Unlock Your Global Business Potential:

UK Medical Device Market
& Business Opportunities

The UK market opportunity for medical technology businesses

- Despite a difficult economic climate, the UK Medical Technology sector has rapidly grown over the last 4 years, and has increased turnover by 50% between 2009-12.
- The number of medical technology companies in the UK increased by 12% from 2009-12 in line with this sector growth, the number of people employed in the sector increased by 40% in the same period.

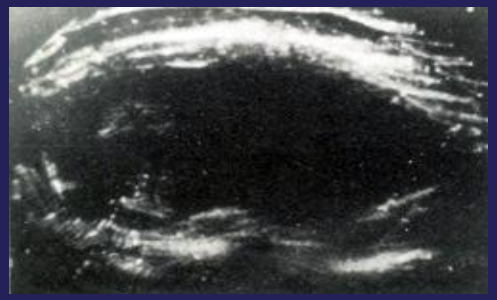
The UK medical devices market was valued at **£6.4bn in 2013**.

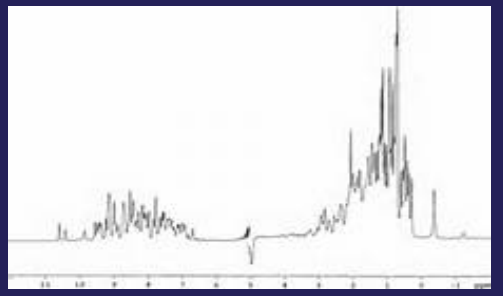
The UK medical devices market is rising by 7.3% per year reaching **£9.1bn by 2018**

The sector is comprised of **3,129 UK-based companies** which employ just over 71,000 individuals.

The global medical technology market is expected to double to approximately £300bn by 2015

The UK medical technology landscape has a rich heritage of innovations in health technologies





- The use of ultrasound equipment in medicine has transformed diagnosis and the observation of prenatal development.
- The invention of a commercially viable CAT scanner in the UK opened the door to a new branch of imaging which has become a mainstay of diagnostic imaging.
- The discovery of the potential of nuclear magnetic resonance has transformed diagnostic imaging.
- Joint replacement technology and orthopaedics improved the quality of life for millions of people through successful replacement of hips, knees and other joints

The UK medical technology landscape has a rich heritage of innovations in health technologies

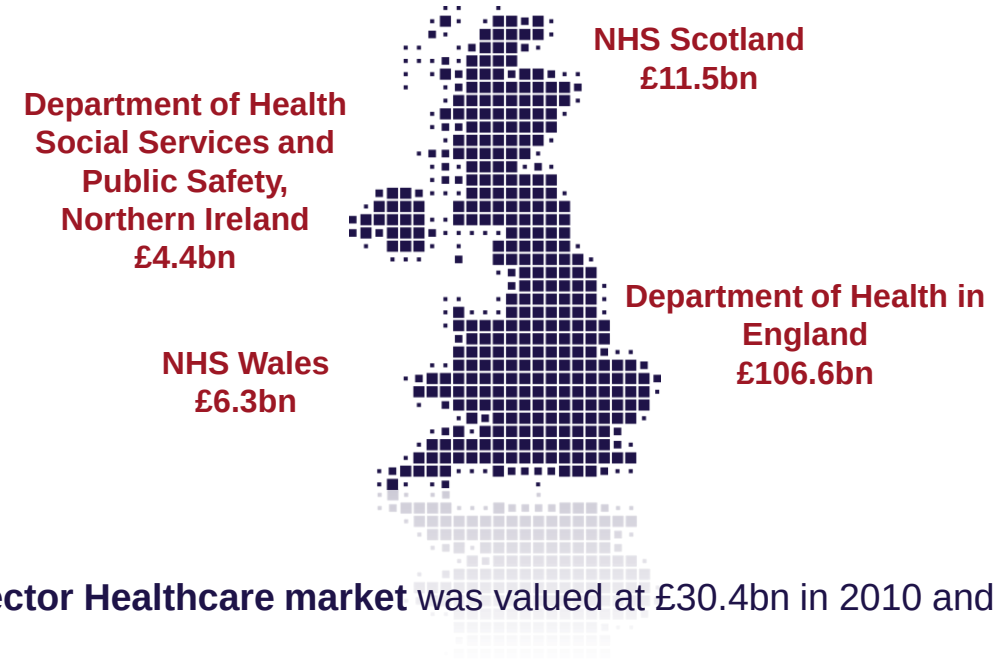
- World-breaking technology for electronic prosthetics which emanated from NHS Scotland is now helping amputees around the world
- The innovations in robotics particularly for minimally invasive surgery are providing quality benefits to patients undergoing surgery.
- UK academic institutions are spinning out a range of innovative companies and technologies centred around DNA sequencing technologies

The UK market opportunity for your medical technology business

Businesses can access the UK medical technology market and supply chain by engaging with a range of UK healthcare markets**:**

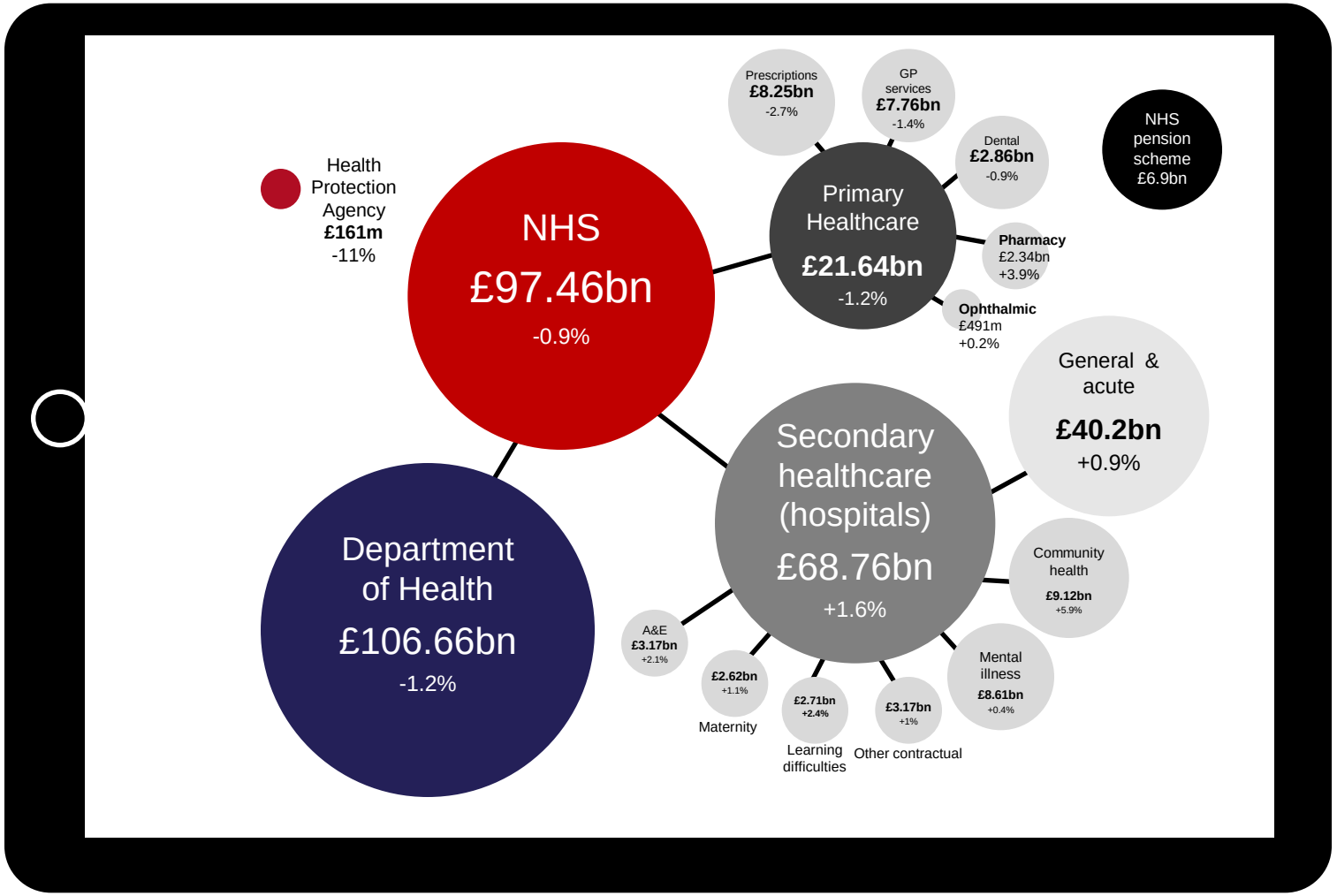
1.The UK in 2011-12 collectively spent approximately £128bn on the **National Health Service**, world's largest publicly funded healthcare system which is free at the point of service.

Breakdown by region (2011-12):



2. The **UK Private Sector Healthcare market** was valued at £30.4bn in 2010 and is anticipated to reach £35.9bn by 2015.
3. The **Social Care market**, dominated by assistive technologies, is set to grow from £2bn in 2012 to £6bn in 2020.

The scale of the NHS in England, breakdown in healthcare spend



Healthcare Spend on Medical Devices

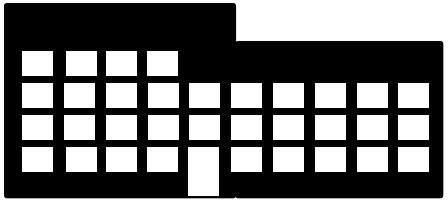
The UK Medical Device Market, 2006-16 (US$ millions)

US$ millions	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Consumables	2,576.0	2,118.5	2,288.9	1,861.5	1,854.2	1,865.0	1,835.4	1,899.1	2,001.7	2,050.2	2,088.6
Woundcare Products	560.2	586.1	646.7	635.5	669.7	711.4	737.8	803.1	888.7	953.7	1,015.9
Syringes, Needles & Catheters	1,819.8	1,384.7	1,491.8	1,096.1	1,053.1	1,019.7	964.3	956.9	965.4	944.6	917.3
Others	196.0	147.7	150.4	130.0	131.4	133.9	133.2	139.1	147.7	152.0	155.3
Diagnostic Imaging	1,400.8	1,343.9	1,347.4	1,257.8	1,272.1	1,297.0	1,291.7	1,350.3	1,435.5	1,480.4	1,515.9
Electrodiagnostic Apparatus	598.5	599.8	664.7	618.5	622.5	631.5	625.6	650.3	687.2	704.3	716.6
Radiation Apparatus	156.3	187.3	193.6	187.8	197.2	208.6	215.6	233.8	257.7	275.5	292.4
Imaging Parts & Accessories	646.1	556.9	489.2	451.5	452.4	456.9	450.6	466.3	490.6	500.5	507.0
Dental Products	329.9	332.8	363.8	339.9	346.6	356.2	357.5	376.5	403.2	418.7	431.6
Dental Capital Equipment	57.3	56.7	65.9	65.9	66.3	67.4	66.8	69.5	73.5	75.4	76.8
Dental Instruments & Supplies	272.6	276.1	297.9	274.1	280.3	288.9	290.7	307.0	329.7	343.3	354.8
Orthopaedic Products	989.4	972.1	1,064.2	807.5	816.9	833.0	829.5	866.8	920.8	948.8	970.4
Splints & Other Fracture Apps	433.4	447.6	471.2	402.8	405.8	412.1	408.6	425.2	449.8	461.5	470.0
Artificial Joints	348.2	336.9	391.7	231.4	233.8	238.1	236.8	247.2	262.3	269.9	275.7
Other Artficial Body Parts	207.8	187.6	201.3	173.4	177.3	182.8	184.0	194.4	208.7	217.3	224.7
Patient Aids	1,287.7	1,310.6	1,579.6	1,470.5	1,521.1	1,586.2	1,615.7	1,727.4	1,877.9	1,980.5	2,073.7
Portable Aids	831.9	877.8	1,068.9	1,008.3	1,054.2	1,110.8	1,143.0	1,234.2	1,354.8	1,442.4	1,524.3
Therapeutic Appliances	455.7	432.7	510.7	462.2	466.9	475.4	472.7	493.1	523.1	538.1	549.5
Others	2,405.2	2,375.9	2,632.9	2,469.9	2,505.9	2,562.5	2,558.8	2,681.2	2,856.3	2,951.1	3,026.5
Total	8,989.0	8,453.8	9,276.8	8,207.2	8,316.7	8,500.0	8,488.5	8,901.3	9,495.4	9,829.8	10,106.7

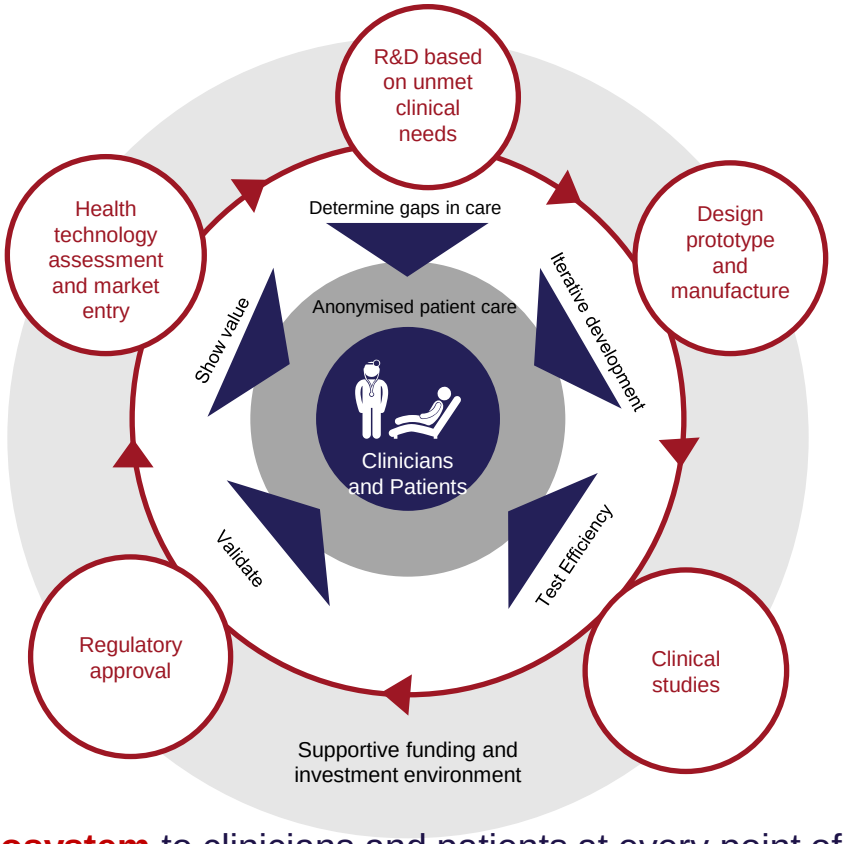
- In 2011, the UK medical device market was estimated at US$8.5 billion and US$136 per capita.
- Investment continues as spending is 'ring-fenced' to 2015.
- Between 85% and 90% of the market is supplied by imports, a percentage which rising demand has boosted in recent years.
- Looking forward, value for money and efficacy will be, more than ever, key factors in deciding purchases.

Accessing the medical technology development pathway in the UK

Now more than ever medical technologies **need to demonstrate improved value at a reduced cost**, with increased quality that can provide **direct benefit to patients** in order to be adopted into global healthcare systems.



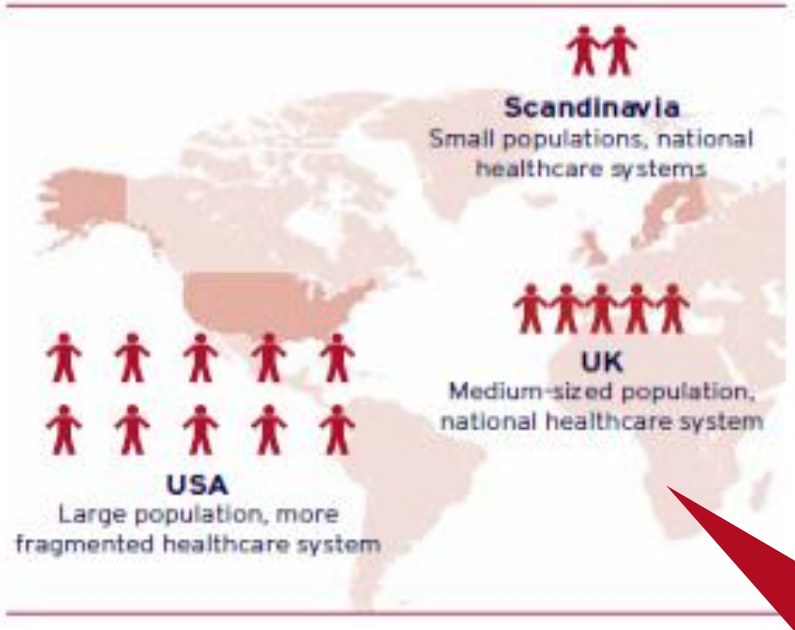
INDUSTRY



The UK offers industry **a rich and diverse connected ecosystem** to clinicians and patients at every point of the med tech development pathway, to ensure technologies can be tested for value, quality and cost.

Unlocking Data to Drive Innovation

- In the UK, businesses have access to unrivalled, clinically-coded health data and bio- repositories, including linked datasets to understand care pathways
- This allows high-quality data to be generated by clinical research to provide information to support world-wide product marketing.



"We have had a very productive relationship with the Cambridge Bioresource over the last two to three years where collaboration has resulted in provision of genetic resource, conduct of clinical and translational trials, and publication of both clinical and immuno-inflammatory mechanistic study results related to pharmacogenetic interactions.."

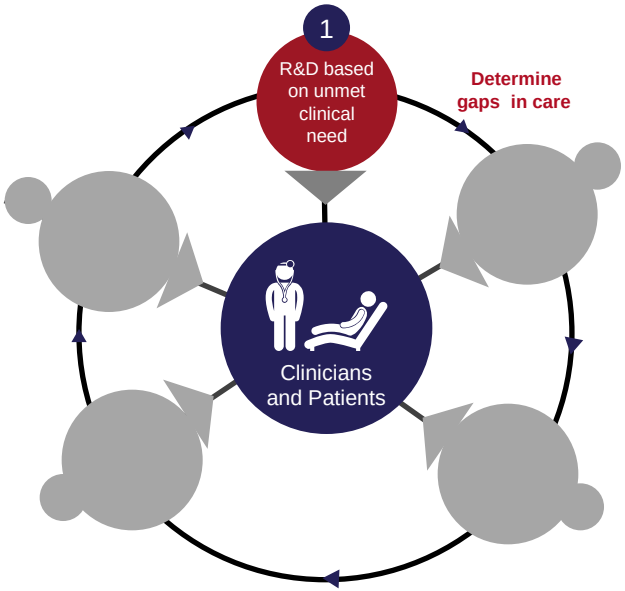
Simon McHugh, Director of Scientific Operations

The UK medical technology ecosystem

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 and research to prove concepts for innovative medical technology
- Advanced manufacturing capabilities to design, prototype and engineer medical technologies
- A national clinical research infrastructure to translate research, access patients and validate 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

1. R&D based on unmet clinical needs



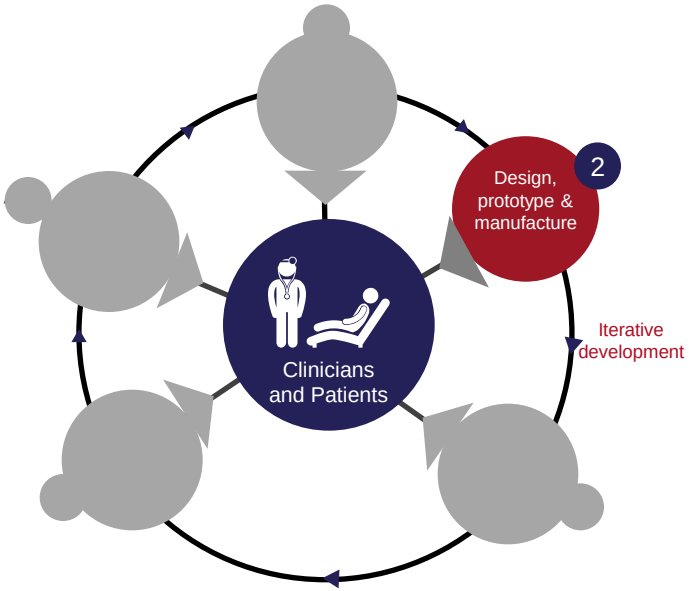
- Treating almost 1 million patients on a daily basis the NHS is the largest unified healthcare system in the world.
- World-class resources, academic institutions and research to prove concepts for innovative medical technology.
- The UK has the highest number of skilled engineers and scientists in Europe and four of the top six universities globally.
- The National Institute for Health Research funds a range of clinical research infrastructure which function across the innovation pathway, including device technology

Specialised Service Commissioning Innovation Fund (SSCIF) a fund to rapidly test and evaluate innovations that have the potential to deliver high impact changes for specialised services.

The Technology Strategy Board's **Knowledge Transfer Partnership (KTP)** help businesses by accessing the knowledge, technology and skills within the UK's world class universities, colleges and research organisations,.

National Institute for Health Research (NIHR) has committed £6.4m to fund eight new NIHR Healthcare Technology Co-operatives (HTCs)

2. Design, prototype and manufacture



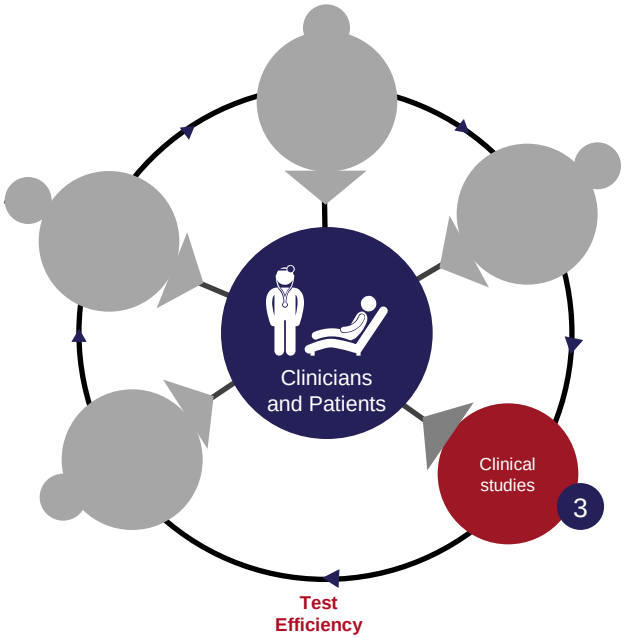
- The UK has a rich and continuing heritage of innovative medical engineering to deliver improved prevention, diagnosis and treatment of illness.
- The UK has a range of globally renowned academic institutions maintaining strong engineering research departments with close links to global industry.
- UK med tech companies benefit from a comprehensive supply chain offering, design and prototyping, through to manufacture, supply and distribution.

The **Wellcome Trust** and the **Engineering and Physical Sciences Research Council** are in partnership funding four Centres of Excellence in Medical Engineering in the UK which your business can access.

Catapult helps businesses work with leading scientists and engineers through £1bn of private and public sector investment
High Value Manufacturing Catapult transforms brilliant manufacturing ideas into valuable products and services

Advanced Manufacturing Supply Chain Initiative is a £125m fund available to your business to support research and development, skills training, and capital investment to help companies achieve world-class standards.

3. Clinical studies



- The combination of the unique NHS, linked to a clinical research infrastructure, offers a range of activities across the product development to build supporting evidence early and on an on-going basis.
- The NIHR Office for Clinical Research Infrastructure (NOCRI) in England enables you to rapidly demonstrate the clinical performance of your medical technology.
- The research infrastructure works with industry to design protocols, and access world leading academic and clinical expertise.

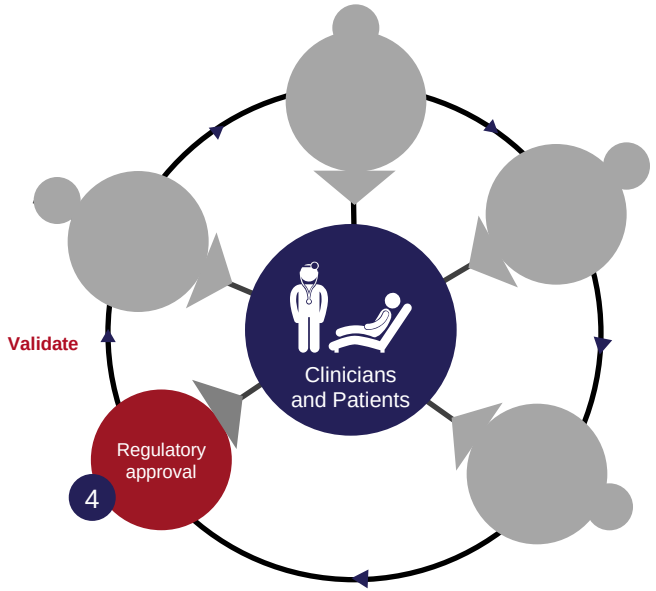
NIHR Medical Device and Diagnostics Industry Partnerships help device and diagnostics companies produce innovative products successfully

NIHR Clinical Research Network support set-up and delivery of medical technology research studies.

NHS Research Scotland provides support for clinical research,
In Wales: The National Institute for Social Care and Health Research supports health and social care research
In Northern Ireland: Health and Social Care Research and Development, funds clinical research networks

- **Clinical Practice Research Datalink**
- **Health and Social Care Information Centre**
- **Hospital Episode Statistics (HES)**

4. Regulatory approval

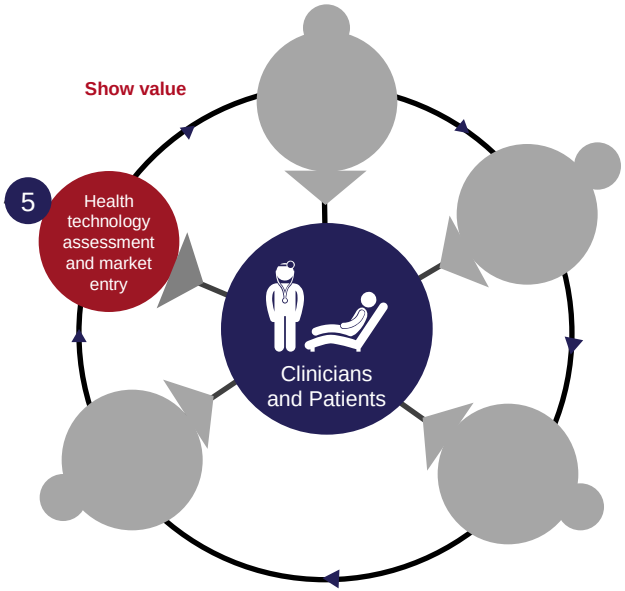


- The European Union's regulatory system for medical devices has proved highly successful, and is recognised as setting a high standard for patient safety.
- The MHRA is an Executive Agency of the Department of Health and has UK-wide responsibility for the regulation of medicines and Clinical Trials and is the Competent Authority in regulating medical devices in the UK.

The **MHRA Innovation Office** helps you navigate around the UK and EU regulatory landscape. The MHRA is launching 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.

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.

5. Health technology assessment and market entry



- Businesses based in the UK gain access to the largest national healthcare system in the world, the NHS.
- The UK Government's Strategy: Innovation, Health and Wealth report aims to embed and spread the uptake innovation at pace and scale
- The UK is a world leader in health technology assessment and home to the National Institute for Health and Care Excellence (NICE)

NICE's Medical Technologies Evaluation Programme identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them.

Emerging **Academic Health Science Networks** will facilitate access into the NHS and align education, clinical research, informatics, innovation, training and healthcare delivery providing a network aimed at facilitating the adoption and dissemination of innovative technologies.

The NICE Interventional Procedures programme evaluates the safety and efficacy of new interventional procedures.
- The Technology Appraisals Programme (TAP)
- The Medical Technologies Evaluation Programme (MTEP)
- The Diagnostics Assessment Programme (DAP)

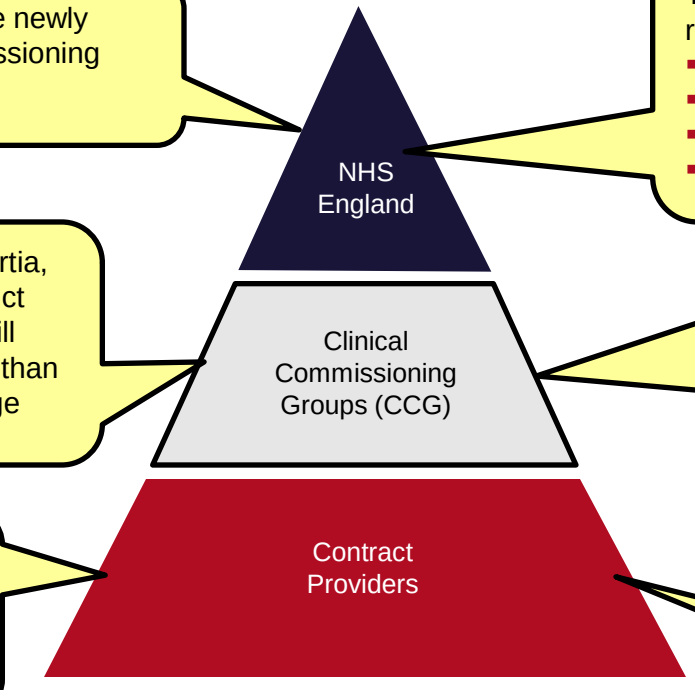
The new NHS Structure in England

Who are they?

The CCGs will be overseen by the newly formed independent NHS Commissioning Board

There will be just over 200 consortia, each will have different and distinct characteristics. Each consortia will have an average budget of more than a £100m and will together manage some £70 billion of NHS funds

Made up of care providers, i.e acute trusts, community services, mental health services



What do they do?

The NHS Commissioning Board will also be responsible for directly commissioning:

- Pharmacy services
- General practice
- Dentistry services
- Specialist services

They will be commissioning or buying health and care services including:

- Elective hospital care
- Rehabilitation care
- Urgent and emergency care
- Most community health services
- Mental health and learning disability services

Provide care to patients and manage allocated budget

CCGs are groups of GPs that have formed from April 2013, they will be responsible for designing local health services In England. They are managed by the NHS Commissioning Board.

Success Stories

A short selection of examples of successful investment and innovation

Toshiba Medical Visualization Systems Europe (TMVS) expands its R&D operations in Edinburgh

- Voxar, an Edinburgh-based technology start-up specialising in advanced visualisation software for medical imaging was acquired by Toshiba Medical Systems, 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.

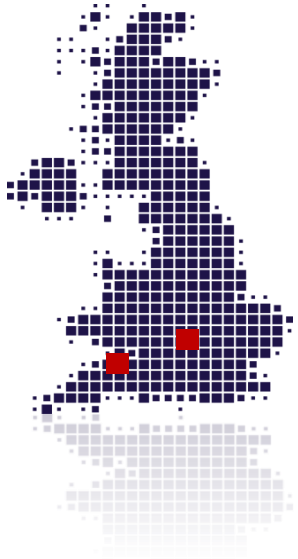
TOSHIBA
Leading Innovation >>>

- "In a global economy, Toshiba's decision to site a major R&D center 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

De Soutter Medical continues to enhance manufacturing capabilities in the UK

- De Soutter is recognised as the leading European manufacturer of surgical power tools, focused on the orthopaedics and trauma marketplace
- 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
- Most of the component parts sourced by the company are manufactured at it's 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 Desoutter, Technical Director, De Soutter Medical

deSoutter MEDICAL

Vidacare utilises the National Institute of Health Research Clinical Research Network in England

- 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 introductions

vidacare

- ”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.”

  Vidacare’s Senior Director, Science & Clinical, Dr Thomas Philbeck

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