financial gearing for projects, along with building strategic alliances, is gaining greater importance for UK businesses.

The Technology Strategy Board will:

- work with our public sector stakeholders, especially the regional development agencies, the research councils, relevant government departments and the Office for Life Sciences, to deliver aligned programmes and create a 'joined-up' approach for companies looking to deliver innovation in this industry.

The Technology Strategy Board will:

- develop tools to stimulate and address bottlenecks in innovation to support UK businesses in the medicines and health technologies sector. This will start with a programme of activity in the field of regenerative medicine
- assess the need for a Technology Strategy Board innovation platform for stratified medicine. Stratified medicine is an approach to identify and classify patients into subgroups that differ in their susceptibility to a particular disease or side effects to treatment
- work with research council initiatives such as the Medical Research Council's Development Pathway Funding Scheme, the Biotechnology and Biological Sciences Research Council's Industry Clubs, and the Engineering and Physical Sciences Research Council's Nanotechnology Grand Challenge in Healthcare, and put tools in place to enable businesses to pull the research that addresses their challenges through to market
- invest in knowledge transfer partnerships and ensure that medicines and health technology companies can fully utilise and appreciate the role of knowledge sharing between disciplines
- work with stakeholders to develop metrology and standards that will stimulate innovation and provide competitive advantage to UK business
- seek to identify, with stakeholders, European and international strategic alignment and financial gearing opportunities to support improvements in UK competitiveness and inward investment.

1. Background and context

The global population is projected to grow from 6.5 billion in 2005 to 7.6 billion in 2020 [1]. At the same time, the population will also be getting older, with the proportion of people aged over 65 increasing from 7.3% to 9.4%. With the increasing aged population comes a growing demand to manage chronic and age-related illnesses, with four in five of those aged over 75 years old taking at least one prescribed medicine and 36% of over 75 year olds taking four or more [2].

The Organisation for Economic Co-operation and Development (OECD) countries spent nearly $3.5trn in 2005 on healthcare services [3] with over $1.8trn being spent by the US alone and the UK spending some $144bn. Projections estimate the healthcare bill for the OECD countries will stand at $10trn per year by 2020 [4], with the US spending some 21% of its GDP and the rest of the OECD countries spending an average of 16% of their GDPs on healthcare by 2020.

Growing demand for integrated healthcare provision is being seen in emerging economies such as India, China and in South America, representing major opportunities for businesses operating in and supplying the medicines and healthcare technologies sectors. Increasing affluence in developing countries will also see increases in chronic diseases associated with lifestyle. For example, obesity levels have been growing steadily and the consequences of the condition threaten to rank among the biggest causes of premature death in both the industrialised and emerging economies.

Diagnosing diseases, and providing treatments and cures for them, requires cutting-edge researchers and innovative organisations in biological and physical sciences, and engineering, to work together. The outcomes of this convergence have led to the translation of basic discoveries in biology, physiology and biochemistry into an understanding in disease pathophysiology, pharmacology and toxicology, and provided the vision and the leadership to bring the next generation of medicines, healthcare diagnostics and devices to market (Figure 1).

The UK has excelled not only in the basic sciences, but also at leveraging this research in the development of medicines and healthcare technologies, resulting in the growth of world-leading businesses and attracting other global companies to establish research and development operations here. However, a number of key factors and challenges affecting the provision of healthcare in the near future and the global industry as a whole have meant a juncture has been reached and key decisions made now will be crucial in ensuring the UK remains a powerhouse for successful innovation.

The importance of the life sciences sector to the UK economy was highlighted by the creation of the Office for Life Sciences announced by Prime Minister Gordon Brown on 27 January 2009 at a Number 10 summit to address key issues affecting the pharmaceutical, medical biotech and devices sectors, and to make a real difference to the operating environment for life sciences companies [5].

This Medicines and Healthcare Strategy provides a business-led vision for the UK medicines and healthcare sectors. Building on the Department of Trade and Industry's Bioscience and Healthcare Technology Strategy published in April 2006 [7], this document provides an overview of the Medicines and Healthcare Application Area: the markets, their drivers, size and structure, and the UK position.

The aim of this strategy is to define the key challenges facing the medicines and healthcare technology sectors in 2009-12 along with our assessment of the key technology priorities in medicines and healthcare that offer significant opportunities to drive business growth. We highlight a number of challenges which the Technology Strategy Board will address with a series of interventions, including investment, with our stakeholders and partner organisations.

We will also consider where exploiting technology-enabling activities, such as standards and metrology, and emerging technologies would significantly advance technology innovation. In the context of the Technology Strategy Board's wider remit to highlight barriers to innovation, we have also considered areas for improvement relating to the uptake and adoption of innovative products and services by healthcare providers.

The strategy is based largely on input from industry, either directly or through our knowledge transfer networks (KTNs) and roadmapping exercises, and has been refined through feedback from a group of stakeholders and internal analysis.

Figure 1 – Pathway for translation of health research into healthcare improvement [6]

In parallel with the development of the *Medicines and Healthcare Strategy*, we have published documents on advanced materials; electronics, photonics and electrical systems; high value manufacturing; information and communication technologies; and emerging technologies. We are also working on strategies for bioscience and nanotechnology. All of these areas underpin the innovations in the medicines and healthcare technologies sectors.

1.1 Global healthcare trends

A number of trends are emerging around the world, which have immediate relevance to the industries providing technologies and solutions into this sector:

- **Global economics:** Emerging economies have seen sustained double-digit growth with increases in scientific, technological and industrial capabilities. The E7 countries (India, China, Brazil, Russia, Turkey, Indonesia and Mexico) are projected to triple their GDPs from $5.1trn in 2004 to $15.7trn by 2020 [4]. In parallel, higher incomes in affluent groups enables more people to afford expensive healthcare technologies to prolong and improve quality of life.
- **Demographics:** An increasingly ageing population in developed countries is driving healthcare demand. The level of healthcare spending on patients aged 80 or older in the US is 11.5 times as much as it is on patients aged 50-64 [4]. The consequences of age-specific ailments will place increasingly difficult demands on healthcare services.
- **Epidemiological trends:** Genetics, diet and environmental factors all impinge on the prevalence and severity of disease affecting different populations. Increasing affluence in developing countries will see increases in chronic diseases associated with environment, age and lifestyle. Obesity levels have been growing steadily and have now reached epidemic proportions, and the condition threatens to rank among the biggest causes of premature death in both the industrialised and emerging economies. The impact of obesity on the rates of chronic conditions such as cardiovascular disease, and on metabolic syndromes such as diabetes, means healthcare providers will have to allocate significant resources to address these problems (Appendix 1) [8, 9].
- **Pharmacogenomics:** Genetic variations also affect the way individuals respond to drug treatments (see panel below). Responses can vary, ranging from poor responses to therapy to quite severe side effects. It is now recognised that not all medicines are suitable for all patients and this will require the development of stratified patient populations to better understand the underlying genetic differences and subsequently the tailoring of 'personalised' treatments.

African-American soldiers who developed severe anaemia after taking the anti-malarial drug primaquine were found to be deficient in the enzyme glucose-6-phosphatedehydrogenase, an enzyme necessary to metabolise this type of drug. This inherited difference in metabolism was later found to affect 400 million people worldwide [10].

- **Environmental change:** The impact of environmental change on human health is difficult to predict; however, an increase in prevalence or geographical reach of vector-borne diseases (such as malaria and sleeping sickness) is highly likely [11]. While western Europe and North America are less likely to be affected due to the cooler climate and better access to healthcare, increased mobility through the growth of international travel and its impact in terms of an increase in the rate of infectious diseases in the rest of the world will have major implications for healthcare providers. In addition, rising CO_2 levels, leading to increases in the occurrence of allergenic plant pollens along with other pollution sources, are likely to lead to increases in chronic respiratory diseases. Changes in food supply, environmental degradation and population movements are all likely to have a large effect.
- **Clinical advances versus financial constraints:** Building on the science base, an improved understanding and knowledge of biological systems has led to the development of new and innovative therapies and devices. Allied with an increasingly well-informed and demanding public seeking the latest treatments, governments, healthcare providers and insurers are under increasing pressure to balance the delivery of healthcare, with growing demand and increasing costs of provision. The importance of outcomes data and the assessment of effectiveness, costs and broader impact of treatments will see changes in the way healthcare is provided, with increasing requirements on companies to present evidence that products work **and** provide value for money.

2. Industry overview

2.1 Market segmentation

The medicines and healthcare industry for the purposes of this strategy and the Technology Strategy Board's Medicines and Healthcare Application Area covers the medicines (that is, pharmaceuticals and biopharmaceuticals, and gene and cell-based therapies) and healthcare technology industries.

Medicines

Traditionally, pharmaceuticals include small molecule compounds such as aspirin or salbutamol (Ventolin®), while the newer biopharmaceuticals include recombinant proteins such as synthetic human insulin or erythropoietin, which controls red blood cell production. The promise of gene and cell-based therapies has seen the emergence of pioneering products treating conditions as diverse as chronic wounds and bladder replacements, leading to a convergence in medicines and medical device technologies.

The sector as a whole has seen much change over the last five years as the traditional fully integrated pharmaceutical companies, with a predominant focus on small molecule therapies, have been moving into areas traditionally associated with biotechnology companies through acquisitions or strategic alliances. This broader focus has led to more of the large pharmaceutical companies becoming involved in the discovery, in-licensing, development and production of biopharmaceuticals (monoclonal antibodies, antibody fragments and recombinant proteins), gene and cell-based therapies, and a renewed interest in the development of novel vaccines.

The drug development process – bringing a new medicine to market – can take 10-15 years after the initial discovery has been made (Figure 2). The costs of bringing a single new drug to market can range from $800m-$1,000m, driven by regulators' increased requirements to prove safety and efficacy and by the high number of compounds that fall by the wayside during the development process [12].

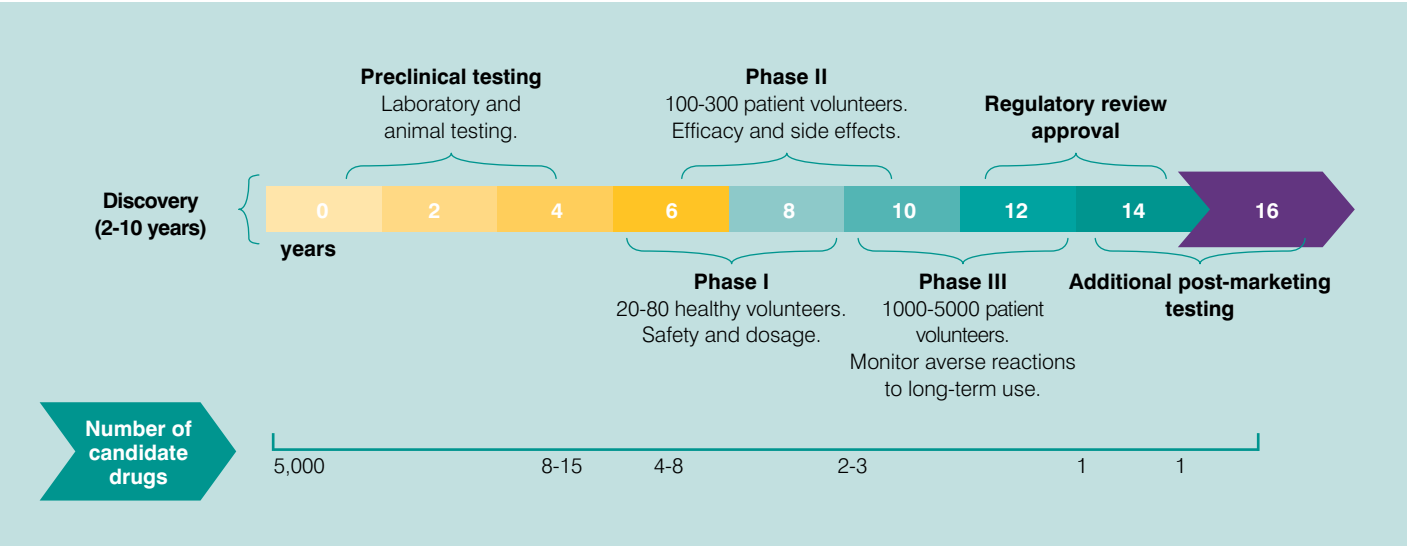
Some 5,000 distinct molecular entities enter the development pipeline and are tested and evaluated in order to bring one medicine to market. So if drug developers can overcome the technical challenges of making these assessments accurately and quickly there can be a substantial increase in their productivity and profitability.

Healthcare technology

Healthcare technologies cover a diverse range of medical and diagnostic devices used to diagnose, prevent, monitor or treat illness or disability. Examples of devices can range from contact lenses, catheters, pacemakers, heart valves, resuscitators and radiotherapy machines, blood glucose monitors, and short and long-term implants, to wheelchairs and other assistive technology products. This is not an exhaustive list, yet the research and innovation in the technologies underpinning these devices has resulted in a dynamic and diverse industry bringing new and innovative products to market.

There is an increasing drive towards combination products that are physically, chemically or otherwise combined and produced as a single entity. Examples include drug-inhaler device combinations or stents incorporating a drug.

Figure 2 – The drug development process



Adapted from diagram courtesy of the British Pharmaceutical Industry

The regulatory requirements for medical devices are more stringent for these more 'active' devices and new combination technologies increasingly cut across the established boundaries for medicines and devices.

The healthcare technologies market is complex with numerous routes for innovation and product development. The result is a fast moving market, with an average product having a life-cycle of 18 months before being upgraded [13]. The product development process is driven by clinical need and a regulatory landscape that determines whether a device is accepted for use. However, regulatory acceptance does not automatically mean the product will be adopted by healthcare providers, and convincing the procurement bodies of the value in adopting new technologies becomes a key factor in success or failure.

The emergence of the e-health field – the use of electronic resources for storing and remotely accessing medical records – coupled with the development of telemedicine for remote diagnosis of patients, offers new opportunities for companies working in the sector. The potential to develop 'integrated solutions' with devices and diagnostics connected into data networks to provide healthcare professionals with information online and in real time, has the potential to provide major step-changes in the provision of healthcare.

3. Medicines

3.1 Global market size

The global audited medicines market grew to $773.1bn in 2008. The market enjoyed a compound annual growth rate (CAGR) of 11% between 1999 and 2003 [14, 15] however, year-on-year growth slowed to 6.6% in 2008, largely as a result of increased competition from generic products and the effects of continued healthcare cost containment across major markets. The largest market in 2008 was North America with sales of $311.8bn, followed by Europe at $247.5bn (Table 1). However, projections see the highest growth in the next 2-3 years being seen in Latin America and Asia, in line with the estimated growth in the economies in these areas.

Looking at the value of sales generated by therapeutic-class medicines (Table 2), the top revenue generators for 2008 were the anti-cancer agents, capturing some 6.2% of the market, followed by the lipid regulators (such as cholesterol lowering drugs). In terms of individual products, the top 10 leading products enjoyed sales of over $67.8bn, with the top seller alone, Pfizer's Atorvastatin (a blood-cholesterol lowering drug), on sales of $13.65bn.

Continuing a five-year trend, the global biopharmaceutical market grew at nearly double the rate of the global pharmaceutical market in 2007, posting sales of over $124bn and a growth rate of 12.5%. Biopharmaceuticals are forecast to grow to around 30% of the total global medicines market by 2015 and currently represent a third of all pharmaceuticals in development [16].

The application of biopharmaceuticals into therapeutic areas once thought of as 'niche' but where there was unmet clinical need, has led to many products achieving blockbuster status – sales of over $1bn a year. Of the 106 blockbusters sold in 2007, 22 were biopharmaceutical products, up from only six products in 2002.

Table 1 – Global medicines market

World market	2008 sales ($bn) audited	Growth YoY 2003-08 (%)	Projected CAGR 2003-08 (%)
North America	311.8	5.7	-1-2
Europe	247.5	6.4	3-6
Japan	76.6	2.7	1-4
Asia, Africa and Australia	90.8	13.7	11-14
Latin America	46.5	12.7	11-14
Total	**773.1**	**6.6**	**3-6**

Table 2 – Therapeutic-class medicines global market

Audited market 2008	Sales ($bn)	2008 Growth (%)
Anti-cancer	48.2	11.3
Lipid regulators	33.8	-2.3
Respiratory agents	31.2	5.7
Antidiabetics	27.3	9.6
Acid pump inhibitors	26.5	0.6
Antipsychotics	22.9	8.0
Angiotensin II antagonists	22.9	12.6
Antidepressants	20.3	0.6
Anti-epileptics	16.9	9.7
Autoimmune agents	15.9	16.9
Top 10	**265.9**	**10.0**
Global market	**773.1**	**4.8**

Source: Audited figures from IMS Health

The emerging fields of gene and cell-based therapies offer the potential for completely new paradigms in treatment if problems in efficacy, safety and production can be addressed. The potential to offer cures for chronic diseases represents significant opportunities for innovative businesses. Examples of early gene therapy trials include the treatment of inherited retinal disease at the Moorfields Eye Hospital and University College London's Institute of Ophthalmology [17], while regenerative medicine saw more than 250,000 people treated worldwide in 2006 with sales of $300m-$400m [18] predominantly in the areas of wound healing.

3.2 Industry structure

Fully integrated large multinational companies dominate the pharmaceutical industry in terms of market capitalisation. These companies owe much of their success to discovering and developing small molecule drugs that have gone on to achieve blockbuster status for treating chronic diseases, resulting in the industry achieving growth and revenues in double digits. Total pharmaceutical sales from the top 10 companies accounted for nearly 40% of the total market in 2008 [5]. Strong sales have driven investment in R&D with the medicine sector responsible for more than 19% of global R&D expenditure in 2007 at $86.5bn [20].

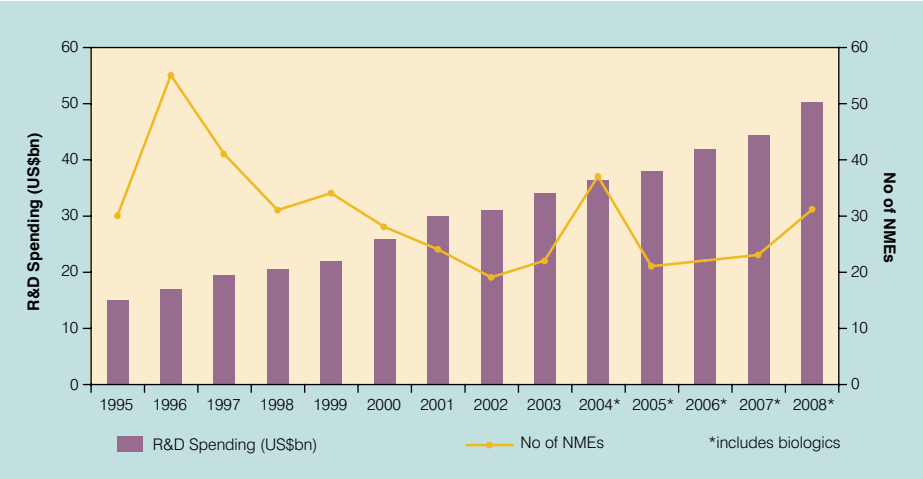
However, returns on expenditure have been diminishing over the last 10 years with fewer new molecular entities entering the market relative to the amount spent on R&D (Figure 3). In addition, generic competition will see an estimated $67bn drop in large pharmaceutical company annual US sales between 2007 and 2012 as more than 36 drugs come off patent. The average effective patent life for major pharmaceuticals in 2005 was 11 years [12], and the increase in time it takes to bring products to market will put pressure on pharmaceutical companies to maximise returns while patent protection remains on their products.

Cost containment in drug discovery and development has become increasingly challenging, with costs reaching in the region of $1bn per new molecular entity arriving on the market. The reasons are essentially twofold: greater demand for assurance on safety and efficacy by the regulators, and late-stage failure of drug candidates during development, an area which is still inherently difficult to predict.

Why drugs fail on safety and efficacy

- highly novel targets, for which there is limited knowledge relating biology to human disease
- a poor understanding of the mechanisms causing some diseases (such as Alzheimer's)
- limitations in the animal models of human disease
- few biological markers (biomarkers) that describe the disease process and help optimise treatment [21].

Figure 3 – Year-on-year R&D spending (US) vs new molecular entities and biopharmaceutical drugs [4]



Sources: FDA/CDER Data, PhRMA data, Pricewaterhousecoopers analysis

Industry estimates indicate that only 30% of drug candidates make it through phase 2 clinical trials and only one in 20 drugs entering clinical trials in the cancer area will actually become approved medicines. The costs and risks associated with such a high attrition rate obviously have the potential to stifle innovation.

The large pharmaceutical companies initially responded to these challenges in a variety of ways including mergers and acquisitions among the big players in order to rationalise costs and exploit competing pipelines. However, the anticipated economies of scale have not materialised and companies have been increasingly looking for strategic alliances, in-licensing technologies and promising candidates from smaller innovative biotechnology-based businesses. Other changes in business models include focusing on new innovation models by opening smaller, focused and more 'nimble' research centres and by outsourcing non-core functions such as manufacturing and clinical trials.

Biotechnology applied to the treatment of disease began in earnest in the 1980s with the launch of a number of biopharmaceutical drugs, the first being E. coli-derived insulin in 1983. Over 70 biopharmaceuticals are on the market, treating many formerly untreatable diseases (such as Trastuzumab for early-stage breast cancer, and Natalizumab for certain forms of multiple sclerosis).

Many biotechnology companies have found their route to market through partnering with the major pharmaceutical companies due to the costs associated with late-stage development or selling into international global markets. Due to the relative immaturity of the industry and the high cost of drug development, the biopharmaceutical sector is heavily dependent on equity funding for start-ups and growing businesses. In 2007 global venture capital investments in the sector reached an all-time record of $5.4bn, although returns can take a long time to realise with the 1,400 or so private biotech companies in Europe collectively losing $3.6bn per year [23].

How biopharmaceuticals can address unmet clinical needs

Examples

Vaccines: Human papilloma virus infections are the major cause of cervical cancer, and the developments of the Gardasil® and Cervarix® vaccines have led to a radical shift in preventing cancer through immunisation of teenage girls. Meanwhile, Wyeth's pneumococcal conjugate vaccine, Prevnar®, reached sales of $700m in the US within 15 months of launch, and reached $2.7bn in 2008 [22, 24] due to its ability to reduce pneumococcal infections.

Antibodies: The drug Humira® is an immunosuppressant that can reduce the signs and symptoms of rheumatoid arthritis. Created using patented technology derived from research at the MRC's Laboratory of Molecular Biology and the Scripps Research Institute in California, Humira® became the first UK-discovered biopharmaceutical to reach blockbuster status with sales of $1.4bn in 2005 and led to the MRC receiving a $265m royalty buyout. In 2008, sales grew to $4bn [15, 25].

The long return on investment timeframes, along with some notable business failures, has dissuaded many venture capital firms from continuing investment in biotechnology businesses. Furthermore the global financial climate over the past few years has meant that the viability of flotation on AIM or NASDAQ have diminished substantially, reducing the options available for companies to grow and restricting exit routes for early investors. This has diminished the ability of the smaller biotechnology firms to grow sustainably. Many biotechnology firms are offering services to other players in the value chain – based on their proprietary technology platforms – in order to minimise their cash burn rates whilst reinvesting the revenues in their own in-house discovery and development pipelines.

The move away from the fully integrated pharmaceutical company and repositioning along the value chain has had major implications for all businesses in the sector. It has led to the emergence of service-based companies, or contract research and manufacturing organisations, providing the necessary capacity and capabilities when required. The customers for these contractors have not just been the major pharmaceutical companies but also the smaller firms, allowing the latter to improve their value proposition in developing their own pipelines. Many of the service-based companies have themselves become global businesses and have taken positions all along the pharmaceutical development and manufacturing value chain.

It is widely recognised that the large pharmaceutical company business model for producing mass market blockbusters is unsustainable due to the high costs and risks in development and limited differentiation between competing products that are, at best, effective in 35-75% of the patients being treated [26].

However, as a better understanding of underlying disease processes emerges it is possible to link patient genetics to disease mechanisms and improve the likelihood of tailoring treatments to patient needs. This will require a major change in business models looking to treat 'fragmented patient markets' and companies becoming more proactively involved in managing patient disease as part of a new value proposition for healthcare providers.

Furthermore, it is increasingly difficult for a single company to bridge the entire value chain between discovery and development to product launch. Collaborative working is important, with companies able to source innovation from a variety of places, either through other businesses or the academic base. However, issues such as protection of intellectual property, unreasonable expectations as to the potential value of innovations, and a lack of transparency and trust among potential partners are key barriers to collaborative working.

3.3 Market dynamics

The global pharmaceutical market is forecast to grow to around $895-1,034bn by 2013, an equivalent CAGR of 3-6% [14]. The big growth markets are unsurprisingly found in the emerging economies with CAGRs for Asia/Africa/Australasia and Latin America projected to be 8-14% over the same period.

According to IMS Health, sales by generic manufacturers in 2006 amounted to $54.1bn, over 2.5 times the value in 1998, with existing generics commanding 60% of US prescriptions.

In 2007, 40% of sales came from 'specialist care'-driven medicines, with the remainder serving the 'primary care'-driven markets [14]. As the number of established 'on-patent' drugs diminishes, there will be a decline in the size of the market for primary care-driven drugs. Value growth will be limited to areas of unmet need, with most growth in specialist care classes such as cancer. Recent trends have shown that the specialist care market contributed up to 65% of the growth seen in the medicines market in 2007 [14].

However, cost constraints within healthcare provision are creating tensions between the industry and the payers, and the drive to cap prices paid or control access to innovative medicines through assessing health economics is creating uncertainty in the long-term relationships between the industry, healthcare providers and governments. A number of programmes have been introduced to improve the productivity in healthcare systems (eg health technology assessment). These are all projected to affect the market for new medicines going forward.

3.4 UK position and global status

UK pharmaceutical industry exports were worth £14.6bn in 2007, with a trade surplus of £6bn [27]. GlaxoSmithKline and AstraZeneca are ranked second and fifth in the world in terms of global sales, at $36.5bn and $32.5bn for 2008 respectively [15]. The industry in the UK employs around 73,000 people directly and generates another 250,000 jobs in related industries.

The pharmaceutical sector is a leading industrial funder of the research base in the UK, with seven major pharmaceutical companies contributing to the provision of 564 PhD studentships and 318 post-doctoral grants in 2007 [28]. In terms of 'value added'[1], pharmaceuticals and biotechnology contributed 4% of total UK value added in 2008: worth £30.1bn or approximately £150,000 per company employee [29]. AstraZeneca and GlaxoSmithKline jointly created over £26.3bn in valued added to the UK.

The UK pharmaceutical industry is responsible for the discovery and/or development of more than 20% of the world's 100 top selling medicines, more than any other country with the exception of the US, and more than the rest of Europe combined [27]. The 2008 Government R&D Scoreboard indicated that pharmaceuticals and biotechnology companies invested around £7.9bn in R&D in the UK in 2007, a 7% increase over the previous year. This underlines the strength and breadth of the UK industry to invest in and exploit innovation and subsequently gain and maintain market share [20]. In 2007 GlaxoSmithKline and AstraZeneca collectively invested £5.7bn in R&D; 26% of the total R&D spend of the top 850 UK companies. Pfizer, the world's largest pharmaceutical company, was the biggest single inward investor in pharmaceutical R&D in the UK [30].

The UK hosts more than 400 pharmaceutical and biotechnology-based companies (UK Trade and Investment and Bioindustry Association estimates) and has the largest and most mature biopharmaceutical product pipeline in Europe and is second only to the US [16]. However, the UK's share of the global biopharmaceutical pipeline has been declining, from 11.4% in 2005 to 8.5% in 2008, accounted for by the rapid growth of pipelines in other countries, especially the US but also Switzerland, Canada, Japan, France and Israel.

Total sales of medicines to the NHS were £10.3bn in 2008, representing 9.2% of total NHS costs [27]. The number of new product launches fell in 2006 in the UK, with the country showing the lowest uptake of drugs based on new molecular entities in Europe, and this is driving concern about the UK's continued role as a major force of innovative research and development [14].

Assessing the cost-effectiveness of new medicines is carried out by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Medicines Consortium, which produce national guidance in public health, healthcare. technologies and clinical practice and make recommendations on the implementation of new and existing treatments. Decisions are based on available evidence and assessment of cost-effectiveness and the concept of quality-adjusted life years (QALY) based on the number of years of life that would be added by a medical intervention. The 'NICE process' is increasingly being seen as the fourth stage-gate in drug development – the others being safety, efficacy and quality – that medicines makers need to clear in order to gain market traction.

The introduction of health technology assessment has meant greater scrutiny of the evidence required to demonstrate the value of new product innovations, and 'payment for performance' will be a key driver going forward. The activities of NICE are being assessed on the world stage, not just by drug companies but also by healthcare insurers, regulators and policymakers as a model for assessing cost-effectiveness and economic value [31]. Indeed, the US Congressional Budget Office has estimated that the US could save up to $700bn annually if physicians and patients had more unbiased data on the effectiveness of medical treatments available to them [32]. However, some of the industry's newest products have had NICE approval denied or restricted, which has disappointed drug companies and patient groups alike. Bridging the gap between patients, healthcare providers and the industry is seen as the key to success.

1. Value added = value of sales – cost of bought-in good and services

Indeed this approach had led to innovative approaches in encouraging the uptake of new treatments. For instance, when the treatment was initially rejected by NICE, the makers of Velcade™, a treatment for multiple myeloma, offered the treatment to the NHS on the basis that the company would refund the cost of treatment in patients that did not show any improvement.

The UK Government's investment in underpinning health research is channelled in a number of ways, focusing on research in the NHS and the academic base. This investment is also increasing with both the MRC and the National Institute for Health Research (NIHR) jointly increasing research funding in the NHS and academic base from £1.4bn in 2007-8 to around £1.7bn for the period 2010-11.

The Government's ongoing investment has led to the establishment of a number of academic and clinical centres of excellence. The Biotechnology and Biological Sciences Research Council (BBSRC) has centres for biomedical and food sciences as well as a number of structural biology and systems biology centres (co-funded with the Engineering and Physical Sciences Research Council, EPSRC).

The MRC has 32 research units and institutes, and supports around 4,000 research scientists, 3,000 staff in universities, hospitals and medical schools, and has provided funding for 27 Nobel Prize winners to date. The NIHR has provided funding for a number of clinical research networks to support a high-quality portfolio of clinical trials and other studies to promote patient and public involvement in health research. It is boosting the numbers taking part in clinical trials, improving their speed, quality and co-ordination, and strengthening NHS links with industry.

The medical research charities also make a significant contribution to health research, spending over £791m annually in 2006-07 [26]. In the six years leading up to 2008, charities spent more than £5bn on research in the UK, contributing significantly to the knowledge and understanding in the life sciences, medicine and health.

4. Healthcare technology

4.1 Global market size

Estimating the global market for healthcare technologies is complex due to the diverse range of products and the myriad number of companies, predominantly small and medium-sized enterprises (SMEs) working in this area. There are around 10,000 generic product types, generally having short life-cycles (typically 18 months), with the majority of new products bringing added functions and clinical value based on incremental improvements [13].

Further complications come through attempts to segment markets, which can lead to distortion in market sizes depending on how certain products are classified. The size of the healthcare market is often under-represented as many companies supply into this field but are not identified as healthcare companies in their own right. This will increasingly be the case as converging technologies result in increasingly complex medical products.

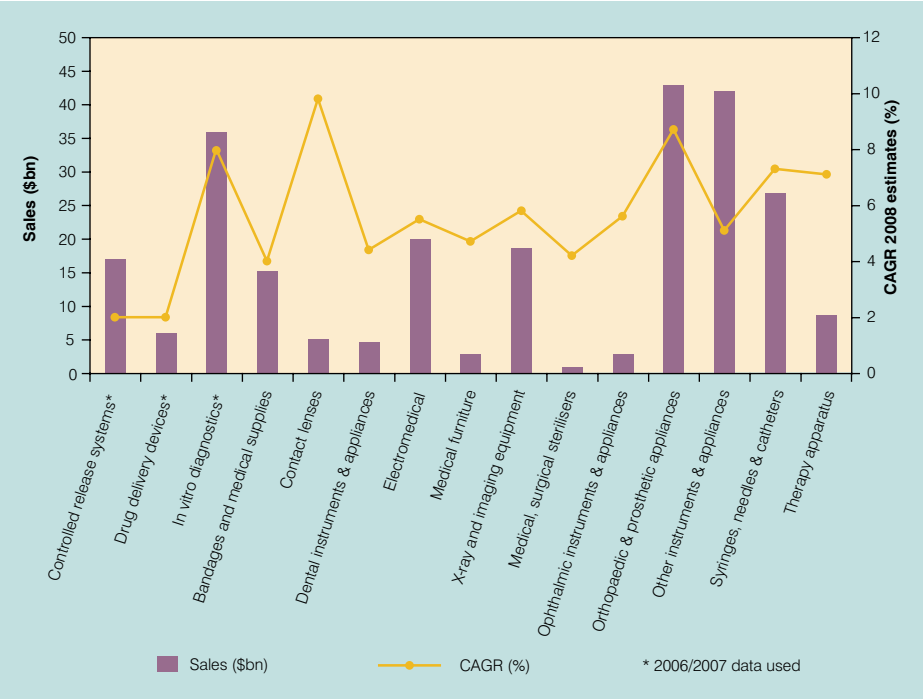
Data from Eucomed indicate a global healthcare technologies market worth around $300bn. The global medical device and equipment market is expected to grow steadily by 4.6% a year over the period 2008-13; however, many sub-sectors have projected growth close to double digits. An indication of market sizes is given in Table 3. Europe spends around 0.55% of GDP on medical technologies while the US spends around 0.84% [13].

Table 3 – Worldwide sales of healthcare technologies

Country	2007 sales ($bn)
US	124
Europe	100
Japan	30
China	5
Brazil	4
Rest of the world	37
Global market	300

Adapted from Eucomed figures [13]

Figure 4 – Global market sizes and segmentation for healthcare technologies



2008 market data from Espicom and McGrath & Associates

We can break the market down by product area in a number of ways for healthcare technologies; Figure 4 indicates one view of the scope of products available and estimates of CAGR from 2008 onwards.

4.2 Industry structure

About 85% of all companies operating in the healthcare technologies market are SMEs making medical devices [13]. However, around 80-85% of the global market by sales is dominated by 40-50 companies [34, 35]. Across Europe there are around 11,000 companies working in the healthcare technologies sector, collectively employing around 435,000 people.

Many large companies owe their success to navigating this complex market space, understanding target markets and adopting strategies to focus their product marketingon specific customer needs. Many SMEs look to license their technology to larger partners to develop their route to market, which in many cases has resulted in mergers and acquisitions, with the SMEs being absorbed by global players.

A number of technologies underpin the medical device supply chain. Table 4 illustrates the technologies used by companies in the sector and their application in key markets, and reflects the multidisciplinary and collaborative nature of healthcare technology development. Supply chain structure has a pronounced effect on the innovation strategies of medical device companies, due to the drivers in the different sub-sectors (such as offshoring and outsourcing in the electronics sector).

The medical devices sector introduces new products and then improves on them incrementally, driving companies to maintain and focus on R&D, sales, marketing and after-sales service as part of their core competencies. Companies usually outsource manufacturing where product complexity is low. However, for orthopaedics for example, where product integrity is a key feature and the manufacturing process is complex, companies maintain these high value-added activities in-house.

Table 4 – Value chain activities and their applicability to key healthcare market sectors

Healthcare market sector						
Value chain activities	**Orthopaedics**	**Respiratory and electromedical devices**	**Advanced wound management**	**Radiotherapy equipment**	**Imaging**	***In vitro* diagnostics**
Precision mechanical engineering	**High**	**High**				
Electronics		**High**		**High**	**High**	**High**
Biochemistry			**Med**	**Med**	**Med**	**High**
Biotechnology	**Med**		**High**			**High**

Successful healthcare technology companies link their R&D capabilities with clinical studies, and the process of observing clinical procedures with healthcare professionals is seen as a key success factor in innovating to address unmet clinical needs. Indeed, competitive advantage can be built around bridging the gap between the technology and the end-user. Interestingly, the AD Little report [34] indicated that R&D and home markets are closely linked, with the latest innovations being trialled and tested in the home market closest to the R&D base. The ability of the home markets to embrace the latest innovations is seen as a key factor in where global companies choose to site their R&D bases.

A range of organisations sit between product development and the eventual sale of the product to the end-user. Regulatory requirements for medical devices are becoming increasingly stringent and there is a growing need to demonstrate cost-effectiveness. However, gaining approval does not always guarantee sales as procurement organisations control access of the product to the end-user. Therefore establishing, demonstrating and communicating the value and economic benefits of new devices and diagnostics will increasingly become part of the innovation processes in bringing new products to market.

4.3 Market dynamics

Many countries are making healthcare technologies one of their priority areas for investment, which is stimulating considerable R&D expenditure in the sector. Not surprisingly, the emerging economies are seen as the highest growth areas as they upgrade their healthcare systems to mirror those of the 'developed' world.

Healthcare models are facing greater challenges, both physically and financially, in addressing a growing, ageing population with an increasing burden of disease. The response has been to give greater emphasis to disease prevention where possible, early identification and diagnosis, and pro-actively managing disease and disability. Increasingly the emphasis will be on supporting chronic illness at home, to meet people's desire for independence and enable them to have a normal life while reducing the burden on acute care providers.

This change in philosophy has driven growth in certain segments of the healthcare technologies market as seen in Table 5 overleaf. Double-digit growth has been projected for the advanced wound care sector as the latest treatments are brought online for intractable wounds. The miniaturisation of diagnostics devices and the growth of self testing in diabetes have seen strong growth in the market for point-of-care diagnostics and this is projected to continue as the push for prevention, early diagnosis and patient-focused monitoring of disease progression continues. Interestingly, the increased public accessibility of diagnostics has opened up new markets in consumer-based testing leading to the development of a wide range of new tests (such as food allergies testing).

4.4 UK position and global status

The UK market, worth around $9.9bn in 2008, is the third largest in Europe behind Germany and France. Per capita expenditure is similar to France and Germany at around $162 a year. The UK market is estimated to show a CAGR of 8.9% for 2009-2013 taking the market to $15.3bn [36].

The UK has a strong medical device and diagnostics sector which benefits from world players and SMEs running R&D bases and operations here. According to Department for Business, Innovation and Skills (BIS) estimates, from Standard Industrial Classification data, the sector consists of around 2,000 medical technology companies, employing around 55,000 people. Industry figures for 2006 collated by BIS are given in Table 5 overleaf.

The NHS is the principal purchaser in the UK, although negotiating the complex procurement environment can be a

disincentive for innovative would-be suppliers. The NHS represents over 700 organisations with differing policies and practices on new technology development, adoption and purchase. Addressing this challenge has led to a number of initiatives to overcome issues in procurement and adoption. The Darzi Review *High Quality Care for All* [38] recommended that 'clinically and cost-effective innovation in medicines and medical technologies is adopted' and tasked strategic health authorities with a legal duty to promote innovation. The Healthcare Industries Task Force brought about the establishment of the Centre for Evidence-based Purchasing, collaborative procurement hubs and the National Technology Adoption Hub. Additionally, the NIHR provides a range of programmes to support innovation across the medicines and health technology pipelines.

The NHS itself represents a major source of innovation for the UK which has been recognised with the establishment of the NHS National Innovation Centre, helping catalyse the development and uptake of innovative technology coming from the NHS, academia or the healthcare industry. The centre also incorporates: the regional NHS innovation hubs, designed to speed up the development of pre-commercial technologies likely to benefit the NHS; the Training Hub; and the National Technology Adoption Centre, to increase the uptake of new technology in all areas of the NHS.

Underpinning health technology businesses in the UK is the investment made by the Government into health research (see section 3, 'UK position and global status'). Between September 2004 and June 2008, the EPSRC supported 231 medical engineering grants to the total value of £73m. This medical engineering portfolio of research includes biomaterials, biomechanics and rehabilitation, drug formulation and discovery, image and vision computing, medical instrumentation and devices, medical modelling and simulation, and tissue engineering and biocompatibility. This has been supplemented by a joint EPSRC/ Wellcome Trust initiative which will see £45m made available to stimulate the formation and support of world-class centres of excellence in medical engineering within the UK. These will be aimed at melding research in the engineering and physical sciences with medical research in order to foster integrated working to address unmet clinical needs. In addition the NIHR's i4i programme, launched in July 2008, is building on previous programme aims to improve the identification of promising healthcare technologies and accelerate the development of new healthcare products for the 21st century.

To be successful, UK businesses need to operate globally, and many companies do this through a distributed global supply chain to access overseas healthcare markets. Most established successful UK businesses have only a small proportion of their sales in the UK market, with their major markets being elsewhere. The UK Trade and Investment Life Science Marketing Strategy [39] sees China, India, Brazil, the US and the Middle East as providing the major market opportunities for UK businesses.

Table 5 – Statistics on the UK healthcare technologies sector for 2006 [37]

	UK company turnover (£m)	UK company profit (£m)	Size of the UK market (£m)	Exports, imports & trade balance (£m)	UK value added per employee (£000s)*
***In vitro* diagnostics and dental materials**	859	86	800.98	Export 896.72 Import 503.36	82.8
***In vitro* diagnostics, dental cement, gels, dressings etc**	610	87	717.49	Export 573.66 Import 408.98	37.3
Invalid carriages	234	9	319.72	Export 32.48 Import 70.92	39.3
Medical and surgical Equipment	3,539	675	6,200.29	Export 3,025.56 Import 3,412.05	45.4
TOTALS	**5242**	**857**	**8,038.48**	**Export 4,528.43 Import 4,395.30**	**47.6 (weighted average)**
				Trade balance 133.13	

* The value added per employee for the pharmaceutical and biotech sector for 2007 was £130,000 [29]

5. Our technology strategy

The Technology Strategy Board vision is 'for the UK to be a global leader in innovation and a magnet for innovative businesses, where technology is applied rapidly, effectively, and sustainably to create wealth and enhance quality of life' [40].

Our UK strategy for medicines and healthcare is challenge-led with a focus on the healthcare market. We have selected some significant challenge areas for investments which we believe are key to addressing market needs and opportunities:

- disease prevention and proactive management of chronic disease
- earlier and better detection and diagnosis of disease leading to marked improvements in patient outcomes
- highly effective treatments that are tailored to patients' needs and either modify the underlying disease or offer potential cures.

UK businesses in the medicines and healthcare technologies sectors face both business and technological challenges in translating promising ideas and concepts into products and services that meet healthcare providers' and patients' needs. Furthermore there needs to be closer alignment between those articulated needs and the research and development programmes not only to ensure the right products and services are designed and built but also to facilitate their adoption and uptake.The pace of change in technology development means that it will be 'innovation supply chains' that compete in the future and not individual companies. Developing and nurturing this network of innovative players is key to continued success for this sector through encouraging collaborative working and knowledge exchange to overcome the technological and business challenges and hence create a robust commercial R&D base, stimulate economic growth and return wider benefits to the UK.

5.1 Addressing healthcare challenges

It is widely acknowledged that current healthcare models are financially and physically unsustainable, with the burden of disease increasing due to epidemiological trends, global warming and an ageing population driving the cost of healthcare provision upwards. This upwards trend will become a major drain on a nation's resources unless provision becomes more efficient and effective with the public fully engaged in the process [41]. This requires a view of healthcare as being an investment rather than a cost, and as such the best use of resources requires a balanced view of the long-term gains. This has driven the selection of the three challenge areas described above for Technology Strategy Board intervention.

Prevention and disease management

Overcoming challenges in disease prevention and management opens up new paradigms in managing risks and disease burden but offers substantial benefits both for patients and providers.

The push towards disease prevention opens up new possibilities for healthcare providers for prophylactic or disease management interventions. Around 80% of UK GP consultations relate to chronic health conditions, yet some of the diseases are predictable or preventable (through lifestyle changes, improvements in diet and vaccination etc), or if managed in different ways would reduce the occurrence of emergency referrals that require GP intervention or admission into hospital.

Treatment failure through lack of patient compliance can also represent a significant challenge and has led, for example, to emergence in disease resistance, as seen with the rise in antibiotic-resistant bacterial strains. Addressing challenges in patient compliance will result in improving the cost-effectiveness of current treatments and reducing costs associated with treatment failure and relapse.

Diagnosis – earlier and better detection of disease

Early detection and identification of disease, ideally at the point of care, can have a significant impact on the process of diagnosis and the overall provision of healthcare. This could affect the course of treatment pursued by clinicians and likely patient outcomes as well as offering significant savings for the healthcare provider. This change in emphasis opens up new possibilities for the application of technology to help patients gain a better understanding of their health risks and the likely impact of early intervention.

As we increasingly understand the underlying causes of disease, it becomes apparent that some patients do not respond optimally to treatments, either due to the intractable nature of the subtype of disease they have or because of the way their body handles exogenous drugs. Many of these underlying differences may be explained by genetic differences between patients, and detecting and understanding these differences will be key in tailoring treatments for patients' needs. The opportunities for healthcare provision based on genomic and biomarkers are twofold: first, to identify those patients in whom a treatment may prove effective, as opposed to the current estimates that products are at best effective in 35-75% of the patients being treated; and second, to identify those patients in whom the side effects are more likely to occur and therefore not expose those patients to treatments that may cause more harm than good. This approach has been described as 'disease stratification'.

Biomarkers

A biomarker is a quantifiable biological variable that characterises a cellular, organ, physiological, pathological or clinical condition. Establishing and validating a relationship between a biomarker and a disease results in a powerful association which means, for example, disease progress can be tracked by measuring biomarker levels.

Biomarkers are valuable tools for accelerating the development of new medical treatments. They can serve to identify groups of people at greatest risk, or who will benefit most from treatment; can provide preclinical evidence of safety or efficacy; and can provide faster or more complete evidence of treatment effects and treatment safety in clinical studies.

The impact of stratifying diseases can be applied to clinical trials as well as disease management, with the potential to bring through treatments targeted for specific patient populations and address the high attrition rate seen in drug development (as highlighted in the Bioscience Innovation and Growth Team 'Review and Refresh of Bioscience 2015' report [42]). The UK already has many of the components in place for a stratified disease strategy as a result of historical strengths and current levels of research interest, both public and private, in relevant bioscience and information technology tools. The future impact of pharmacogenomics and more personalised healthcare is therefore inextricably linked to diagnostics.

Highly effective treatments and cures

There are still some disorders (such as psychiatric disorders, asthma and diabetes to name but a few) with treatment regimes which can alleviate symptoms but not the underlying disease. A better understanding of disease pathophysiology, coupled with developments in novel therapies or medical devices, will look to address the gaps in the treatment armoury.

The next generation of treatments are more likely to come from biotechnological sources (such as biopharmaceuticals, regenerative medicines and nucleic acid therapies) or medical devices with increased biological activity, and there is an increasing likelihood that the treatments will be used to cure disease rather than just for symptomatic control.

As we have mentioned, the convergence of technologies, such as biosciences, the physical sciences, materials, electronics, IT and nanotechnology, has led to different business sectors coming together, as seen with the emergence of regenerative medicine. Regenerative medicine is widely seen as the next major source of innovation in healthcare, with an emerging industry base and highly disruptive potential. The ability to repair and replace damaged cells and tissue in the body could offer lifetime cures for many currently unmet medical needs, including chronic and debilitating conditions such as Alzheimer's, heart failure, blindness and joint degeneration. These are conditions linked to an ageing population and so are of particular interest for the developed economies. Nurturing the development of these products and ensuring that products can be realised and targeted to patients will be critical to addressing the disease burden.

5.2 The challenges for business

Historically, UK-based medicines and health technology businesses have enjoyed substantial success in exploiting the science base, investing in research and development and producing innovative products and services. However, continued success for UK-based firms is not guaranteed and indeed many companies now acknowledge that there will be serious consequences for the industry as a whole unless they embrace new business and innovation models to overcome the development hurdles.

Recently, *A Review of UK health research funding* [6], led by Sir David Cooksey, found that the UK was 'at risk of failing to reap the full economic, health and social benefits that the UK's public investment in health research should generate'. A number of reports [6, 42, 43, 44, 45] have examined innovation in the medicines and healthcare technologies sectors and made recommendations to Government based on barriers that hinder health research leading to economic, social and health benefits. These can be summarised as:

Gaps in translation

- addressing gaps or a lack of coordination in the funding and other support mechanisms for taking ideas from the lab to a stage at which a commercial partner might take them on, or to a stage where an SME developing such ideas might be able to access commercial financing or partnership opportunities to bring products to market [42, 45]
- improving and speeding up the discrimination between potential new therapies at earlier stages of development [6]

Failure to implement novel products/ services in clinical practice

- involving NICE earlier in the process of development to accelerate assessment of clinical and cost-effectiveness [6]
- attempting to gain earlier 'conditional licensing' of new drugs [6]
- speeding up the uptake of cost-effective drugs [6]

Lack of collaboration

- the need to develop strong working relationships between the NHS, universities and industry partners [42]
- involving big pharmaceutical companies in the development of stem cells [45]
- overcoming cultural, institutional and financial barriers to translating research into practice [6]
- improving the regulatory support for the development, approval and use of innovative medicines in the UK [42] especially for stem cells [45].

5.3 The focus for the Medicines and Healthcare Application Area

Our UK strategy for medicines and healthcare is challenge-led with a focus on the healthcare market. We have selected some focus areas for investments which we believe are key to addressing market needs and opportunities. Our focus areas are:

- commercial translational research
- uptake of innovation
- facilitating collaboration.

We selected these areas on the basis of the Technology Strategy Board criteria for investment (see *Connect and Catalyse* for further information).

- Does the UK have the capability?
- Is there a large market opportunity?
- Is the idea ready?
- Can the Technology Strategy Board make a difference?.

Commercial translational research

Translational research refers to the process of taking the findings from basic or clinical research and using them to produce innovation in healthcare settings, or the process of converting 'basic and clinical research into ideas and products… and introducing those products into clinical practice' [6].

Medical translational research is multidisciplinary, involving basic, applied and clinical scientists focused with the end in mind of delivering real and cost-effective benefits to patients. The scope of commercially focused translational research includes lead and early prototype optimisation, preclinical and early clinical development as well as manufacturing, and could lead to improvements in disease prevention and management, diagnosis, or treatments or tools that increase the effectiveness of the development process.

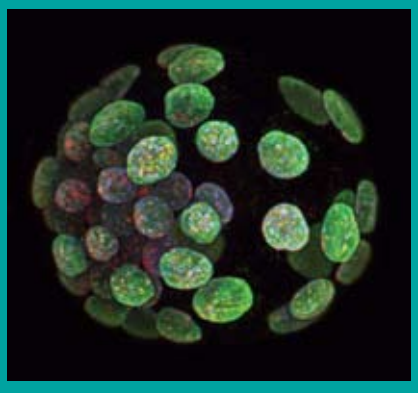
Translation

It is often argued that the single most significant contribution to medicine has been the 1928 laboratory discovery of the antibiotic, penicillin, by Alexander Fleming at St Mary's Hospital, London. However, it was the translation of this discovery by Howard Florey and Ernst Chain at Oxford University that resulted in the development and use of penicillin in patients [6].

Translational tools: CellCentric

CellCentric is a company with a focus on epigenetics – which concerns those modifications and mechanisms that sit on top of DNA and influence cellular control and cell fate. This is an emerging area of science that has great potential as a source of novel therapeutic approaches for multiple intractable diseases, including cancer. However, much of the scientific understanding of epigenetics is early and fragmented.

In May 2006 the Technology Strategy Board awarded £1.15m to Cambridge-based CellCentric as part of a £2.3m collaborative programme with three leading research institutions. The investment has enabled CellCentric to rapidly progress its development of epigenetics-based products by establishing multiple cell-based screens for identifying proteins and small molecules that cause epigenetic change. These will have a wide range of potential uses including: bioprocessing, regenerative medicine and therapeutics including for cancer.



Technological challenges in commercial translational research

We have evaluated the industry challenges and technology opportunities against the four Technology Strategy Board investment criteria.

Fit against criteria for investment	
UK capability	High
Global opportunity	High
Timeliness & impact	High
Added value	High

The following technological and industrial challenges scored 'High' against all four Technology Strategy Board criteria:

- **Improving the process of drug discovery:** The process of turning the vast amounts of information produced from the multiple 'omics' disciplines (such as genomics, proteomics and metabolomics) into useable knowledge creates a number of challenges in data analysis which, if met, could ultimately lead to the identification and validation of new drug targets. Furthermore, understanding the way in which molecules interact with biological targets and how this can be improved is critical to progressing compounds from the discovery phase into development.
- **Improving drug development:** Improvements in predicting bioactivity, potency and safety/toxicology profiles are necessary, with the latter being critical in assessing whether a candidate compound should be progressed into clinical trials. Improvements in informed decision-making will save the industry time and many millions in costly clinical trials by improving the efficiency and productivity of the discovery process.
- **Formulation and delivery to site of action:** Companies need to ensure new molecules can be formulated into a medicinal product. Targeted delivery of medicines to the target tissue can help minimise side effects and utilises less of the active ingredient. There are particular difficulties with biopharmaceutical products, and addressing the formulation and delivery of proteins, peptides, nucleic acid and cell therapies will prove critical to the development of successful products.
- **Manufacturing:** There are inherent difficulties in scaling up production from early experimental stages to making products for clinical trials and ultimately for product launch, in terms of maximising yields while working within regulatory restrictions to control batch processes. Overcoming these processing and bioprocessing challenges would involve addressing a number of technical challenges such as reactor and bioreactor design, metabolic engineering and cell biology, process optimisation, separation and purification, sensor technologies and stem cell production technologies.
- **Regenerative medicine and advanced therapies:** The technical challenge of bringing forward the next generation of therapeutics, such as nucleic acid and living cell therapies, will rely on an understanding of stem cell differentiation technologies, scale-up for manufacturing, 3D tissue scaffolds, tissue engineering technologies and delivery mechanisms, as well as methods to induce the body to regenerate healthy functional tissue

Translational tools: Critical Pharmaceuticals

Critical Pharmaceuticals conducts research into supercritical fluids. When gases reach a certain temperature and pressure (the critical point) they become 'supercritical' and take on both gas and liquid-like properties. Critical Pharmaceuticals found that supercritical carbon dioxide can penetrate and liquefy certain polymers and this can be used to mix temperature or solvent-sensitive substances into the polymers. When the pressure is released the polymers solidify around the substance, thereby trapping it within the solid material. The technology is ideal for overcoming problems with sensitive proteins and peptides that can decompose very easily, which makes them unsuitable for development as treatments.

The Technology Strategy Board awarded £414,000 funding to Critical Pharmaceuticals (with partners Nottingham University and Upperton Ltd) through an open R&D competition, to help translate the proof of concept into a robust production process. The award enabled the team to carry out process development and optimisation work and has resulted in a process that can be commercialised, with a pilot product ready for phase I clinical trials.

and to provide replacement parts. Greater promotion and support for this emerging area was highlighted in the Bioscience Innovation and Growth team *Review and Refresh of Bioscience 2015* report [42].

- **On-body and in-body devices:** It is a challenge to produce implants that have improved biocompatibility and can dwell in the body for many years; smarter and more 'intelligent' wound-healing products; and more 'active' devices that incorporate treatments that bring together physical technologies (photonics, electronics, microfluidic, nanomaterials and telecommunications) and biological entities (such as antibody technology).

Table 6 – Links between medicine and healthcare technological challenges and Technology Strategy Board technology and application areas and innovation platforms

Technology areas	Areas of cross-over
Biosciences	■ Systems approaches to genomics and biology ■ Gene identification ■ Genomic-based diagnostics leading to genome-based healthcare
Materials	■ Biomaterials and smart materials (including surface modifications) for innovative medical devices, wound dressings, implants and drug delivery vehicles ■ Biocompatibility between the body and implanted devices and for 3D scaffolds
Nanotechnology	■ Development of high-sensitivity diagnostics ■ Development of nanomaterials and nanoparticles for medical devices and implants ■ Nanocapsules for drug delivery ■ Technologies for enabling developments in regenerative medicine and nanomedicine
High Value Manufacturing	■ Design and operation of 'next-generation' manufacturing facilities ■ Lean and agile approaches to improving manufacturing ■ 'Quality by design' and optimising manufacturing processes while ensuring regulatory approval
Electronics, Photonics and Electrical Systems	■ Development of sensors and hardware critical for diagnostics, imaging, medical devices and implants
Information and Communication Technologies	■ Modelling disease and toxicology mechanisms to develop in silico methods of predicting drug efficacy or toxicity. ■ Wireless communications with devices and implants ■ Health informatics for storing and mining electronic patient records ■ Software tools for understanding health benefits and modelling unmet medical needs ■ Developing models to evaluate safety, efficacy and cost-effectiveness in patient populations

Application areas	Areas of cross-over
High Value Services	■ Managing risk in developing innovations ■ Extending and adapting modelling concepts for risk and value determination

Innovation platforms	Areas of cross-over
Assisted Living	■ Technology applied to the management of chronic conditions ■ Design of smart homes and applications of smart sensors/devices for independent living of ageing population ■ ICT with the devices to enable telecare and telemedicine ■ Technology for preventative approaches and improving wellbeing
Detection and Identification of Infectious Agents	■ Early and more rapid detection of infectious disease ■ Identification of antibiotic-resistant organisms and managing the risk of resistance forming ■ Reducing the overall infectious disease burden

- **Diagnostics, imaging and screening technologies:** Miniaturised point-of-care devices, imaging devices that are more amenable to the primary care setting, and low-cost tools for self diagnosis would all improve patient access to diagnosis. The challenge of developing routine genomic screening for patients opens up new possibilities for stratifying patient populations. Such screening depends on identification and validation of biomarkers as well as the development of technologies to make genomic screening more amenable to the healthcare setting.
- **Assistive technologies:** ICT-enabled devices and technologies could help meet the demand for independent living from people suffering from chronic long-term conditions, and aid rehabilitation in the community through intelligent and non-invasive monitoring feeding into telemedicine and virtual healthcare teams.
- **Data management, e-health and health informatics:** Harnessing the vast amounts of data generated from high throughput technologies or clinical trials requires innovative and intelligent data mining and translation technologies. The creation of electronic patient records presents complex and rich datasets from medical records, diagnostics and interventions. These all feed into the development of evidence-based medicine, stratification of patient populations and health economics for health technology assessment.

The Technology Strategy Board technology areas (www.innovateuk.org/ourstrategy/technology-areas.ashx) are responsible for ensuring companies can develop many of the underpinning technologies that will overcome the technological challenges listed above. Furthermore, the Technology Strategy Board innovation platforms (www.innovateuk. org/ourstrategy/innovationplatforms.ashx) are responsible for addressing key focal points that are experiencing specific technological challenges – for example, the Assisted Living Innovation Platform is looking at how to deliver effective care closer to the community. Table 6 and Appendix 3 summarise how the technological challenges are covered within the Technology Strategy Board technology areas, application areas and innovation platforms.

The Technology Strategy Board will:

- work with industry to identify and articulate key challenges faced by medicines and healthcare technologies companies in translating ideas into products and services that have the potential to lead to step changes in disease prevention and management, diagnosis and treatment; and
- focus our investments and support to address the business challenges, through engaging the technical and knowledge base in academia, in clinical research and industry to enable the development of the best solutions.

Uptake of innovation

A significant challenge facing innovators is ensuring that their products are taken up by healthcare providers. The provision of healthcare can be an emotive issue and payers have to try to make objective decisions on whether a new diagnostic or treatment should be used. In many cases only limited usage information is available at the time of product launch. The innovators need to provide the relevant information and demonstrate the value of their innovative products in the context of how they will help address the healthcare providers' challenges.

Failure in the uptake of innovative products and services is due to:

- the difficulties industry faces in demonstrating the value in innovative products over and above current regimes
- healthcare providers and procurers view the expenditure as a cost rather than an investment, or fail to see the overall economic benefit across the healthcare landscape
- the complex procurement landscape makes it difficult for innovators to demonstrate cost-effectiveness due to the differing drivers of the many players in the procurement process.

The drivers to prompt innovators to address the challenge of innovation uptake are:

- patients being unable to access the latest technology available to improve their quality of life
- cost containment measures leading to a lower return on investment for innovative drug and device manufacturers, potentially stifling innovation
- poor uptake of innovation is not allowing companies to carry out critical post-marketing surveillance for novel drugs and devices, and hence delays their ability to carry out incremental improvements to their products.

To enable recognition and adoption of new treatments, it is essential that benefits are well understood and there is a growing role for the use of health economics to provide the evidence of improved costs and clinical outcomes.

A multi-agency approach is needed to address the challenge of ensuring innovation is taken up by healthcare providers. However, the UK is in an ideal position to address this challenge due to the work of a number of individual bodies:

- NICE is in the forefront in the application of health technology assessment, with many countries now looking to develop

similar models. Nearly $400bn of global pharmaceutical sales are subject to health technology assessment evaluations of product value [46]. The outcomes of health technology assessments have a major impact on success or failure for innovative companies. The development and application of modelling algorithms to predict potential health and economic benefits of products early in the product development process could offer real business benefits in steering the direction of innovation programmes.

- England's National Programme for IT represents the world's largest civil IT programme aimed at capturing the patient records for all users of the NHS in England. This offers countless possibilities for assessing the evidence for therapeutic interventions and the use of diagnostics. The emergence of e-health onto the UK healthcare scene will act as a major driver for redesigning and re-engineering how patients are treated within the NHS and could help guide the direction of innovation for businesses.

The Technology Strategy Board will:

- work with industry to identify the need for knowledge exchange, between key players at the early stages of product development, with the aim of developing new tools for demonstrating the value of innovative treatments and interventions, and new business models for the industry; and
- work with the Department of Health, the devolved health departments and the NHS National Innovation Centre to understand and clearly articulate the problems and needs of end-users and patients so that businesses can design and build the best solutions.

Facilitating collaboration

The UK has the right environment to provide significant opportunities for collaborative working between the large pharmaceutical companies, health technology companies, SMEs and the academic and clinical base, to address challenges in healthcare together. However, there are cultural, institutional and financial barriers to such collaborative working [6]. Addressing these barriers is a key challenge to ensure the UK sector continues to be successful. The Cooksey review [6] highlighted the need for an increased focus on improving links between academia, the NHS and business to enable more effective translation. This includes new arrangements for the strategic oversight of UK health R&D through the creation of the Office for the Strategic Co-ordination of Health Research in 2007 to co-ordinate the joint MRC-NIHR translational research interface.

This realignment represents a significant opportunity for innovative UK businesses to start or renew collaborative engagement with the academic and clinical bases in order to access leading-edge basic and clinical research that can be applied in the commercial setting. Following on from its review of the Technology Strategy Board's KTN portfolio, it was decided to bring together the BioprocessUK KTN and the Health Technologies KTN to form a new Health Technologies and Medicines KTN. The role of the KTN is to facilitate and enable knowledge exchange and collaborations across the diverse technological and scientific disciplines involved in the medicines and health technologies sectors, as well as exploring new opportunities in the converging technology space between medicines and health technologies.

The Technology Strategy Board will:

- work with newly created Health Tech and Medicines KTN and existing collaborative programmes and networks to engage industry in building 'innovation supply chains' to create an integrated approach to collaborative working.

5.4 Implementation

Working in partnership

To maximise the benefit of any of the activities we initiate to support the industry in meeting the challenges, we will take a partnership approach both internally and externally. The different technology and application areas within the Technology Strategy Board will work together as well as collaborating with key government departments (BIS, the Department of Health, NIHR and the National Innovation Centre), the Office for Life Sciences and the Office for Strategic Co-ordination of Health Research, research councils (the Economic and Social Research Council, the Science and Technology Facilities Council, EPSRC, BBSRC and MRC), and the regional development agencies and devolved administrations. Involvement in international activities (in collaboration with UK Trade and Investment) will be essential to ensure a global perspective when we position our work in support of innovation in the UK, as well as to ensure international markets are accessible to companies investing in innovation in the UK.

An increased focus on developments within the EU and the Framework programmes will also feature heavily in this sector as opportunities for increased financial gearing for projects, along with building strategic alliances, gain greater importance for UK businesses.

Within a collaborative R&D context, we must help businesses to work effectively with both the academic and clinical base. The clinical and user base (including patients and patient groups) adds real value in determining and informing on the clinical need as well as demonstrating efficacy and providing input to improved product design.

Innovative approaches of working with the medical charities and the development of a suite of interventions that complement those already available from the Technology Strategy Board and other agencies will also be explored to maximise the impact of joint working – a key advantage of the Technology Strategy Board's position in bridging the gap between the public and private sectors. This will include building on the current tools we use – to overcome some of the issues raised by the various stakeholder communities with regard to 'advanced warning' of competitions and support for consortium building and thereby to increase engagement with the Technology Strategy Board programmes.

The Technology Strategy Board will:

- work with our public sector stakeholders, especially the regional development agencies, the research councils, relevant government departments and the Office for Life Sciences, to deliver aligned programmes and create a 'joined-up' approach for companies looking to deliver innovation in this industry.

Mechanisms

We will use some well-defined tools to stimulate innovation in the medicines and healthcare sector:

- **Collaborative R&D programmes**
  The Technology Strategy Board's investment portfolio from 2004-07 includes some £68m worth of investment in translational activities. Developing a coherent structure for translation and co-ordinating our future commitments will be critical to ensuring the greatest impact is gained from the UK's investment in health research.
- **Innovation platforms**
  The Technology Strategy Board currently runs two innovation platforms in the healthcare sector to address societal challenges as articulated by the Department of Health – the Assisted Living Innovation Platform and the Detection and Identification of Infectious Agents Innovation Platform. These were set up to try to meet the specific challenges facing the UK. The Assisted Living Innovation Platform addresses key challenges in enabling people (particularly the elderly) who suffer from chronic long-term conditions to live independent lives. The Detection and Identification of Infectious Agents Innovation Platform will address the need to reduce the number of deaths and cases of illness caused by infectious diseases, currently costing the NHS around £6bn every year. The Technology Strategy Board is currently examining a new opportunity for innovation platforms in the Medicines and Healthcare application area in the area of stratified medicine.
- **Knowledge transfer networks**
  The Technology Strategy Board recognises that networks are a central component of an effective innovation culture. They drive the flow of people, knowledge and experience between business and the knowledge base, between businesses and across sectors. The need for networks to support this exchange within the medicines and healthcare sectors is clearly demonstrated in the challenges described above. The principle KTN responsible for the Medicines and Healthcare application area is the Health Technologies and Medicines KTN, however a number of KTNs represent the numerous communities that provide technology for the medicines and healthcare area, such as the Chemistry Innovation KTN, the Biosciences KTN, the Nanotechnology KTN and the Materials KTN.
- **Knowledge transfer partnerships**
  Around one in 20 knowledge transfer partnerships undertaken are in healthcare-related projects. However there has historically been a poor take-up of knowledge transfer partnerships across the commercial medicines and health technologies sectors. Understanding the reasons and addressing any concerns will be a part of the Technology Strategy Board's *Medicines and Healthcare Strategy*.
- **The SBRI programme**
  It is recognised that industry and academia engagement – working with the NHS – is critical to successful innovation in healthcare. The new Small Business Research Initiative (SBRI) provides an important route to enable SMEs to win government contracts to develop innovations. Two pilot SBRI programmes have been run with the Department of Health and the East of England Strategic Health Authority to enable businesses to engage with and support innovation in the NHS.

Furthermore, the Technology Strategy Board will strengthen its collaboration with the NHS National Innovation Centre to speed up the commissioning of innovations that meet clearly defined clinical needs.

- **Other support activities**
  We have also invested in:

Two **pilot health technology co-operatives:** Devices for Dignity and Bowel Function. These are designed to develop collaborative working between clinicians in the NHS, patient groups and business, to catalyse the development of new healthcare products that will empower people with debilitating conditions and enhance their lives. see www.devicesfordignity.org.uk and www.bowelfunctionhtc.org.uk).

The **Stem Cells for Safer Medicines** initiative: a public-private partnership, formed from the Pattison recommendation in the UK stem cells initiative [45] to enable the creation of a bank of stem cells, open protocols and standardised systems in stem cell technology suitable for toxicology testing in high-throughput platforms, to improve the effectiveness of safety and efficacy testing (see www.sc4sm.org).

The **Regenerative Technologies and Devices Innovation and Knowledge Centre** aims to provide a sustainable regional and international platform to help create new technologies in regenerative therapies and devices, and accelerate their adoption within the complex global market place and its increasing cost constraints.

- **Metrology and standards**
  Current measurement technologies for biological drugs need improvements, and more robust, cost-effective and innovative alternatives need to be found. The importance of metrology for medical devices and technologies is already recognised at national level, and with the increased use of diagnostics away from laboratory settings will require the development of metrology and standardisation for new applications such as stratification of patient populations.

  The development of standards in the emerging area of regenerative medicine will help in the development of the regulatory landscape for new technologies and demonstrate a common compliance route for entry to all markets. The Technology Strategy Board has invested in the development of standards with the British Standards Institute for cell-based therapeutics (Publicly Available Specification, PAS 83 [47]) and regenerative medicine (PAS 84 [48]).

- **International engagement**
  Innovation in healthcare technologies and medicines is international in nature. Awareness and involvement in key international networks and programmes will enable effective positioning for the UK to take leadership in key areas in innovation in this sector.

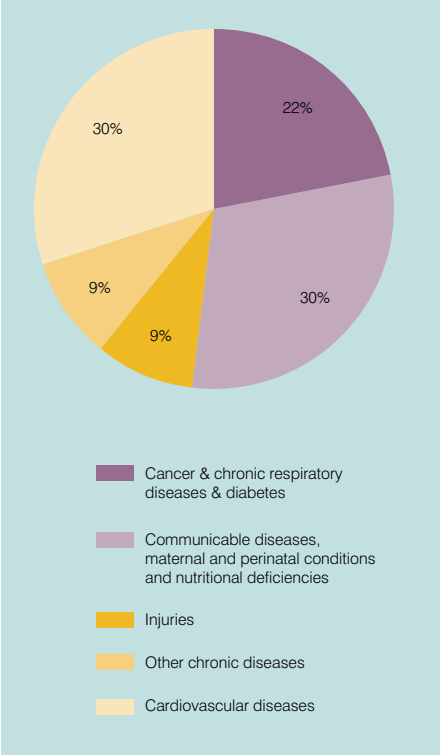
The EU Framework programme presents a significant opportunity for innovative companies to access highly relevant scientific and technical expertise across Europe, with some €6bn in funding available for transnational co-operation for the health theme alone. Examples of other EU programmes available to businesses include the Innovative Medicines Initiative, a joint technology initiative focusing on solving the generic problems that impede successful drug discovery and development. The IMI stakeholders' Strategic Research Agenda set forth recommendations to overcome these bottlenecks through joint public-private partnerships (see http://imi.europa.eu/index_en.html). The Technology Strategy Board has a key role to play in encouraging businesses to engage in EU and other international programmes as well as influencing the scope and shape of future programmes.

The Technology Strategy Board will:

- develop tools to stimulate and address bottlenecks in innovation to support UK businesses in the medicines and health technologies sector. This will start with a programme of activity in the field of regenerative medicine
- assess the need for a Technology Strategy Board innovation platform for stratified medicine. Stratified medicine is an approach to identify and classify patients into subgroups that differ in their susceptibility to a particular disease or side effects to treatment
- work with research council initiatives such as the Medical Research Council's Development Pathway Funding Scheme, the Biotechnology and Biological Sciences Research Council's Industry Clubs, and the Engineering and Physical Sciences Research Council's Nanotechnology Grand Challenge in Healthcare, and put tools in place to enable businesses to pull the research that addresses their challenges through to market
- invest in knowledge transfer partnerships and ensure that medicines and health technology companies can fully utilise and appreciate the role of knowledge sharing between disciplines
- work with stakeholders to develop metrology and standards that will stimulate innovation and provide competitive advantage to UK business
- seek to identify, with stakeholders, European and international strategic alignment and financial gearing opportunities to support improvements in UK competitiveness and inward investment.

Appendix 1 – Global burden of disease

Global leading causes of death 2005 [9]



WHO statistics 2008 [8]: The WHO assessment of the global burden of disease

Income Group	Rank	Disease or Injury	% Total DALYs
World	1	HIV/AIDS	12.1
	2	Unipolar depressive disorders	5.7
	3	Ischaemic heart disease	4.7
	4	Road traffic accidents	4.2
	5	Perinatal conditions	4.0
	6	Cerebrovascular disease	3.9
	7	COPD	3.1
	8	Lower respiratory infections	3.0
	9	Hearing loss, adult onset	2.5
	10	Cataracts	2.5
High-income countries	1	Unipolar depressive disorders	9.8
	2	Ischaemic heart disease	5.9
	3	Alzheimer and other dementias	5.8
	4	Alcohol use disorders	4.7
	5	Diabetes mellitus	4.5
	6	Cerebrovascular disease	4.5
	7	Hearing loss, adult onset	4.1
	8	Trachea, bronchus, lung cancer	3.0
	9	Osteoarthritis	2.9
	10	COPD	2.5
Middle-income countries	1	HIV/AIDS	9.8
	2	Unipolar depressive disorders	6.7
	3	Cerebrovascular disease	6.0
	4	Ischaemic heart disease	4.7
	5	COPD	4.7
	6	Road traffic accidents	4.0
	7	Violence	2.9
	8	Vision disorders, age related	2.9
	9	Hearing loss, adult onset	2.9
	10	Diabetes mellitus	2.6
Low-income countries	1	HIV/AIDS	14.6
	2	Perinatal conditions	5.8
	3	Unipolar depressive disorders	4.7
	4	Road traffic accidents	4.6
	5	Ischaemic heart disease	4.5
	6	Lower respiratory infections	4.4
	7	Diarrhoeal diseases	2.8
	8	Cerebrovascular disease	2.8
	9	Cataracts	2.8
	10	Malaria	2.5

The disability adjusted life year (DALY) is a measure to quantify the equivalent years of full health lost due to diseases and injury.

Appendix 2 – Medicines and healthcare technologies: a comparison of the sectors

While both the medicines and healthcare technologies sectors address needs in human health, there are marked differences in how both sectors operate, for a number of reasons. However, there are clear opportunities for collaboration between the two sectors as seen with the emergence of companion diagnostics for cancer therapeutics or regenerative medicine.

Healthcare technologies	Medicines
Global market size	
Around $300bn in 2007 [13]	$773.1bn in 2008 [14]
Industry	
80% SMEs	Market predominated by fully integrated multinationals with many SMEs involved in discovery, development or contract research
R&D investment typically 6-7% of sales [13]	R&D investment around 16% of sales [12]
Products	
Estimated costs for new product development can range from $100,000s – $10,000,000s	Estimated costs for new product development can range from $800m – $1bn
More than 10,000 generic groups leading to around 500,000 products	Small molecules, antibodies, proteins, vaccines, nucleic acid and cell based
Generally based on mechanical, electrical and/or materials engineering	Based on pharmacology, chemistry, and biotechnology and genetic engineering
Generally act by physical means (though some products are increasingly incorporating biologically active rather than passive products	Biologically active: effective when absorbed into the human body
Continuous innovation and iterative improvements based on new science, technology and available materials	Continuous innovation based on new science and technology 'Me-too' drugs seen as incremental innovations
Short product life-cycle and investment recovery period (typically 18 months on the market) The majority of new products typically bring added functions and clinical value based on incremental improvements	Extensive product life-cycle (around 10 years of patent protection from product launch), long investment recovery period
High cost of distribution High cost of user training and education Provision of service and maintenance for high-tech devices	Lower distribution costs, though increasing as the threat of counterfeit products increases Training of clinicians in the use of treatments is linked into continuing professional development
User education and training are essential for safe and effective use and often become integral to clinical procedure	Training becomes part of the education process for clinicians, pharmacists, nurses and other healthcare providers
Regulation	
Based on the 'New Approach' (CE marking) applicable processes depend on risk-category Government-appointed Notified Bodies certify the conformity assessment procedures Improvements often result from user feedback	Prescriptive approach: pre-market approval/licensing of individual product

Source: Adapted from Eucomed

Appendix 3 – Analysis of technological challenges

Degree of relevance to Technology Strategy Board technology areas

Technology challenges	Biosciences	Nanotechnology	Advanced Materials	ICT	Electronics, Photonics and Electrical Systems	High Value Manufacturing	Metrology and Standards
Drug discovery	High	High	Medium	High	Medium	Low	Medium
Drug development	High	Medium	Medium	High	Medium	High	Medium
Formulation and delivery	Medium	High	High	Low	Low	Medium	Medium
Manufacturing	Medium	Low	High	Low	Medium	High	Medium
Regenerative medicine and advanced therapies	High	High	High	Medium	Medium	High	High
On body and in body devices	High	High	High	Medium	Medium	High	High
Diagnostics, imaging and screening technologies	High	High	High	High	High	High	High
Assistive technologies	Medium	Low	Medium	High	High	Medium	High
Data management, e-health and health informatics	Medium	Low	Low	High	High	Low	High

Appendix 4 – Glossary

BBSRC	Biotechnology and Biological Sciences Research Council
BIS	Department for Business, Innovation and Skills
CAGR	compound annual growth rate
EPSRC	Engineering and Physical Sciences Research Council
KTN	knowledge transfer network
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
OECD	Organisation for Economic Co-operation and Development
SBRI	Small Business Research Initiative
SME	small or medium-sized enterprise

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