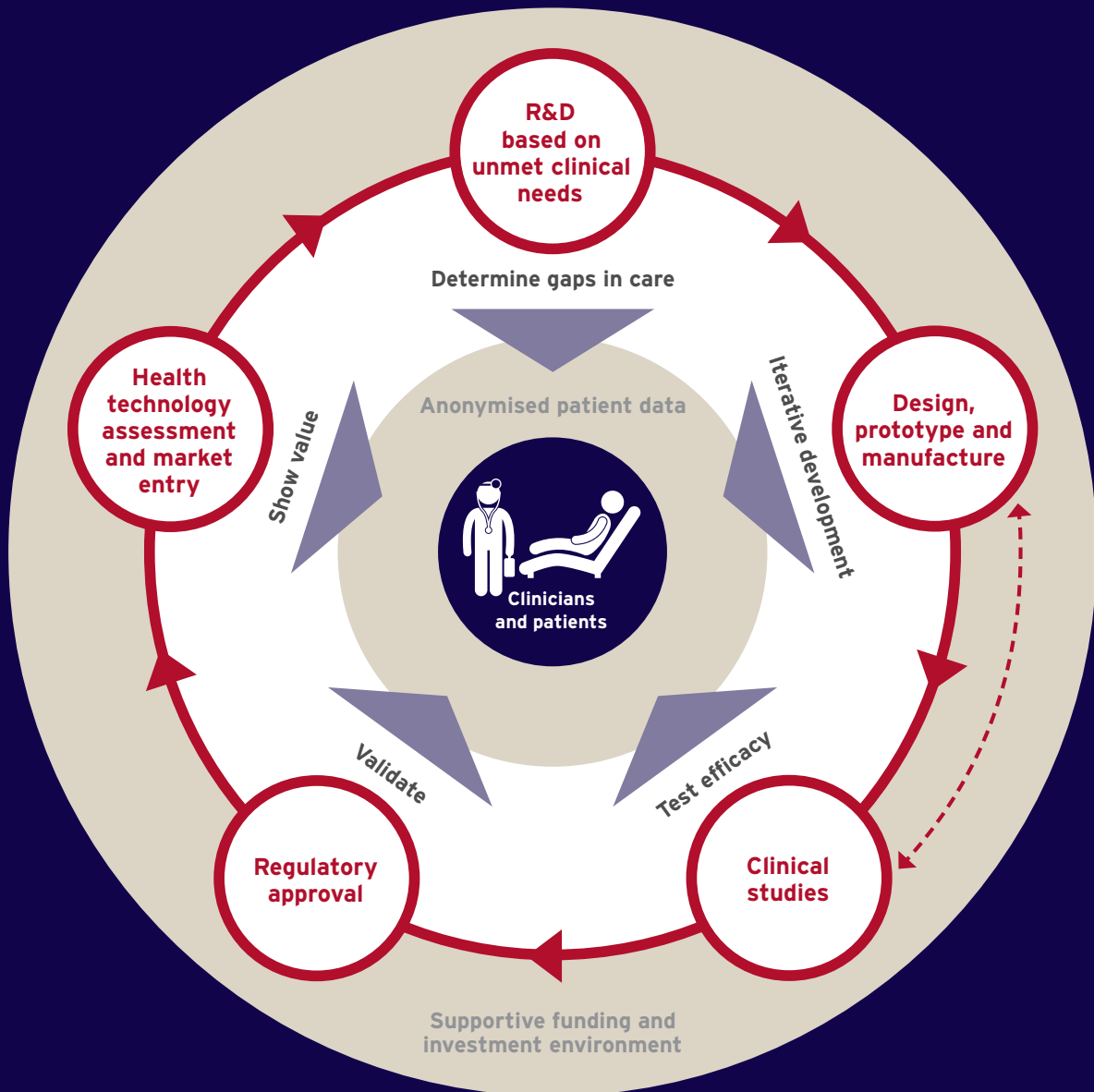


# Unlock Your Global Business Potential

The UK Medical Technology Opportunity

INNOVATION  
IS  
**GREAT**  
BRITAIN





### The UK offers your medical technology business:

- A nationalised health service providing unrivalled access to a single healthcare market of over 60 million people
- World-class resources, academic institutions and research to prove concepts for innovative medical technology
- Manufacturing capabilities to design, prototype and engineer medical technologies
- A national clinical research infrastructure to translate research, access patients and validate and design, utility and effectiveness of your medical technology
- A fast and supportive regulatory system for CE Marking
- Health economic assessment to build evidence towards early adoption and market entry
- Access to anonymised patient data
- Access to government incentives and tax breaks
- A supportive investment environment for your business' growth
- Support available from UK Trade & Investment (UKTI) to help launch your business into the UK and then into international territories.

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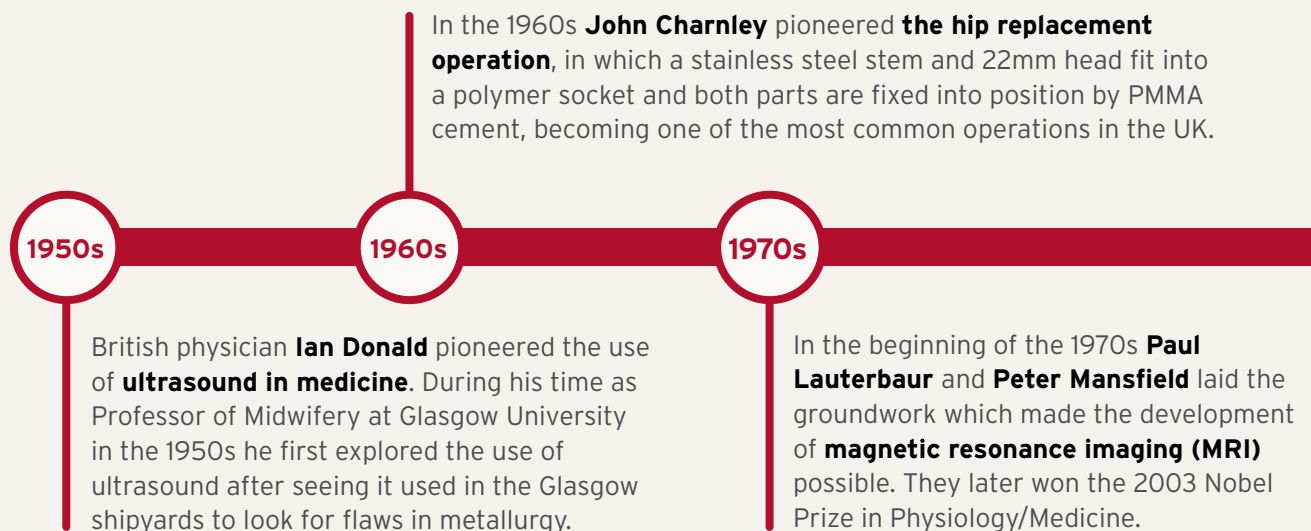
# The UK Medical Technology Opportunity

**Despite a difficult economic climate in which other sectors have struggled, the UK medical technology sector has rapidly grown over the last 4 years, with the combined turnover of UK medical technology companies increasing by 50% between 2009 and 2012.**

Additionally, the number of medical technology companies based in the UK increased by 12% from 2009 to 2012. In line with this, the number of people employed in the sector has also seen an increase of nearly 40% in the same period.

Further potential for growth is seen in the medical device market, an important subset of the medical technology market, where growth in the UK is forecast at 7.3% per annum reaching a value of £9.1bn by 2018. The UK medical device domestic market is the sixth largest in the world and third largest in Europe, valued at £6.4bn in 2013.

## The UK has a rich heritage of medical technology development



As well as medical devices the medical technology sector represents a broad range of technologies, including medical and assistive technologies imaging platforms, telehealth and diagnostics to name but a few new technologies in this field.

The UK medical technology sector is a thriving ecosystem of researchers, scientists, engineers, designers and NHS clinicians which your business can access. Together, these specialist groups drive the path of a novel technology from innovation through the process of design and manufacture to the bedside in the UK and internationally. There are over 3,000 UK-based companies in this sector, made up primarily of innovative SMEs. A third of these companies have significant R&D and manufacturing activity in the UK. Also, with over 71,000 individuals employed in this sector, your business can be guaranteed to access the intellectual capital to grow and expand.

## Accessing the UK Medical Technology Market

Your company can access the UK medical technology market and supply chain by engaging four growing healthcare markets:

- 1. The National Health Service (NHS) market.** Since 1948 disease prevention, diagnosis and treatment have been brought together under one umbrella organisation in the UK to create one of the most comprehensive healthcare services in the world. The NHS is a publicly funded healthcare system which is free at the point of access. In 2011-12, the NHS systems across the UK collectively spent approximately £128bn.
- 2. The UK private healthcare market** is growing and is estimated to reach £35bn by 2015. More than ever the private sector is increasingly benefiting from greater levels of outsourcing by the government. Private medical insurance represents the primary source of funding into the private sector healthcare market in the UK, where policies are either sold to private individuals or via corporate schemes as part of an employee benefit scheme.

1975

**Godfrey Newbold Hounsfield** developed the diagnostic technique of X-ray **computed tomography (CT)**, building the whole body scanner in 1975.

1978

In 1978, **Patrick Steptoe and Robert Edwards** pioneered artificial conception through **in vitro fertilisation** leading to the birth of Louise Brown, the first human to be born using such techniques.

1985

**Alec John Jeffreys** developed techniques for **DNA finger printing** and **data profiling**, translating capabilities in genetics into use within the world of forensic science.

CONTINUES...

**3. The social care market**, dominated by assistive technologies and private care homes, is set to grow from £2bn in 2012 to £6bn in 2020 due to the demand for delivery of care closer to home.

**4. The consumer health markets.** As patients become more empowered to take care of their own health they are increasingly demanding healthcare products to match this ambition. Fitness products, mobile apps, vitamin supplements and devices that enable patients to monitor their own vital signs on a real-time basis, are just a few of the opportunities available to medical technology companies.

As with the majority of western governments, the healthcare system in the UK is facing challenges due to an ever increasing ageing population, the rise of chronic conditions and the spiraling cost of new therapeutics. Now, more than ever, medical technologies must demonstrate improved value at a reduced cost. For a new technology or product to be adopted (reimbursed) by the NHS, improved clinical outcome and or cost reduction will need to be robustly demonstrated.

By **designing, developing, validating and selling** your medical technology in the UK you will have the opportunity to align your concept with the quality, cost effective and health outcomes-focused values of service commissioners who have an in-depth understanding of patient care pathways. In support of this process, NHS England is delivering the strategy *Innovation, Health and Wealth* which sets out an agenda to accelerate the adoption and diffusion of innovation at pace and scale throughout the NHS.

The global medical technology market was estimated to be worth £170bn in 2011 and is expected to almost double to approximately £300bn by 2015.

Looking beyond the domestic British market, the UK offers the ideal gateway to markets in Europe and beyond. The UK has strong trade links with Europe, Japan and the USA, not to mention the added value that gaining regulatory approval and adoption in the UK can add to approval within other healthcare systems.

1998

Together with their chemistry department's group research, Cambridge scientists **Shankar Balasubramanian** and **David Klenerman** progressed the use of clonal arrays and massively parallel sequencing of short reads using **solid phase sequencing by reversible terminators** as the basis of a new DNA sequencing. They formed Solexa in 1998 and the first Solexa sequencer, the Genome Analyzer, gave scientists the power to sequence 1G of bases in a single run.

2000

In **early 2000** the Scottish engineer **David Gow** developed the first **multi-articulated prosthetic hand**, now manufactured by Touch Bionics as i-Limb and ProDigits.

2001

Professor **Chris Toumazou** founded the company DNA Electronics based on his 2001 invention of **detecting protons released during DNA synthesis** as a method for DNA sequencing using a standard silicon-chip based transistor.

The UK is also establishing strategic relationships with high-growth markets such as China, India and the Middle East.

**Support is available from the UK Government department, UK Trade & Investment (UKTI), to help launch your business into the UK and then into international territories.**

The UK Government has shown commitment to the life science and healthcare sector by its vision in the *Strategy for UK Life Sciences*. Government meets with industry on a regular basis in the form of Ministerial engagement with a view to improving the fiscal and policy landscape to ensure the UK environment is an inviting place to grow and expand your medical technology business.



**Endomagnetics** was founded in 2007 by academics at University College London and the University of Houston to aim to solve cancer staging and healthcare challenges through the application of **advanced magnetic sensing technology** and **nanotechnology**.

Companies such as **Cambridge Temperature Concepts Limited (CTC)** founded in 2006 by scientists at the University of Cambridge aims to improve healthcare through the application of **sensing technology** and **statistical analysis**. CTC's DuoFertility product helps infertile patients to conceive naturally by providing continuous at-home fertility monitoring linked to expert support.

2005

2007

CONTINUES

Professor **Hagan Bayley** co-founded Oxford Nanopore in 2005 and continues to lead research into the exploration of membrane protein structure and function, and the use of molecular engineering techniques that transform these proteins into unique measurement systems for exploring the chemistry of individual molecules. Including the **analysis of DNA at the single molecule level**, and the potential for ultra-fast gene sequencing using nanopores.

# The UK's Commitment to Medical Technology

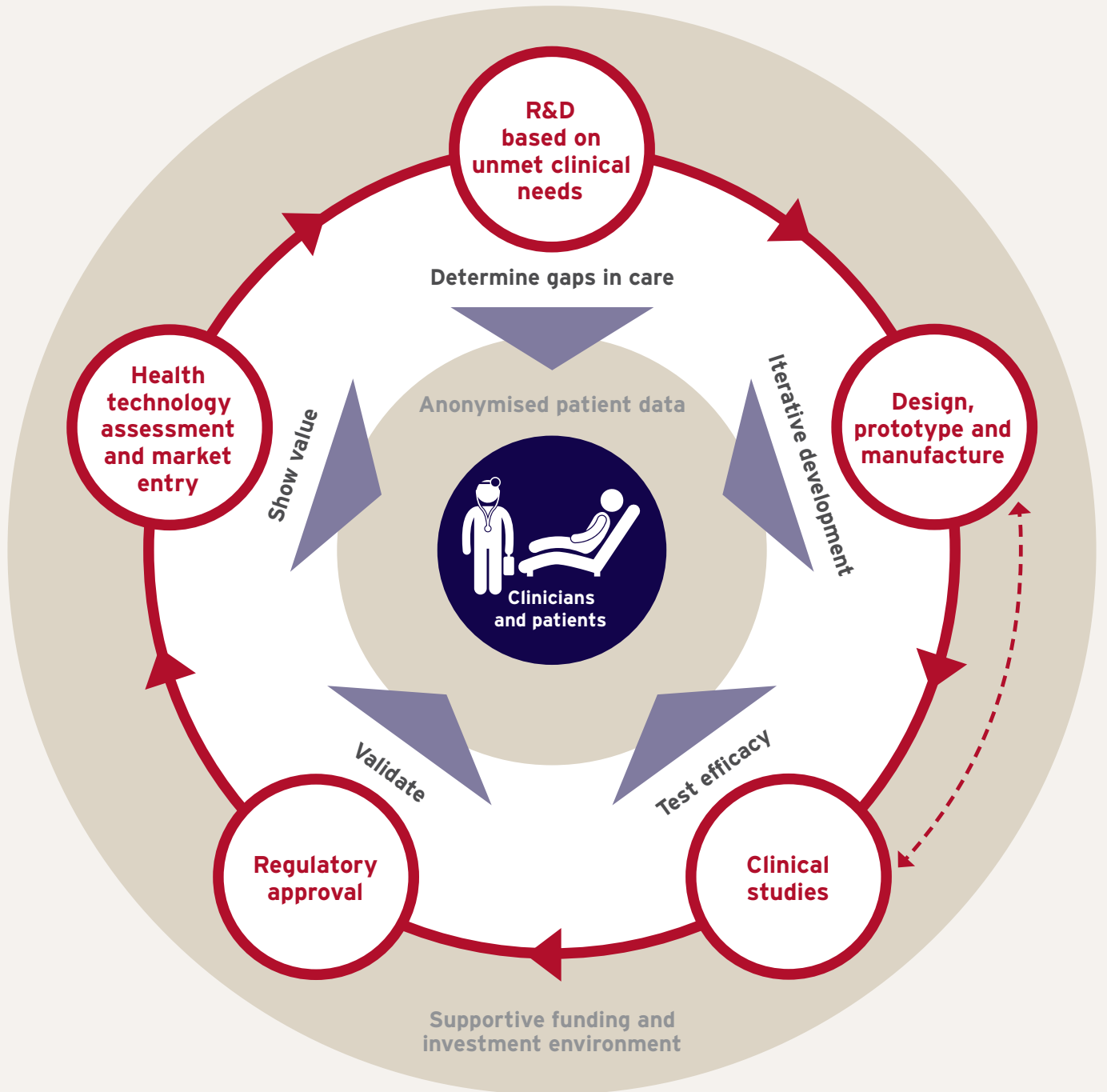
Medical technology brings many benefits. Many people now live healthier, more productive and independent lives as a result of innovations in medical technologies. Additionally, medical technology is improving the productivity and efficiency of healthcare systems and will drive economic growth by creating a centre of healthcare innovation. The UK Government recognises the positive impact the sector plays in bringing innovation, health and wealth to society and is working to consolidate the unique features of the UK medical technology development ecosystem to make it an attractive place for you to locate your business.

The diagram opposite is a simplified representation of the medical technology development pathway. The medical technology development pathway is not sequential. There is a role for involving clinicians, patients and organisations at multiple points in the research development and manufacturing processes of a technology. The UK offers this access to engage with patients, academics, clinicians, designers, regulators and manufacturers. Many of the organisations within the UK ecosystem, as described in this document, will span the development lifecycle providing support, funding and/or a network for your business to grow.

## **The UK offers your medical technology business:**

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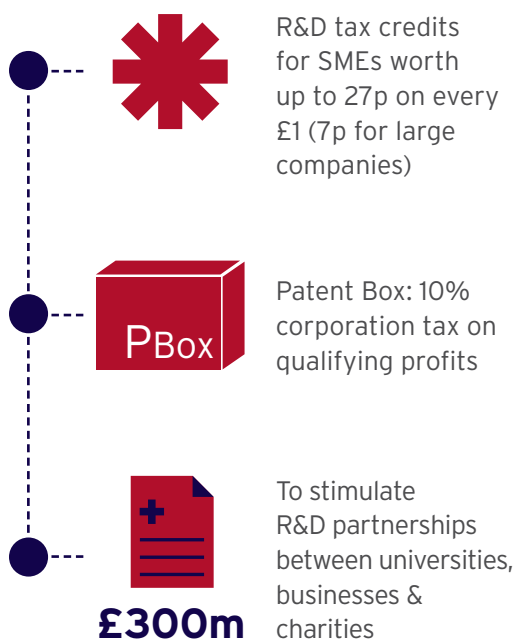


# Ease of Doing Business

**With the increasing cost, risk and complexity of research and development, it is ever more challenging for medical technology companies to move through the development pathway and commercialise innovations.**

To address this challenge, the UK Government has introduced a suite of fiscal measures including: targeted investment, funding initiatives and tax incentives to stimulate innovation and growth; funding R&D and manufacturing for start-ups and SMEs to large global enterprises. By locating in the UK your business also becomes eligible for funding initiatives from the European Commission.

## The UK Government has introduced fiscal measures to stimulate innovation and growth for companies



## Incentivising and Rewarding Innovation

- **Low corporation tax rate:** Dropping to 21% by April 2014 and 20% from April 2015.
- **R&D tax credits:** Up to 27p back per £1 of qualifying R&D expenditure. For companies investing in R&D the system is easy to navigate and self-assessment facilitates a simpler application process than anywhere else in Europe.
- **Patent Box:** As of April 2013, companies are able to apply a lower rate of corporation tax (10%) to profits earned from their UK-registered patented inventions and certain other innovations. The Patent Box provides one of the strongest offers of its kind in Europe.
- **UK Research Partnership Investment Fund (UKRPIF):** The £300m UKRPIF, managed by the Higher Education Funding Council for England, will lever more than double this from private investment into higher education research facilities and stimulate strategic research partnerships between universities, businesses and charities.

## Funding for Business Growth

- **Private funding:** The UK is globally relevant in attracting private funding. The UK's world class researchers and the NHS enable innovative medical technology breakthroughs and partnerships as well as access to patients and data. This is opening up an external funding environment from 'frontier markets', where opportunities for private sector investment in the UK, via **corporate funds** and **high net worth individuals**, are emerging.
- **Venture Capital (VC)** investment into medical devices, equipment and information systems has had a CAGR of 3% from 2007 to 2011. In addition to the private sector investment via both **VC** and **Private Equity** funding, there are other accessible schemes, such as the **Enterprise Investment Scheme (EIS)** and the **Seed Enterprise Investment Scheme (SEIS)**. The **EIS** is designed to help smaller high risk trading companies to raise finance by offering a range of tax relief to investors who purchase new shares in those companies. The **SEIS** is designed to help small, early-stage companies to raise equity finance by offering a range of tax relief to individual investors who purchase new shares in those companies.
- **The Business Growth Fund (BGF):** Shareholder banks Barclays, HSBC, Lloyds Banking Group, Royal Bank of Scotland, Standard Chartered and the British Bankers' Association have together committed a total of up to £2.5bn, making BGF the largest long-term equity investment company in the UK.
- The **National Endowment for Science, Technology and the Arts (NESTA)** is an independent body with a mission to make the UK more innovative. NESTA invest in early stage companies across all technology areas including diagnostics, devices and imaging.
- A **£2.4bn Regional Growth Fund (RGF)** is operating across England up until 2015 supporting projects and programmes that lever private-sector investment to create economic growth and sustainable employment.

## Funding for Business Growth within the Devolved Administrations

### Scotland

**Scottish Enterprise** provides a wide variety of support for investment including Regional Selective Assistance (RSA), Training Assistance and R&D Grants. The **SMART:SCOTLAND** programme offers support of up to 75% of project costs for technical and commercial feasibility studies.

**The Scottish Investment Bank** offers access to a range of equity finance products to support the growth of companies across the entire lifecycle of a business.

### Northern Ireland

**Invest Northern Ireland** offers some of the most attractive incentive packages in Europe as well as financial support to help set up in Northern Ireland, along with comprehensive advice to facilitate the investment process.

The connections Northern Ireland has with the Republic of Ireland means there are synergies through organisations such as **IntertradeIreland** which provides funding for strategic North/South collaborative innovation partnerships to develop new products, process or service development or to build on existing innovations.

### Wales

**Wales recently created a £100m Life Sciences Investment Fund.** This will contribute to an already well-established Welsh life science sector. The Fund will invest into businesses at all stages of growth, including seed capital funding.

## Funding for Research, Development and Manufacturing

■ **Health Innovation Challenge Fund (HICF)** is a funding partnership between the Wellcome Trust and the Department of Health. The funders are collaborating to stimulate the creation of innovative healthcare products, technologies and interventions, and facilitate their development for the benefit of patients in the NHS and beyond. The HICF has a succession of thematic calls for proposals, each selected to focus on unmet needs in healthcare relevant to the NHS.

■ The **Specialised Service Commissioning Innovation Fund (SSCIF)**. NHS England has established a fund to rapidly test and evaluate innovations that have the potential to deliver high impact changes for specialised services throughout the NHS. This will make innovations available to NHS patients much earlier than currently possible.

■ The Technology Strategy Board's **Collaborative R&D** programme encourages businesses and researchers to work together on innovative projects in strategically important areas of science, engineering and technology - from which successful new products, processes and services can emerge. SMART is a Technology Strategy Board scheme offering funding to SMEs to engage in R&D projects in science, engineering and technology.

■ In 2011 the Government established the **Biomedical Catalyst**, a 3 year £180m programme of non-dilutive funding designed to deliver growth to the UK life science sector. Delivered jointly by the Medical Research Council and the Technology Strategy Board, the Biomedical Catalyst provides responsive and effective support for the best healthcare opportunities arising in the UK by funding the so called 'valley of death' between the academic bench and the patient bedside. This programme has proved incredibly popular and has recently been extended into 2015/16.

■ **The National Institute for Health Research (NIHR) Invention for Innovation (i4i)** is a research award from the NIHR which aims to support and advance the development of innovative medical technologies and their translation into the clinical environment for the benefit of patients in the NHS in England and Wales. The i4i Programme supports R&D collaborations between UK healthcare academics, clinicians and industry to develop innovative healthcare technologies including medical devices, active implantable devices and in vitro diagnostic devices.

■ **Advanced Manufacturing Supply Chain Initiative (AMSCI)**. Up to £120m is available to support research and development, skills training and capital investment to help UK supply chains achieve world-class standards and encourage major new suppliers to locate in the UK. AMSCI is open to applications from all organisations operating as part of a manufacturing supply chain. Applications are welcomed from foreign investors who wish to use AMSCI to establish or strengthen their UK manufacturing presence.

# Rich and Diverse Ecosystem



## Research and Development Based on Unmet Clinical Needs

**Treating almost 1 million patients on a daily basis, with 1.7 million employees across the UK, the National Health Service (NHS) is the largest unified healthcare system in the world and one of the world's largest employers. This platform provides insight into illness and diseases affecting the population, their treatment and the impact medical technology can have upon the lives of patients. The UK's rich knowledge economy is adept at innovating to create solutions to problems faced by western medicine, impacting upon the lives of patients both at home and abroad. This combination of potential collaborators, along with the rich data repository the NHS makes the UK the ideal location from which to research, test and develop your idea.**

When balancing the attractiveness of a new medical technology concept in terms of how well the concept can provide solutions to unmet clinical needs and generating financial returns, the UK's NHS provides a unique platform for testing your innovation in comparison to other health economies. With a population of over 60 million patients and access to unrivalled, clinically-coded, granular health data that can track patients through care pathways, the UK enables unrivalled identification of unmet needs and gap(s) in current healthcare solutions.

In England, the Government has embarked on a substantial reform programme for the management of the NHS, resulting in clinicians becoming the budget holders for the majority of NHS spend as part of Clinical Commissioning Groups (CCGs). This provides an opportunity for access and dialogue with service commissioners who understand the clinical needs of their patients and can spot unmet opportunities in care where medical technology can provide efficiency savings, drive up the quality of care delivered and improve patient outcomes.

## Success story

### **Belfast based HeartSine® Technologies continues to invest in R&D to create innovative next-generation life saving devices**

Over a period of 5 years, HeartSine Technologies has invested over £2m in life saving research with the aim of further strengthening the company's position as a global leader in the development of cardiac emergency devices.

Additionally, HeartSine has established R&D activities in Northern Ireland and initiated a formal collaboration with the University of Ulster's Bioengineering Centre and its partner the Royal Victoria Hospital, a local teaching and research hospital, to augment and enhance its in-house development activities. HeartSine's light, portable and easy-to-use defibrillators place lifesaving technology in the hands of ordinary people in more than 40 countries. Every cardiac defibrillator in use today can trace its roots to technology envisioned and initially developed by HeartSine technologists.

***"Sudden Cardiac Arrest (SCA) kills more people globally every year than lung cancer, breast cancer and HIV/AIDS combined. If a 'shock' from a defibrillator was administered within 5 minutes many of those deaths may be prevented. With CPR alone the chance of survival after an SCA is less than 5%, if an AED (Automated External Defibrillator) - such as those manufactured by HeartSine Technologies - is used, survival rates can increase to over 70%."***

*Joy Taggart, Inside Sales Manager, HeartSine Technologies*

These CCGs are monitored and supported by a national body - NHS England - that will itself commission some specialist services. NHS England brings together expertise to ensure patients and the public get the highest standards of care and the best clinical outcomes wherever they live and whatever their needs.

By making commissioning the responsibility of those clinicians on the frontline, NHS England is enabling your business to work with customers who directly interact with patients and the wider healthcare system on a daily basis. In Scotland, Wales and Northern Ireland there are independent and devolved National Health Service systems

committed to supporting innovative technologies and therapies to reduce costs and improve patient outcomes.

The National Institute for Health Research (NIHR) is a large, multi-faceted and nationally distributed organisation, funded through the Department of Health in England to improve the health and wealth of the nation through research. Its mission is to maintain a health research system where the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public.

Since its establishment in April 2006, the NIHR has worked with key partners involved in the different elements of NHS research to transform research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public driving faster translation of basic science discoveries into tangible benefits for patients and the economy.

The **NIHR** funds a range of clinical research infrastructure which function across the innovation pathway. A number of these are supporting the medical device and diagnostic industries in their clinical research.

#### ■ **NIHR Translational Research**

**Partnerships** provide a single point of access to collaborate with the UK's world-class academic and NHS centres, working in partnership with industry, they drive early and exploratory development of new technologies, drugs and interventions.

#### ■ **NIHR Biomedical Research Centres**

provide a direct route to work with the UK's leading investigators and clinicians to translate fundamental biomedical research into new and improved approaches to healthcare across a range of disease and clinical areas. The Centres are based within the most outstanding NHS and university partnerships in England.

#### ■ **NIHR Biomedical Research Units**

focus on translational research in individual priority clinical areas. They provide access to internationally recognised research leaders working in areas of high disease burden and unmet clinical need. Biomedical Research Centres and Units have links with other research specialties across their host institutions and can provide access to expertise in areas such as engineering to support prototype development and refinement.

#### ■ **NIHR Healthcare Technology**

**Co-operatives** are based within NHS Trusts, as national centres of expertise in developing new concepts, demonstrating proof of principle and devising research protocols for new medical devices, healthcare technologies or technology-dependent interventions in areas of unmet clinical need.

#### ■ **The NIHR Diagnostic Evidence**

**Co-operatives (DECs)** have been set up to improve the way diseases are diagnosed. DECs will focus on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of in vitro diagnostic medical devices (IVDs) has the potential to lead to improvements in healthcare services and the quality of life of NHS patients. Based in NHS Trusts in England, DECs will bring together a range of experts and specialists from across the NHS, patients, the IVD industry, pathology services, NHS commissioners and academic researchers.

#### ■ **The NIHR Horizon Scanning Centre**

aims to supply timely information to key policy and decision-makers within the NHS (for example, National Institute for Health and Care Excellence (NICE)) about emerging health technologies that may have a significant impact on patients or the provision of health services in the near future.



## Success story

### University of Warwick and Bosch Healthcare open research facility

The Institute of Digital Healthcare (IDH) in Warwick Manufacturing Group (WMG) at the University of Warwick and Bosch Healthcare have opened a major research facility for developing digital healthcare technologies for people with life-threatening and chronic illnesses. WMG at the University of Warwick is working with Bosch Healthcare, Warwick Medical School and other partners on selected healthcare activities. A new IDH Learning Lab will design and trial novel digital healthcare technologies and will aim to understand and evaluate the effectiveness of digital programmes in the health service.

*“This approach is at the very heart of our healthcare products, which connect patients to services and assist them in having more control over their own wellbeing. It is therefore, very exciting for Bosch to be a founding partner of the IDH Learning Lab, which will enable new technology to be developed and tested and we look forward to the results it will produce.”*

*Peter Fouquet, President of Bosch, UK*

The NIHR infrastructure spans across a range of stages in the medical technology development pathway from R&D based on unmet clinical need through to clinical research. The NIHR Office for Clinical Research Infrastructure (NOCRI) has been set up to help industry and other research funders work in partnership with the NIHR infrastructure. NOCRI supports companies by:

- Research signposting - help with navigating the clinical research environment and finding the sought after expert researchers and world class facilities and technologies.
- Research collaboration management - support for the development of collaborative research partnerships.

#### **The National Institute for Social Care and Health Research (NISCHR)**

Biomedical Research Centre (BRC) and Units (BRU) were established to support high-quality translational research in Wales. The Centre/Units have the highest quality research records and are based on health areas of particular importance to Welsh Assembly Government. BRC and BRUs are partnerships between the NHS and universities.

The success of the **Academic Health Science Centres (AHSC)** in England continue to develop as the NHS opens up to work in research partnerships with industry. The role of the Academic Health Science Centre is to develop and take the discoveries made through research partnerships and translate them into new therapies and techniques, and promote their application in the NHS.

#### **The Technology Strategy Board (TSB)**

stimulates technology-enabled innovation and assisted living and advises government on how to remove barriers to innovation and accelerate the exploitation of new technologies. Aside from initiatives like the Biomedical Catalyst, the TSB also runs a series of competition and funding schemes based on identified areas of unmet clinical need or high health need.

- The TSB's **Assisted Living Innovation Platform** is a competition that promotes independent living and improved quality of life by making technology better, cheaper and more desirable. Specific funding options available through this platform include:
  - **DALLAS: Delivering Assisted Living Lifestyle at Scale** aims to support scalable technology and services to enable independent living.
  - **Ambient Assisted Living** aims to extend the time older people can live in their home environment by using intelligent products and the provision of remote services including care services.
- The TSB's **Knowledge Transfer Network (KTN)** facilitates the UK's innovation communities to connect, collaborate and find out about new opportunities in key research and technology sectors. There is a dedicated KTN on HealthTech and Medicines which helps your business to connect with other organisations to catalyse innovation. This could include companies, the science and clinical base and the public sector from both within and outside your sector.
- The TSB's **Knowledge Transfer Partnership (KTP)** help businesses (based in the UK) to improve their competitiveness, productivity and performance by accessing the knowledge, technology and skills that are available within the UK's world class universities, colleges and research organisations through the development of collaborative partnerships which stimulate innovation.

**Manchester Integrating Medicine & Innovative Technology (MIMIT™)** is the first international affiliate of the highly successful Center for Integrating Medicine & Innovative Technology (CIMIT®) based in Boston, USA. MIMIT™ is an exciting initiative which facilitates collaborations between clinicians, scientists, engineers and industry to develop innovative technology for patient benefit. It will seize opportunities to enable clinical problems to be identified more readily and, most importantly, improve patient outcomes by bringing innovative technology developments to fruition.

**The Strathclyde Institute of Medical Devices (SIMD)** is part of the Biomedical Engineering Department (University of Strathclyde), an internationally recognised centre of excellence for research on the interface of engineering and life sciences. Harnessing close ties to the NHS, the interdisciplinary team at SIMD works closely with industry to support the advancement of health and technology through research, teaching and commercialisation.

## Success story

### Johnson & Johnson opens a Global Innovation Centre

Johnson & Johnson established one of its four regional innovation centres in London. The Innovation Centre serves as a European Hub to accelerate innovation across the healthcare landscape. The Centre focus on identifying early-stage innovations, and establishing novel collaborations to invest in and speed development of those innovations to solve unmet needs in patients.

*"The innovation centres will help to deepen our relationships with the communities in key innovation hotspots and better support local entrepreneurs. Ultimately, they will serve to help us more quickly identify and tap into technological advancements that have the potential to benefit the health of people in the future."*

*Patrick Verheyen, Head of the London Innovation Centre*

## Success story

### **Toshiba Medical Systems Corporation is now a major R&D centre for Toshiba's international medical business**

Voxar, an Edinburgh-based technology start-up specialising in advanced visualisation software for the medical imaging sector was acquired by Toshiba Medical Systems Corporation, forming TMVS, now a major R&D centre for Toshiba's medical business internationally. The products and expertise of TMVS support a diverse range of imaging systems, such as CT, MR, Ultrasound and X-ray systems, together with associated informatics solutions.

In December 2010 TMVS, aided by a Scottish Enterprise R&D grant of approximately £3m, saw a significant expansion of its R&D operation in Edinburgh stimulating innovation to provide cutting edge medical imaging solutions to improve the quality and efficiency of patient treatment.

*"In a global economy, Toshiba's decision to site a major R&D centre in Scotland is noteworthy. In a technically challenging and rapidly evolving sector such as ours, access to the best talent, expertise and research facilities is paramount. The UK not only offers this, but also the infrastructure and environment to foster innovation and help continue to keep our business at the leading edge."*

*Ken Sutherland, President, TMVS, Europe Ltd*

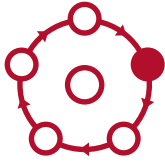
## Success story

### **Cardiff University spin out Microvisk utilises R&D funding to develop coagulation testing**

A medical device company from North Wales, with technology originating from Cardiff University is poised to revolutionise the management of patients with blood disorders the world over.

The device, the size of a mobile phone, measures minute but critical changes in the thickness of blood and will allow millions of people taking anti-coagulant drugs to monitor the treatment in their own homes and feed results online to their doctors

Microvisk had initial support for R&D funding and the Welsh Government has taken a £1.6m stake in the business via its investment arm, Finance Wales, adding to the £13.5m raised in private funding by the firm. Microvisk indicated that the manufacturing heritage and highly skilled local people combined with bringing in highly qualified international scientists helped the world's first online viscometer to be developed in Wales.



## Design, Prototype and Manufacture

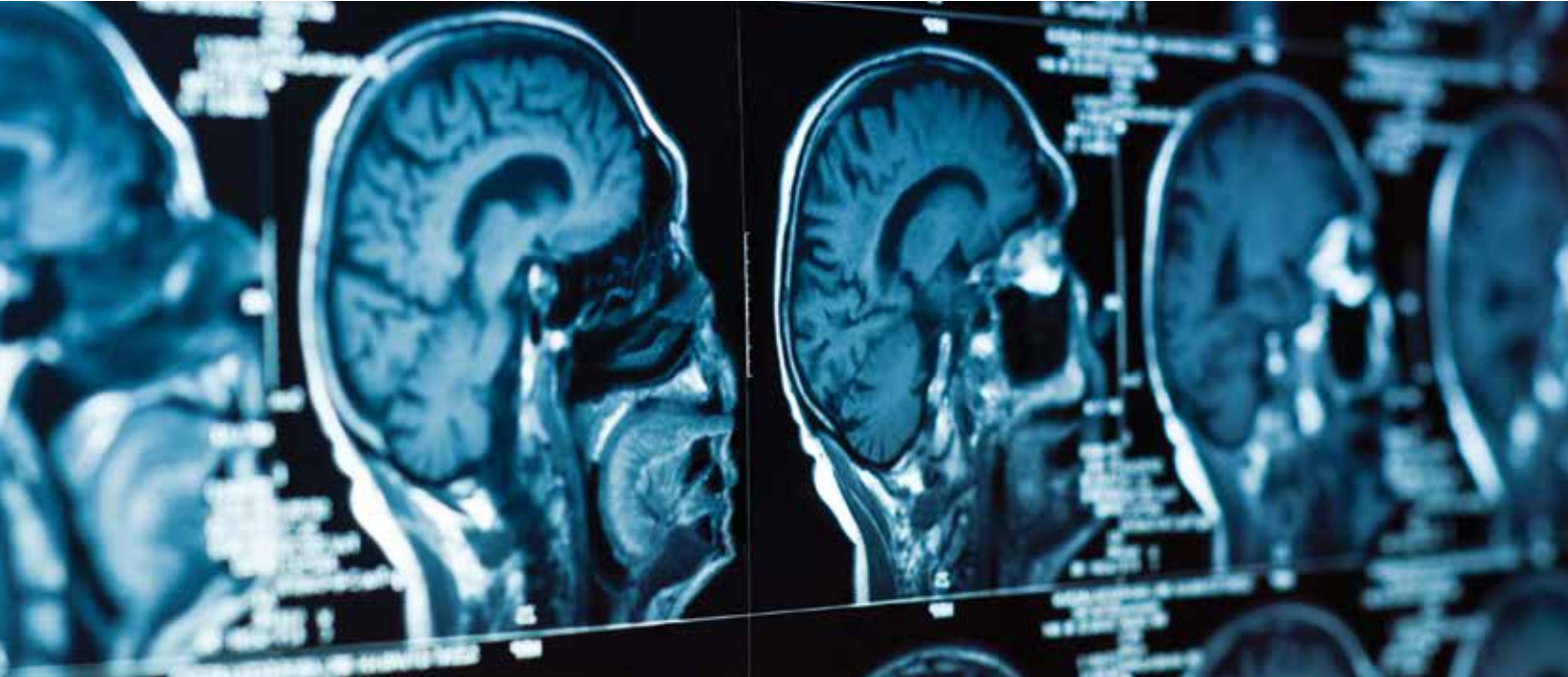
**For centuries UK engineering has been a driving force for the world's industries. As the birthplace of the industrial revolution the UK is home to countless inventions and developments from the steam engine to the jet engine, the telephone to the World Wide Web. The UK has a rich heritage of innovative medical engineering, design and development and continues to deliver improved prevention, diagnosis and treatment of illness. These capabilities are vital to the delivery of efficient health services through the NHS and the reason why many of the leading multinational medical devices companies have an engineering and manufacturing base in the UK.**



The UK is renowned not only as the source of new ideas but also crucially for its ability to translate cutting-edge research into commercial revenues.

Both overseas and UK based medical technology companies can benefit from a comprehensive supply chain offering professional support and/or contract service for product development, design and prototyping, through to manufacture, supply and distribution.

In terms of international competitiveness the UK ranks highly in comparison to its global competitors with many funding schemes, competitions and government policies developed to encourage investment and growth.



- The **Technology Strategy Board** runs a series of funding programmes that aim to advance partnerships and catalyse ideas into products and services. **The High Value Manufacturing Catapult** is a specific catalyst that transforms brilliant manufacturing ideas into valuable products and services. Working with the Catapult, businesses small and large will undertake joint projects with researchers and businesses and equipment that is normally inaccessible to individual companies will be available as a national resource. Many big companies recognise they need smaller companies in their supply chain to help develop progressive technology.
- **Advanced Sustainable Manufacturing Technologies (ASTUTE)** aims to enable the manufacturing industry in West Wales and the Valleys to grow by adopting more advanced technologies. This is achieved by a partnership of universities throughout Wales that harness the engineering, science and business expertise within them to improve the economic prosperity of the convergence region.
- The **Wellcome Trust** and the **Engineering and Physical Sciences Research Council (EPSRC)** in partnership, fund four Centres of Excellence in Medical Engineering in the UK which your business can access. Each centre presents the potential hot house clusters providing an environment for mathematics, physical science, engineering and medical research to come together to encourage exploratory research and its translation into specific product developments of benefit to healthcare. The Engineering and Physical Sciences Research Council (EPSRC) through its public funding of around £800m per year is at the heart of discovery and innovation. It generates fundamental knowledge and skilled people essential to business, government and other research organisations in the 21st century.

## Success story

### University of Exeter uses Engineering and Physical Sciences Research Council (EPSRC) funding to set up modeling software company Simpleware

Simpleware, a company set-up to commercialise EPSRC-supported research at the University of Exeter, won The Queen's Award for Enterprise in Innovation 2012 for its pioneering 3D computer modeling software solutions. The company employs 19 staff, including many University of Exeter graduates, and has enjoyed an average 40% growth rate per annum over the last five years. Simpleware's software has been successfully adopted in a wide range of healthcare-related projects in areas such as early stage diabetes detection, and is also used in engineering applications such as inspection, materials research and non-destructive testing. Over 85% of the company's sales are export-based with customers ranging from international blue chip corporations to research institutes including high-profile organisations such as NASA, the US Naval Research Laboratory and Siemens as well as a wide range of universities world-wide.

*"The ability to generate robust and accurate numerical models from various sources of image data has started a revolution in the world of multi-physics simulation. The level of accuracy that is now possible is allowing us to more closely replicate what is happening in the real world. This is giving a new level of impact to the findings that are being generated in the projects we are partners with, and it is ultimately opening doors for the research to progress even further."*

*Professor Philippe Young, Simpleware Founder*

- **Manufacturing Advisory Service (MAS)**, funded by BIS (Department for Business, Innovation and Skills), provides manufacturing business support for companies based in England helping them to improve and grow.
- **Scottish Manufacturing Advisory Service (SMAS)** provides expert advice, one-to-one support, training and events for manufacturing businesses of all sizes throughout Scotland. The practitioner team consists entirely of hands-on experts in process improvement, lean manufacturing, innovation and allied disciplines. SMAS offers a free manufacturing review which will identify ways to improve the productivity and competitiveness of your business.
- The **Design Council** is a charity which places design at the heart of creating value by stimulating innovation in business and public services, improving the built environment and tackling complex social issues. Design Council projects in the healthcare space have included: designing healthcare buildings and estates; 'Design Bugs Out' a design program to reduce Healthcare Acquired Infections and 'Reducing Violence and Aggression in A&E'.
- **The Royal Academy of Engineering (RAE)** is the UK's national academy and brings together the most successful and talented engineers from across sectors for a shared purpose - to advance and promote excellence in engineering across the UK. The RAE has a Panel for Biomedical Engineering which provides a forum for organisations to communicate, debate and jointly act upon issues in this area.

## Success story

### De Soutter Medical continues to enhance manufacturing capabilities in the UK

De Soutter is recognised as the leading European manufacturer of surgical power tools. With a goal to develop and produce advanced surgical cutting solutions for a rapidly changing global healthcare market. The De Soutter Medical product range is primarily focused on the orthopaedics and trauma marketplace with instruments used for both large and small bone surgery.

De Soutter Medical moved to its new purpose built facility in Aylesbury, UK in 2011 which is where its products are designed and assembled, this facility also hosts a clean room packaging plant. All De Soutter Medical products are designed in house by a dedicated team of experienced design engineers.

Most of the component parts sourced by the company are manufactured at its sister company based in Tewkesbury, UK and one of the company's core strengths is maintaining complete control over the entire production processes, ensuring high product quality and reliability.

The company welcomes the improved fiscal measures that improve their ease of doing business.

*"Patent Box is a great initiative which focuses UK manufacturers on designing innovative products. In times of recession, growth must come from creating new markets through innovation in design and manufacturing."*

*George De Soutter, Technical Director, De Soutter Medical*

- At the **Institute of Design Innovation, Glasgow School of Art**, the researchers work with businesses, medical and social care practitioners to apply design innovation to create healthcare solutions and medical business models for the future.
- **The National Centre for Product Design and Development Research** in Cardiff is a world renowned design and innovation consultancy and research centre. Over the last 18 years they have used a unique approach to help large and small companies from around the world to discover, design and develop successful products and services.

### The Royal College of Art

The Royal College of Art has a strong track record in design for patient safety, dating back to the 1960s, when the Nuffield Foundation funded an initial scoping study into the function and design of non-surgical equipment in hospitals. This led to a major design-research programme funded by the King's Fund leading to the revolutionary new design of the hospital bed, which had not changed significantly since the time of Florence Nightingale. This new standard or 'King's Fund' hospital bed is still used in 85% of UK hospitals today.

## Success story

### **Magnesium Elektron taps into a pool of UK research and furthers its UK manufacturing capabilities**

Founded in 1936, Magnesium Elektron is a recognised global expert in the development of magnesium alloy technologies used in lightweight applications for the aerospace and defence industries. With a strong record of innovation, the company continues to push the metallurgical boundaries of magnesium.

Magnesium Elektron has been working for several years to develop its range of Synermag® bio-absorbable magnesium alloys for use in absorbable medical implants. This work, conducted at the company's Magnesium Technology Centre in Manchester, UK, has involved extensive research into numerous alloy systems and development of novel manufacturing technologies to combine the mechanical property benefits of metallic implants with the bio-absorbable nature of degradable polymers.

*"There is particular interest in the use of bio-absorbable materials in the field of vascular intervention. In carrying out this research in the UK, we have been able to tap into our existing pool of expertise whilst utilising our strong links with the UK university knowledge base. In 2013, we will complete construction of a new, dedicated manufacturing centre for production and further development of our Synermag® range of technologies."*

*Graham Wardlow, Managing Director of Magnesium Elektron's UK Operations*

## Success story

### **Clamason Industries Ltd provides components to world leading pharmaceutical company**

Sanofi identified a need for a re-usable device that could be assembled in a low-cost environment yet still conform to internationally recognised standards. Along with German, Swiss, Indian and Taiwanese suppliers Clamason Ltd. was invited to assist in the development program for two precision pressed metal springs within the device. These components ensure that each time the insulin vial is replaced it sits correctly. The pen was designed by UK-based product design house DCA in Warwick and Clamason. Production started in 2012 and is set to rise significantly.

*"The medical sector is now a key global market for Clamason and is exemplified by our relationship with the French-German Sanofi Group. Our contracts with Sanofi exemplifies the UK's ability to compete and operate on a global scale. Several UK companies were involved in this project and shows that global medtech companies still look to the UK for high quality design and manufacture."*

*Philip Clarke, Managing Director of Clamason Industries Ltd*





## Success story

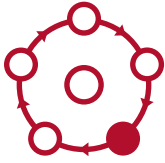
### **Plexus opens new manufacturing facility in Scotland**

Plexus opened a new manufacturing facility in West Lothian, creating 130 jobs. This £9m expansion will provide product realisation solutions including design of a European centre of excellence for prototyping, manufacturing and sustaining solutions. The facility complements Plexus' existing manufacturing facility in Kelso.

Plexus operates in the defence/security/aerospace, industrial/commercial, networking and communications sectors as well as healthcare/life sciences and is an example of a company with a global presence in providing full product realisation solutions, who are investing in the UK.

*"Plexus' ability to provide full product realisation solutions within the UK market has attracted several new customers. This increasing demand is the fuel for the expansion of our UK operations. This demand sends a very positive signal that companies need a UK-based solution for the design and manufacturing of their mid-low volume, high complexity electronic products."*

*Ronnie Darroch, Plexus, Regional President*



## Clinical Research

**The need for clinical investigation is a critical component in meeting regulatory requirements for high risk medical devices. It is also essential to build a base of clinical evidence and cost effectiveness to sell to health economies across the globe. The combination of the uniqueness of the NHS linked to a clinical research infrastructure offers a range of activities across the development life of a product to build this evidence early and on an on-going basis as you move through the medical technology development pathway.**

The NIHR supports medical device and diagnostic companies across all stages of product development from identifying unmet clinical needs to designing and running clinical studies. Ensuring there is a continuous dialogue between industry, clinicians, researchers and patients as you develop your technology from concept to testing it in a clinical study. NIHR can support your activities including prototype development and product refinement, clinical research evidence on clinical effectiveness, clinical utility, care pathway impact and clinical research studies for regulatory purposes.

The NIHR Office for Clinical Research Infrastructure (NOCRI) enables you to demonstrate the clinical performance of your medical technology at pace.

The research infrastructure works with industry to design protocols, providing access to world leading academic and clinical expertise, enabling you to output high quality evidence. As well as enabling you to trial your product with 'innovation hungry' healthcare professionals and enter into a health eco-system that has governance processes designed to meet commercial objectives, it is responsive to industry time and cost pressures, and is performance managed for its delivery to industry.





**NIHR Clinical Research Networks** are able to support set-up and delivery of high quality medical technology research studies across a range of disease and clinical areas. For companies with studies that have a defined protocol and full funding, networks can provide a comprehensive service, including:

- Expert support for study and protocol feasibility assessment
- Access to systems to speed clinical trial set up including costing, contracting and R&D approvals
- Staff and resources to ensure efficient patient recruitment and study delivery.

#### **NIHR Clinical Research Network Key Achievements 2012/2013**

- At the end of 2012/13, the NIHR Clinical Research Network was supporting more than 4,200 studies in the NHS, a 12% increase on the previous year
- The NIHR Clinical Research Network recruited 20,500 patients onto commercial contract studies in 2012/13, a 19% increase on the previous year
- The NIHR Clinical Research Network recruited more than 630,000 patients to clinical studies in 2012/13, a 7% increase on the previous year. This means the Network has tripled patient recruitment in just six years. 99% of NHS Trusts offered research opportunities to NHS patients.

The UK is committed to making clinical study start-up more time and cost efficient by: investing in the health research infrastructure; encouraging patient participation in research studies; measuring this through performance metrics; introducing the health research authority to streamline approvals for clinical research; unlocking data and simplifying access for industry.

## Success story

### NOCRI brings Vidacare Corporation to the UK for clinical research

Vidacare Corporation, a medical device company based in San Antonio, Texas, has developed the OnControl® Bone Access System. This is a handheld rotary-powered device that has been shown to improve the safety, control and comfort of biopsy procedures.

The NIHR Office for Clinical Research Infrastructure (NOCRI) supported Vidacare by linking it with the right clinical research experts in the UK who are currently working to help the company develop and set-up a randomised controlled trial.

NOCRI was able to communicate the benefits of doing research through the NIHR, including where to find relevant MedTech expertise in the NIHR Clinical Research Network and make the necessary introduction.

*"Thanks to NOCRI's expert help, the development of a study within the NIHR will benefit not only Vidacare, but patients within the NHS. We're very keen to work with the NIHR and look forward to when the trial is developed and can fully progress."*

*Dr Thomas Philbeck, NOCRI, Vidacare's Senior Director, Science & Clinical*

### The Devolved Administrations (DAs) offer opportunities to deliver well supported clinical trials with single access points into each of their respective research infrastructures.

#### In Scotland:

**NHS Research Scotland (NRS)** aims to ensure that NHS Scotland provides the best environment to support clinical research. The **NRS Permissions Coordinating Centre (CC)** is a single point of contact for researchers and companies wishing to conduct multicentre clinical research in Scotland. The NRS Permissions CC liaises directly with NHS Board R&D offices to identify investigators and streamline the Scottish R&D permissions process. The average R&D permission time is currently 18 days for both commercial and non-commercial NRS projects.

The **NRS Permissions CC** provides a streamlined process which has delivered impressive R&D permission times and efficiency gains achieved through the adoption of a Scottish-wide document set, including standard non-commercial

and commercial model clinical trial agreements. Recent R&D permission times for commercial multicentre NRS projects are currently 18 days. For UK-wide studies, the NRS Permissions CC links with national health research infrastructures across England, Wales and Northern Ireland.

**Health Science Scotland** is a partnership of medical universities and their associated NHS Health Boards in Scotland to promote and enhance Scotland as a world-leading hub of innovative health research and development. Some of the objectives of the organisation are to improve and facilitate collaborative and innovative early phase clinical trials between academic and industry partners and to increase the speed and adoption of high quality clinical and health improvements, particularly for medical technology companies.

## Success story

### Scottish Care Information Diabetes Collaboration use big data to drive integrated care to benefit patients with diabetes in Scotland

University of Dundee's Professor Andrew Morris, also Chief Scientist at the Scottish Government Health Department Directorate, set up The Scottish Care Information Diabetes Collaboration (SCI-DC) at NHS Tayside to provide a real-time, web-based IT solution for the whole of Scotland. Each Scottish patient with diabetes (n>270,000) has a SCI-DC electronic record and data from all areas of healthcare (primary, secondary and tertiary care) are collected. This visionary use of 'big data' has transformed the way diabetes is managed and treated in Scotland culminating in:

- An information-rich database containing a large number of patients that have agreed to take part in clinical research on diabetes, making patient recruitment into clinical trials very fast and successful
- Improved clinical outcomes, the quality of care of patients with diabetes in Scotland with decreased amputation rates and decreasing rates of diabetic retinopathy.

## Success story

### GlaxoSmithKline tests the effectiveness of pre-license medicine using real world data in Manchester\*

The study is a collaboration between the pharmaceutical company GlaxoSmithKline (GSK) and North West e-Health (NWeH), The University of Manchester, Salford Royal NHS Foundation Trust, NHS Salford's local general practitioners and local community pharmacists. The purpose of the Salford Lung Study is to test the safety and effectiveness of a new treatment for asthma and COPD, compared with standard medications used for these conditions. The study is sponsored by GSK.

The initiative draws on Salford's e-Health records infrastructure, a clinical information system that provides a single, integrated electronic patient record across primary and secondary care. This will ensure patients are closely monitored over the course of the study, yet with minimal intrusion into their everyday lives.

Professor Martin Gibson, associate director of industry at the National Institute for Health Research Comprehensive Research Network, described the Salford Lung Study as "a major advance in the way we do clinical trials".

***"This study is a first in the world, testing a pre-license medicine in a real world setting and is a tribute to the partnerships we've created together, our collaborators and the health care professionals and people of Salford."***

*Dr David Leather, Medical Director of GSK's Respiratory Centre of Excellence*

\*This project highlights the role of the UK in using data to validate technology. The medical technology sector has a significant opportunity to benefit from this as a valuable tool.

**In Wales:**

The **National Institute for Social Care and Health Research (NISCHR)** is the Welsh Government body that develops strategy and policy for research in the NHS and social care in Wales. NISCHR delivers its strategy and policies through commissioning services, running research schemes and initiatives and through strategic investment and partnership working with other funding bodies and industry.

NISCHR fund two key elements of infrastructure to assist in the delivery of research and development. The NISCHR **Academic Health Sciences Collaboration (AHSC)** facilitates collaboration between industry, academia and the NHS. The NISCHR Clinical Research Centre (NISCHR CRC) provides an expert research workforce to support and develop research activity within health and social care.

**Health Research Wales** has been established to provide a one-stop source of information and support for companies wishing to undertake clinical research in Wales. Health Research Wales will provide your company with a comprehensive service which supports the set-up and management of clinical studies in Wales, offering fast and simple processes and effective delivery of studies with a streamlined Permissions Co-ordinating Unit.

**In Northern Ireland:**

**Health and Social Care Research and Development** funds the Northern Ireland Clinical Research Network to support high quality clinical trials, promote research, develop partnerships and ensure that targets are achieved and maintained.

The Northern Ireland Clinical Research Network develops close partnerships and productive working relationships with key individuals and groups across the Network and the wider research community and ensures that targets, including accrual of patients into trials, are achieved and maintained.

**The UK research infrastructures are supported by the following robust data sets:**

**The Clinical Practice Research Datalink (CPRD)** is the English NHS observational data and interventional research service, maximising the way that anonymised NHS clinical data can be linked to support research, clinical trial feasibility and protocol optimisation. Already CPRD is helping companies perform feasibility studies to inform new clinical trials and international groups look to the CPRD as a source of critical data to enable post-market surveillance.

In therapeutic areas such as cardiovascular, joint replacement and wound care, CPRD is already making available data that can inform assessments of the benefits and risks of the use of devices.

**The Health and Social Care Information Centre** is England's central authoritative source of health and social care information for frontline decision makers. The information centre provides healthcare information to enable the improvement of healthcare decision making, patient outcomes and the identification of efficiency savings. The HSCIC plays a fundamental role in driving better care, better services and better outcomes for patients.

It is the trusted source of authoritative data and information relating to health and care. It supports the delivery of IT infrastructure, information systems and standards to ensure information flows efficiently and securely across the health and social care system to improve patient outcomes.

**Hospital Episode Statistics (HES)** is the national statistical data warehouse for England, documenting and analysing the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. HES is a unique data source, whose strength lies in the richness of detail at patient level. HES is a data source that can add substantial value for industry in understanding the landscape for their product in the UK. It is used by a wide variety of people including the NHS, government, regulators, academic researchers, industry, the media and members of the public.

Each year, HES adds an additional 19 million inpatient records, 90 million outpatient records, and 18 million A&E records.





## Regulatory Approval

**The European Union's regulatory system for medical devices has proved highly successful and is recognised as setting a high standard for patient safety, while remaining pragmatic. In addition, it has proved efficient in rapidly bringing the benefits of innovation to people much faster than some other regions. The UK is home to the globally-respected medical device regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) and follows the EU wide Medical Devices Directive, providing an effective and robust decentralised approval system.**

The MHRA is an Executive Agency of the Department of Health and has UK-wide responsibility for the regulation of medicines and clinical trials and is the Competent Authority in regulating medical devices in the UK, supported by accredited Notified Bodies. The MHRA works with other Competent Authorities in the EU and the European Commission, together with stakeholders, to develop additional guidelines to aid interpretation and implementation. For example on clinical investigations clinical evaluation as well as Harmonised European Standards are providing concrete processes and measures for manufacturers to follow in order to meet the 'Essential Requirements' to get CE marking.

Obtaining CE marking in Europe ensures your business is often able to provide your technology to patients 2-3 years ahead of the USA and 5 years ahead of Japan. The MHRA is one of the most heavily utilised Competent Authority in the EU and by undertaking health research in the UK and being assessed by a rigorous and globally renowned health regulator, your business can ensure better portability and prestige of your product(s) across the rest of the world.

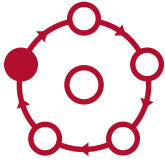
Clinical studies carried out in the UK will be regulated as clinical investigations and require approval from the MHRA. The Agency has an obligation to process clinical investigations in 60 days but often achieves it within this timeframe.

The UK Government is removing regulatory barriers and pushing for a more efficient, and innovative, regulatory environment and is committed to adopting innovative manufacturing technology.

The **Integrated Research Application System (IRAS)** is a UK-wide system that streamlines the process for applying for permissions and approvals to conduct health and social care research, including clinical investigations of medical devices. It allows users to enter the information for the relevant permissions and approvals once instead of having to complete several separate application forms for each review body.

**The MHRA has launched an 'Innovation Office'** to help organisations who are developing innovative medicines, medical devices or novel manufacturing processes navigate the regulatory processes in order to be able to progress their products or technologies.





## Health Technology Assessment and Market Entry

**Demands on health and social care systems continue to rise as demographics change and expectations from the public continue to increase. The need for better healthcare solutions supported by innovative and disruptive medical technology will play a critical role in managing this challenge. Cost effective and high quality healthcare solutions are critical to ensuring improved patient outcomes. The globally renowned National Institute for Health and Care Excellence (NICE) provides robust health technology assessment of the clinical and cost effectiveness of health technologies to ensure all NHS patients have equitable access to the most clinically and cost-effective technologies that are available.**

### Health Technology Assessment

By basing your business in the UK you gain access to the largest national healthcare system in the world. The NHS, as with other healthcare systems globally, is facing financial constraints. This challenge can only be overcome by embracing the uptake of innovation, as outlined in the UK Government's Strategy: *Innovation, Health and Wealth, accelerating adoption and diffusion in the NHS*.

The UK is a world leader in health technology assessment and home to the National Institute for Health and Care Excellence (NICE).

NICE produces independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation. NICE guidance is used by the NHS, industry, local authorities, charities, and anyone with a responsibility for commissioning or providing healthcare, public health or social care services. NICE also support these groups to put the guidance into practice.

For medical technologies, NICE produces guidance and recommendations to the NHS on the use of new and existing technologies as well as on new or novel interventional procedures.

The NICE Interventional Procedures programme evaluates the safety and efficacy of new interventional procedures. Other guidance programmes evaluate the full range of value propositions for medicines and medical technologies, these include:

- The Technology Appraisals Programme (TAP)
- The Medical Technologies Evaluation Programme (MTEP)
- The Diagnostics Assessment Programme (DAP).

These value propositions typically have the following characteristics:

- The technology costs more than current care but provides incremental benefits (usually suitable for evaluation by the TAP or DAP) or
- The technology is clinically non-inferior to current care and releases resources when measured across the health system within a plausible timeframe (usually suitable for evaluation by the MTEP).

### Medical Technologies Guidance

The Medical Technologies Evaluation Programme acts as the single point of access for medical technologies to the different guidance programmes at NICE, based on the claimed patient and healthcare system benefits compared with standard care. There is a particular emphasis on technologies that have the potential either to provide additional benefit to patients at the same or lower cost to the NHS or to provide equivalent benefit to patients at lower cost to the NHS.

### Diagnostics Guidance

The NICE DAP is suitable for evaluating diagnostic tests and technologies where such evaluation is complex. For example, where recommendations can only be made on the basis of clinical utility and cost-effectiveness analysis or where meaningful assessment requires the consideration of multiple technologies or indications.

The DAP evaluates diagnostic technologies that have the potential to improve health outcomes but whose introduction is likely to be associated with an overall increase in cost to the NHS. Diagnostic technologies that may offer similar health outcomes at less cost, or improved health outcomes at the same cost as current NHS practice, are likely to be more suitable for evaluation by the MTEP.

Within both MTEP and DAP, guidance development can also identify important gaps in the evidence and NICE then works with selected companies and their products, independent assessment centres and the research infrastructure to generate evidence on the clinical utility and healthcare system benefits of selected technologies.

NICE also offers a Scientific Advice Programme for developers of medical technologies and members of the investor community. This programme provides introductory training seminars to help participants understand how NICE defines value and to help companies develop a value proposition for their products. The one-day seminars cover approaches to: the assessment of costs and benefits for devices and diagnostics; types of evidence considered by NICE; information on UK resources for generating evidence; and general principles of health technology assessment.

NICE will also produce new **Medtech Innovation Briefings** that will provide objective information on promising devices and diagnostics. The briefings will describe new products, summarise the evidence of their clinical and cost effectiveness and the care pathway in which they can be used.

The briefings will include input from experts about the potential use of the technology in the pathway of care but they will not contain judgements from NICE on their value. The briefings will not be restricted to healthcare products as they will also cover those relevant to social care.

### Market Entry

The creation of **Academic Health Science Networks (AHSN)** will facilitate access into the NHS and align education, clinical research, informatics, innovation, training and healthcare delivery. AHSNs present a unique opportunity to pull together the adoption and spread of innovation with clinical research and trials, informatics, education, and healthcare delivery. They will develop solutions to healthcare problems and get existing solutions spread more quickly by building strong relationships with regional scientific and academic communities and industry.

## Success story

### Oraya Therapeutics utilises various organisations across the UK to gain rapid clinical uptake

California based Oraya Therapeutics Inc has developed a new therapy for Wet Age Related Macular Degeneration (wet AMD). The Oraya Therapy™ uses highly targeted, low-voltage X-rays to inhibit and prevent the growth of abnormal blood vessels under the macula (choroidal neovascularization) that is most often associated with wet AMD. Oraya Therapy™ is a first line treatment designed to maintain or improve vision while reducing the required number of expensive monthly intravitreal injections. UK Trade & Investment (UKTI) worked closely with Oraya Therapeutics and their UK MedTech Market Access consultancy Device Access UK Ltd to gain market access in Europe before eventual FDA approval.

An introduction to the National Institute for Health and Care Excellence (NICE) enabled Oraya Therapeutics to understand the appraisal processes in the UK. When an additional clinical trial site was required UKTI made introductions to the Manchester Royal Eye Hospital, using the National Institute for Health Research local Clinical Research Network. Manchester Royal Eye Hospital was able to initiate the trial very rapidly and the first patient was recruited within 6 weeks of the initial discussions.

Following the successful outcome of the initial trial Oraya Therapeutics continues to work with the Manchester Royal Eye Hospital team to review the longer-term impact of the therapy. Oraya Therapeutics has now successfully completed their clinical research and incorporated in the UK, continuing to gain clinical uptake in the private healthcare sector with expected adoption within the NHS by the end of 2013. Oraya Therapy™ has now been included in the NHS England list of High Impact Innovations, which will enable them to gain a high market penetration in the NHS. The Company aims to extend its UK base substantially in the next year.

The **Scottish Health Technologies Group (SHTG)** is an advisory group set up to provide assistance to NHS Scotland boards when considering selected health technologies, excluding medicines. The remit of the SHTG is to provide advice on the evidence about the clinical and cost effectiveness of existing and new technologies likely to have significant implications for patient care in Scotland. SHTG works in partnership with NICE and routinely use and disseminate their advice.

**Procurement** plays a valuable role in driving growth and improving quality and value in the NHS. Companies based in the UK procure on the same basis as other companies in the European Union.

*Better Procurement, Better Value, Better Care: Procurement Development Programme* recognises that there is considerable scope to improve the NHS' contribution to economic growth.

For this reason the Department of Health and NHS England will aim to ensure that the way the NHS undertakes its procurement does not preclude SMEs from gaining business. That the NHS is responsive to innovative solutions and ideas from industry and that early signals are sent to the market about strategic direction and future investments so that suppliers can talk to the NHS well before procurements are actually undertaken.

The release of the Procurement Development Programme for the NHS in England outlines a series of initiatives including an initiative to fundamentally re-think clinical engagement in the procurement of high-value medical devices and the subsequent relationship with the device industry, initially focusing on orthopaedic implants by improving outcomes at reduced cost through clinical procurement review partnerships.

## Success story

### PatientsLikeMe establishes its European base in the UK

US Healthcare Company PatientsLikeMe was co-founded in 2004 by three MIT engineers: brothers Benjamin and James Heywood and longtime friend Jeff Cole. Five years earlier, their brother and friend Stephen Heywood was diagnosed with ALS/MND (Lou Gehrig's disease) at the age of 29. The Heywood family soon began searching the world over for ideas that would extend and improve Stephen's life. Inspired by Stephen's experiences, the co-founders and team conceptualised and built a health data-sharing platform that they believe can transform the way patients manage their own conditions, change the way industry conducts research and improve patient care.

PatientsLikeMe draws experience from patients worldwide and in 2010 looked to the UK to establish a European base. To explore the opportunities in the UK the company participated in a UKTI sponsored competition, 'Go for Gold.' It was successful in winning the competition and obtained a broad based package of support that included flights and Britrail passes to travel around the country to meet with new prospective clients. Most importantly, a roundtable discussion with senior leaders from the NHS enabled the team to share its vision and gain valuable input into how its unique offering could integrate with key activities in the NHS. The company established its base in London in 2012. As PatientsLikeMe continues to grow, it enables patients to better understand their condition and drives better understanding of patient experience and the ways in which patient reported outcomes can be utilised to improve healthcare.

## Success story

### Hitachi links up with the Greater Manchester health ecosystem

Japanese technology giant Hitachi has established a presence in Manchester to work with the Manchester Academic Health Science Centre (MAHSC) and Network (GMAHSN) building on the expertise of North West eHealth and the NHS in Salford. The collaboration aims to develop IT designed to manage and improve patient care and population health.

The discussions between Hitachi and the Manchester health ecosystem have been supported by UK Trade & Investment (UKTI) and the Department of Health.

***"The UK has a huge amount to offer in health innovation specifically within the health informatics space. The NHS with 60+ million patients has access to unrivalled, clinically coded, granular health data, providing a unique opportunity to test innovative approaches to health informatics in order to meet end patient benefit."***

*Mark Treherne, Chief Executive, UKTI's Life Science Investment Organisation (LSIO)*

# How UK Trade & Investment (UKTI) Can Help Your Business

UK Trade & Investment (UKTI) can advise you on how to set up a new business in the UK, expand an existing business and choose the best route to market success. UKTI can also provide further information in a range of areas such as market opportunities, local skills and expertise, industry clusters, universities, incentives and funding support.

## Our Network

UKTI combines the expertise of professional trade and industry advisers in the UK alongside a global network of experts based in British diplomatic offices overseas, giving your business access to a well-connected presence on the ground at home and in the UK.

Your business' journey is important to us, from when your business is first considering making an investment in the UK to when it is well established - we are here to support your business' ongoing and future activities.

## UKTI Life Science Investment Organisation (LSIO)

UKTI has established a dedicated unit focused on UK life science. The UKTI Life Science Investment Organisation (LSIO) is your partner acting as a simple interface to the UK life science sector. The LSIO is your guide to identifying research, development and delivery partners and will support you through every step of investing in and working in the UK.

## Our Services

Our practical help and advice for inward investment is free and confidential. We work closely with other government departments and the wider UK life science community to provide excellent service and present the best UK offer.

*"I trained as a surgeon in the UK and moved to the USA over 20 years ago. Throughout my career I have enjoyed collaborating with the medical technology, pharmaceutical and biotechnology industries to help liberate innovation from bench to bedside and grow new life science enterprises. Working with British companies is a breath of fresh air. They are fast-moving, open to new ideas and great to interact with.*

*An added bonus is the interaction UK companies have with academic institutions and the NHS, providing an immense amount of cross working, sharing of innovative ideas to ultimately benefit patient outcomes.*

*I relish every opportunity to work with UK companies along with the supporting research and development ecosystem that underpins it."*

*Professor Jonathan Sackier,  
Director of Rex Bionics*

Once your business has a presence in the UK, we consider it a UK company and open up UKTI's global trade services to help your business launch into other international markets.

### Trade Associations and Professional Bodies

The UK has a range of medical technology sector specific trade associations and professional bodies that provide access, advice and guidance throughout your journey of the development pathway. A selection of which include:

The **Association of British Healthcare Industries (ABHI)** - the trade association for the medical equipment and supplies industry in the UK.  
**[www.abhi.org.uk](http://www.abhi.org.uk)**

The **British In Vitro Diagnostics Association (BIVDA)** - the national industry association for companies with major involvement and interest in the in vitro diagnostics (IVD) industry.  
**[www.bivda.co.uk](http://www.bivda.co.uk)**

The **British Healthcare Trades Association (BHTA)** - the healthcare association with member companies that focus on assistive technology products that help people live more independently.  
**[www.bhta.net](http://www.bhta.net)**

**Medilink UK** - the national health technology business support organisation, increasing the viability of manufacturers, service providers, designers, OEMs and suppliers of medical technology.  
**[www.medilinkuk.com](http://www.medilinkuk.com)**

**For a complete list of trade associations and professional bodies contact UKTI.**



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**UK Trade & Investment's (UKTI) practical help and advice for inward investment is free and confidential. We work closely with other government departments and the wider UK life sciences community to provide excellent service and present the best UK offer.**

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Note: This document seeks to illustrate the support the UK Government and Associated Institutions within the UK can provide to your medical technology business. Given the dynamic nature of Government-Academic- Industry partnerships this document cannot capture all measures in the sector. This document is intended as an introduction to some of the measures available and seeks to illustrate some recent successes.

# Acronyms

<b>AHSC</b>	Academic Health Science Centre	<b>MHRA</b>	Medicines and Healthcare products Regulatory Agency
<b>AHSN</b>	Academic Health Science Network	<b>MTEP</b>	Medical Technologies Evaluation Programme
<b>AMSCI</b>	Advanced Manufacturing Supply Chain Initiative	<b>NESTA</b>	National Endowment for Science, Technology and the Arts
<b>ASTUTE</b>	Advanced Sustainable Manufacturing Technologies	<b>NHS</b>	National Health Service
<b>BBA</b>	British Bankers' Association	<b>NICE</b>	National Institute for Health and Care Excellence
<b>BGF</b>	Business Growth Fund	<b>NIHR</b>	National Institute for Health Research
<b>BIS</b>	Department for Business, Innovation and Skills	<b>NIHR i4i</b>	National Institute for Health Research Invention for Innovation
<b>BRC</b>	Biomedical Research Centre	<b>NISCHR</b>	National Institute for Social Care and Health Research
<b>BRU</b>	Biomedical Research Unit	<b>NOCRI</b>	NIHR Office for Clinical Research Infrastructure
<b>CCG</b>	Clinical Commissioning Group	<b>NRS</b>	NHS Research Scotland
<b>CIMIT</b>	Center for Integrating Medicine & Innovative Technology	<b>NRS Permissions CC</b>	NHS Research Scotland Permissions Coordinating Centre
<b>CPRD</b>	Clinical Practice Research Datalink	<b>RAE</b>	Royal Academy of Engineering
<b>CRC</b>	Clinical Research Centre	<b>R&amp;D</b>	Research & Development
<b>DA</b>	Devolved Administration	<b>RGF</b>	Regional Growth Fund
<b>DALLAS</b>	Delivering Assisted Living Lifestyle at Scale	<b>RSA</b>	Regional Selective Assistance
<b>DAP</b>	Diagnostics Assessment Programme	<b>SEIS</b>	Seed Enterprise Investment Scheme
<b>EIS</b>	Enterprise Investment Scheme	<b>SHTG</b>	Scottish Health Technologies Group
<b>EPSRC</b>	Engineering and Physical Sciences Research Council	<b>SMAS</b>	Scottish Manufacturing Advisory Service
<b>HES</b>	Hospital Episode Statistics	<b>SMEs</b>	Small and Medium Sized Enterprises
<b>HICF</b>	Health Innovation Challenge Fund	<b>SSCIF</b>	Specialised Service Commissioning Innovation Fund
<b>HSC R&amp;D</b>	Health and Social Care Research and Development	<b>TAP</b>	Technology Appraisals Programme
<b>HSCIC</b>	Health and Social Care Information Centre	<b>TSB</b>	Technology Strategy Board
<b>IRAS</b>	Integrated Research Application System	<b>UKTI</b>	UK Trade & Investment
<b>KTN</b>	Knowledge Transfer Network	<b>VC</b>	Venture Capital
<b>KTP</b>	Knowledge Transfer Partnership		
<b>LSIO</b>	Life Science Investment Organisation		
<b>MAS</b>	Manufacturing Advisory Service		

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## UKTI

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