The AHSN Network

HealthTech landscape overview

Making sense of the MedTech innovation maze

Office for Life Sciences

NHS

Contents

Foreword

The Secretary of State for Health has spoken at length about his vision for a more technology-driven NHS and the benefits that this approach will bring. We are at the early stages of technology adoption at scale in the NHS but the NHS Long-Term Plan has made it clear that innovation in general, and technological innovation in particular, are fundamental to the goal of delivering improvements in clinical outcomes and patient experience, whilst responding to the significant budgetary and workforce pressures faced by health and care systems the world over.

One of the UK government's first steps towards achieving this vision has been to create the Accelerated Access Collaborative (AAC), which brings industry, government and the NHS together to remove barriers to the uptake of innovations in health and technology (HealthTech), so that NHS patients have faster access to innovations that can transform care.

HealthTech spans the continuum of wellbeing, disease prevention, diagnosis, treatment and maintenance. It plays a significant role in the UK's economic growth and is now the largest employer in the broader UK Life Sciences sector, employing 127,400 people in 3,860 companies, with a combined turnover of £24bn. New HealthTech innovations are coming to market daily. Some of these, such as blood pressure monitors, activity monitors and blood glucose monitors, are aimed directly at the consumer for the purposes of disease prevention, care management and fitness tracking. Others, such as the use of AI in radiology and pathology, are aimed at healthcare professionals and have the potential to enable faster and more informed disease diagnosis and precision treatments.

HealthTech is fast evolving to meet the changing needs and expectations of the public. Consumers are seizing the opportunity to become more empowered to take control of their own health needs and there is a growing policy shift towards wellbeing and disease prevention. Treatments for many illnesses are now becoming personalised thanks to advances in genomic medicine and long-term maintenance programmes for chronic conditions are frequently available. All these developments require greater collaboration and an easier exchange of information between clinicians and patients. This is a complex journey and we are still in its early stages.

Given our universal single-payer system, and our comprehensive national datasets, the UK is uniquely placed to play a leading role globally as a test bed for the deployment of innovations in HealthTech. We have already put in place several collaborations to achieve these aims:

- Academic Health Science Networks (AHSNs) were established in 2013 and form a key innovation arm of our healthcare system, bridging gaps and strengthening the connections between research, life sciences industry and healthcare systems. AHSNs also work with many national bodies including the Association of British HealthTech Industries (ABHI), Association of the British Pharmaceutical Industry (ABPI),

British In Vitro Diagnostics Association (BIVDA) and the BioIndustry Association (BIA). AHSNs have also developed systems – notably SBRI Healthcare and the NHS Innovation Accelerator – to support early-stage innovations with significant potential impact.

- The Accelerated Access Collaborative (AAC) has established a new integrated innovation and medicines senior management team to coordinate medicines policy, commercial agreement and broader innovation policy and delivery The Life Sciences Industrial Strategy, published in August 2017, engaged industry, the third sector and the NHS to publish a vision and strategy for the life sciences sector, which includes collaboration with industry and facilitates better care for patients through better adoption of innovative treatments and technologies.
- The UK Government has partnered with industry to set out a series of Life Sciences Sector Deals to help ensure that pioneering treatments and medical technologies are produced in the UK, improving patient lives and driving economic growth.
- Health Data Research UK (HDR UK) brings together 22 research institutes across the UK in a one-institute approach to ensure that large scale data and advanced analytics benefit every patient interaction, clinical trial, biomedical discovery and enhance public health.
- Seven Health Data Hubs are being rolled out across the UK, involving representatives from academia, industry, patient groups, research and the NHS to exploit the potential of anonymised clinical data for driving research and innovation.

No single authority has the ability to manage the roll-out of these different aspects of technology to deliver the healthcare of the future. It should therefore be no surprise that the government's approach in this area has been to encourage the development of new types of partnership.

It will also be clear that innovation in the HealthTech sector is often hindered by our complex and dynamic wider healthcare system, which can be difficult to navigate. For this reason, I am delighted to introduce this practical guide which sets out the MedTech innovation pathway, providing innovators from the UK and wider afield a step by step practical guide for launching products in the UK market and a more informed view of the UK MedTech ecosystem.

Piers Ricketts, Chair, AHSN Network and CEO, Eastern AHSN

Introduction

HealthTech is defined by the World Health Organisation (WHO) as 'the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives'. This umbrella term incorporates a diverse range of products ranging from over the counter consumer devices for health monitoring (e.g. smart phone apps, pregnancy testing) to complex robotic surgical systems used by specialist clinicians. HealthTech spans the entire health continuum of disease prevention, diagnosis, treatment and maintenance incorporating a number of industrial sectors including MedTech, digital, Artificial Intelligence, Robotic Process Automation, and consumer health, with recent advances often sitting at areas of convergence between different clinical disciplines and between industries.

The review is split into five main sections:

1. What do we mean by MedTech? A description of how MedTech is defined
2. An overview of the MedTech industry in England, outlining sector distribution, turnover and employment
3. A step by step guide to navigating the MedTech innovation pathway, outlining key organisations and bodies that can support innovators during the process
4. An overview of MedTech regional strengths across England, focusing on established and emerging clusters of innovation
5. An overview of routes to achieving growth, and a selection of case studies of companies that have successfully navigated the MedTech innovation pathway

The sheer diversity of the HealthTech sector means that while there are common aspects to the innovation pathway, the journey for innovators in this space is often puzzling, with ambiguity around the actions and approvals required in order to bring their products to market. This report takes the first step to demystify this maze by providing an in-depth "how to" guide for innovators in MedTech.

This guide incorporates an in-depth view of the UK's MedTech ecosystem and provides a practical, comprehensive guide for innovators attempting to navigate the MedTech innovation Pathway. It signposts some key organisations who can support innovators in their endeavours. It also sets out some case studies, which bring to life how MedTech innovations are being harnessed and implemented within the UK healthcare system to bring about patient benefits and health outcomes.

What is MedTech?

Medical technologies are products, services or solutions used to save and improve people's lives[1]

The MedTech sector comprises businesses developing, manufacturing and selling medical technologies, supported by an extensive network of service and supply businesses[2]. The sector sits within life sciences alongside biotech and is characterised in particular by the influence of medical device regulations and by the health economic considerations that impact on adoption and diffusion in key customer groups such as the NHS.

It is estimated that there are more than 500,000 different MedTech products on the market, available in hospitals, in the community-care setting and in patients' homes. MedTech crosses all parts of the care pathway including prevention, diagnosis, monitoring, treatment and care. The product range is vast, ranging from sticking plasters, to wheelchairs, to total body scanners to joint replacements.

Fresh opportunities are opening up in the MedTech sector driven by the growing need for healthcare systems to deliver greater value and fuelled by advances in science and the convergence of technologies. Healthcare systems globally are looking for solutions that enable earlier diagnosis of disease, new precision treatments and improved patient experience, such as the ability to take high quality care closer to home, enabling patient empowerment. Significant trends in recent years include the evolution of drug-device combinations, the convergence of digital and medical technologies in connected medical devices, especially in new forms of diagnostic testing, the application of artificial intelligence, and the emerging fields of precision and regenerative medicine. Scientific advances such as nanotechnology and robotics are also opening up new possibilities. Medicine is moving towards a more preventative approach, and MedTech plays a crucial role in this.

Companies within the MedTech sector can be broadly classified into two groups:

Core MedTech

Includes all businesses whose primary business falls under developing and producing their own MedTech products.

Core MedTech accounts for 70% of the companies and 80% of the turnover in the MedTech sector (excluding digital).

MedTech Service and Supply

Includes Contract Research and Manufacturing Organisations, suppliers of consumables and reagents, providers of specialist legal and regulatory expertise, medical device design, analytical, IT, recruitment and logistics services as well as finance businesses specialising in MedTech investments.

The MedTech industry in England

The MedTech sector covers a wide range of technologies, serves global markets and accounts for around 40% of Life Sciences employment in England.

Working with the NHS in England offers significant market opportunities for MedTech companies as well as a globally respected ecosystem for conducting research and development.

£6bn NHS annual spending on MedTech

£3bn

Medical consumables –
dressings, syringes

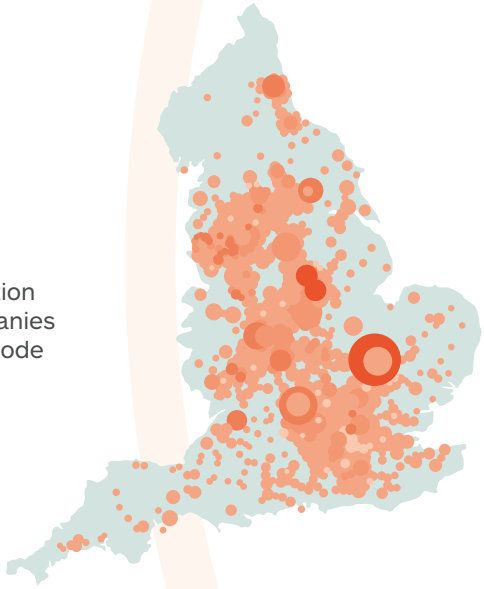
£3bn

Complex devices –
hip joints, cardiac devices

MedTech is a national endeavour

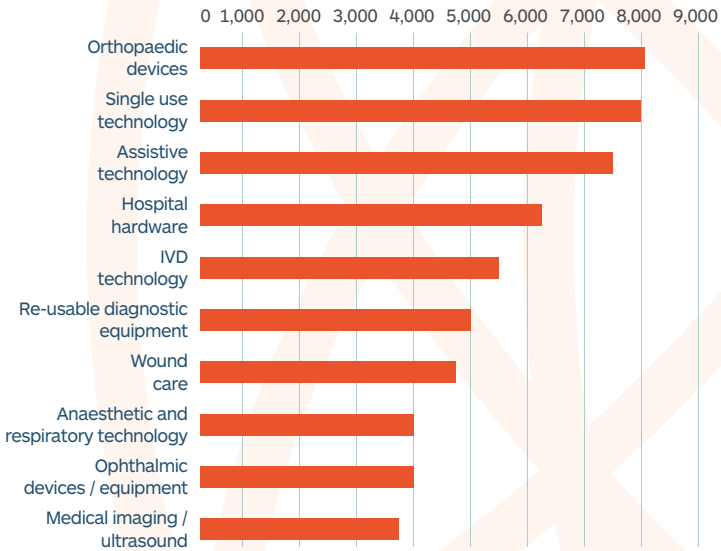
MedTech sector company distribution

Distribution of companies by postcode



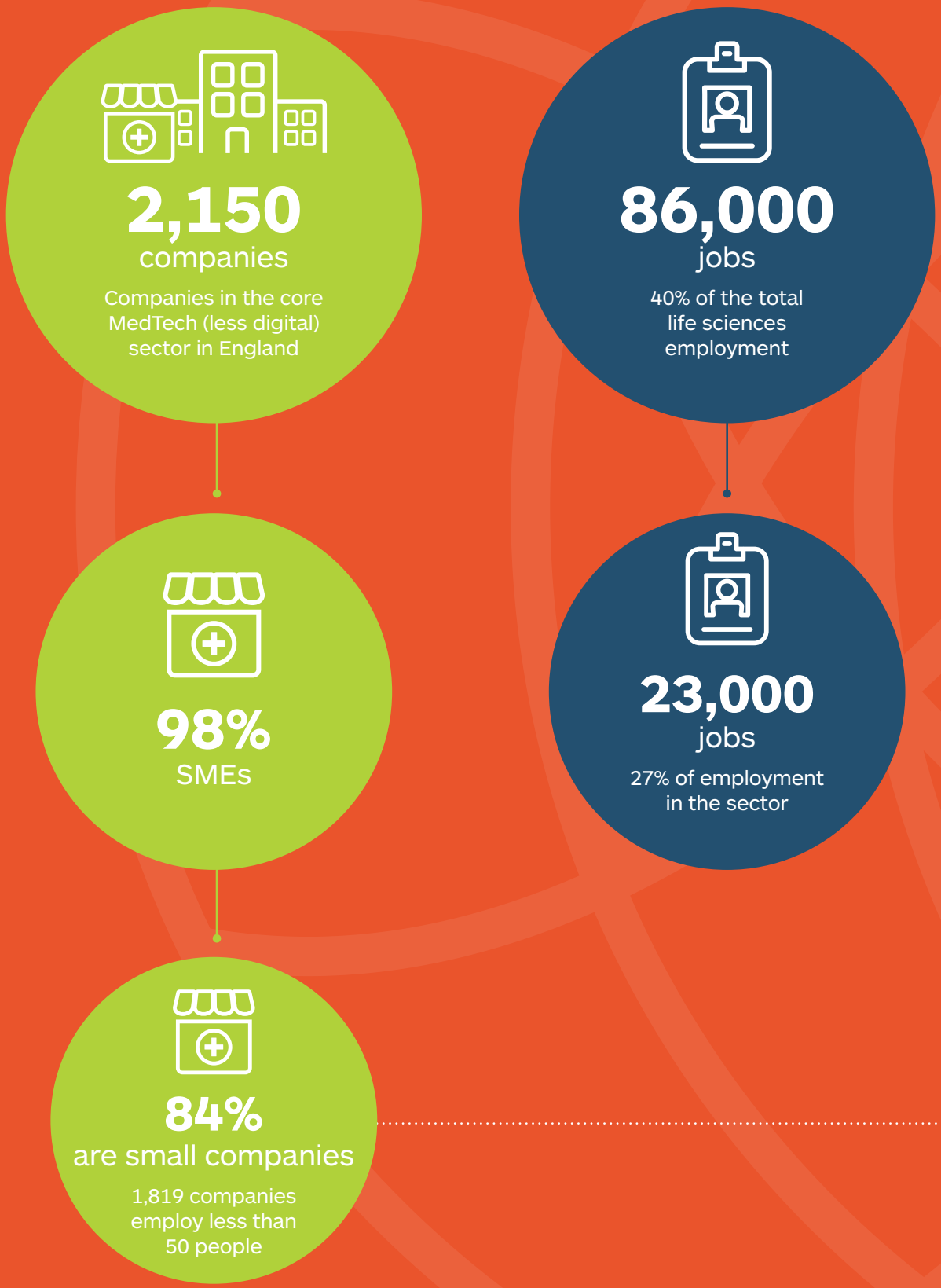
10 segments account for 75% of employment

Core MedTech segments employment



100+ science and innovation parks

Providing facilities for MedTech companies to grow



Sources:

- *PA Consulting analysis of company data from "Strength and Opportunity 2017: life sciences companies data" published by The Office for Life Sciences*
- *NHS procurement data from "Operational productivity and performance in English NHS acute hospitals: Unwarranted variations", an independent report for the Department of Health by Lord Carter of Cole*

£16.8bn
Turnover
including services

13,000+
MedTech patents filed with the European Patient Office in 2017

Less than
3%
of the MedTech companies across England have a turnover of over £50m

£5.7bn
Around a third of the total turnover comes from small companies

Navigating the innovation pathway

The MedTech landscape is shifting, with challenges in the form of new regulatory requirements, and strong market forces driving the need for more competitively priced profitable products into a complex and increasingly diverse healthcare procurement landscape.

The MedTech innovation pathway

The innovation pathway for MedTech products is formed of 6 steps:

The aim of this section is to navigate developers and other interested parties through a MedTech innovation pathway, highlighting key activities to be undertaken at each step, and signposting the specialist support potentially available to ensure that new innovations achieve both patient benefit and commercial success.

The key activities underpinning each step of the MedTech Innovation pathway are outlined below:

Creation	Identification of market value of concept, impact on outcomes and market access barriers	Page 16
Development (Prototype)	Development and refinement of product ready for regulatory assessment and clinical evaluation	Page 21
Development (Clinical evaluation)	Clinical evaluation of product to demonstrate that it is safe and performs as intended	Page 22
Regulation	Assessment of product to ensure it conforms to the requirements for the relevant legislation in each jurisdiction in which the product is to be marketed	Page 25
Evaluation / reimbursement	Evaluation and endorsement of the health and economic case, clarification of reimbursement approach	Page 28
Commissioning and adoption	Preparation for, and entry to market, development of business case	Page 34

The information in this guide relates to the innovation pathway steps and core activities for the MedTech sector. However, in some instances some information is also applicable to other healthcare sectors. The MedTech Innovation pathway steps are aligned to published OLS guidance[3].

Creation

It is important to consider the MedTech market at an early stage of development to avoid unnecessary investment of time and expense for innovators in maturing technologies that offer limited market value.

Q: What is the market value of the product?

A: Identifying consumer wants and needs, and subsequently developing the product or service to meet them, is an initial step that must be completed before moving onto other steps in the process.

- Will the MedTech concept deliver a product that is novel to the market, or deliver a product with technology offering a competitive advantage over existing products in the market?
- Will the existing technology align to published NHS priorities and/or address an unmet need for providers and patients? The NHS Five Year Forward View[4] and the recently published NHS Long-Term Plan[5] provide a strong indicator of the focus for NHS investment going forward, highlighting where innovators need to match the value of their products.

Q: What outcomes will the product deliver?

A: The economic case for the product must also be extended to take into consideration impacts of the technology on outcomes through the lenses of the patient, the user of the technology and the health and care system as a whole. It is relatively easy to determine the short-term benefits of those technologies impacting on patients and providers, e.g. increased speed and accuracy of procedures, improved recovery rates, improved bed utilisation.

However, the longer-term impacts of technologies on the health and care economy, such as an increased life expectancy of a particular patient cohort (and the concomitant increase in the duration and cost of care provision) as a consequence of improved diagnostic capability, are more difficult to estimate. Patient involvement in research and development is increasingly a priority for regulators and other official bodies. Involving patients and other relevant stakeholders at this early stage will ensure a holistic view of the relevance of the final product, identify its value, highlight any accessibility issues and ultimately strengthen the business case.

Patient and user engagement

Patient and user can be accessed through a range of mechanisms, including direct engagement with NHS Trusts, the AHSNs, through medical charities and through the NIHR national advisory group, INVOLVE[6]. INVOLVE is a large public participation charity aiming to put people at the heart of decision making. INVOLVE ensures the views of patients and the public are incorporated during the research phase of the innovation pathway.

Q: What data will be required to enable the NHS to buy?

A: It is advisable, at this stage, to understand how healthcare providers in the target market buy MedTech products. In a climate of significantly high cost pressures, and a healthy competitive landscape, market access for MedTech products is challenging. A convincing economic case, underpinned by supporting clinical data, will be needed for procurement teams to overlook cheaper competitor products and understand the value of the innovation. NICE endorsement of the product and a vocal stakeholder group will add weight to the case for procurement.

Q: Are there any barriers to market access?

A: In addition to identifying drivers for market uptake, it is also wise to consider hurdles to market penetration at this stage. These may include situations where a MedTech product requires a change to Government policy for its use, or where additional regulatory assessments are required to enable certification in the target market. Consideration at this point will avoid costly issues further downstream in the innovation pathway. NICE's Office for Market Access (NICE OMA) provides expert advice on market access. Further information on market access can be found in later sections of this guide.

PICO methodology

Focusing on the problem itself and trying to address it with the technology enables a higher rate of success of getting a product into the health and social care system. PICO is a framework methodology employed by National Institute for Health and Care Excellence (NICE) to evaluate a MedTech product for the NHS. Employment of this methodology early on in the innovation pathway will help validate the potential case for a technology having a successful entry to the NHS.

Population	What population of patients will your technology address?
Indication	What does your technology do? How does it work? How does it solve the problem?
Comparator	What happens at the moment in the healthcare system and how are those patients treated?
Outcome	What is the difference between the current therapy and your new technology?

NICE Office for Market Access (NICE OMA)

NICE OMA[7] provides expert advice to the life sciences industry, helping innovators to understand the impact on their technology, of programmes such as the AAC, and the wider life sciences strategy. NICE OMA helps navigate the differing approaches to market access, considering the implications for the technology offering.

Q. How will this phase be funded?

A. Sourcing investment is almost always one of the first challenges that arises. Many investment avenues are available at this stage including, but not limited to, seed, angel, patient capital, venture capital, research grants, and family and friends. UK Research and innovation The National Institute of Health Research (NIHR)[9] is the largest national clinical research funder in Europe, with a budget of over £1 billion, although it concentrates on discovery science and applied scientific research rather than on technology per se. UK Research and Innovation (UKRI)[8] and its research councils also have access to a wide range of government funding for early stage research and development.

UK Research and Innovation (UKRI)

Established in April 2018, UKRI[8] works in partnership with universities, research organisations, businesses, charities and the government, offering a diverse range of funding opportunities. It enables the fostering of international collaborations and offers access to facilities and infrastructure to support research and innovation. Current UKRI funding opportunities are publicised on its website and are accessed via a competitive process.

National Institute of Health Research (NIHR)

Known as the 'research arm of the NHS', NIHR[9] is a Government body funded to improve the health and wealth of the nation through research. It has the infrastructure and expertise to support early stage research and development, and to identify health and care provider and patient needs.

Q: What opportunities are there to collaborate at this stage?

A: A number of organisations and national programmes are in place to support innovators in their networking with potential customers, partners and investors, driving collaboration at this early stage of innovation. These include Innovate UK[10] and its network partner, the Knowledge Transfer Network (KTN)[11], and the newly launched NIHR Applied Research Collaborations (ARCs)[14]. In addition to these national initiatives, the AHSN network operate local innovation exchanges which support the development of HealthTech solutions to meet specific local health and care challenges, ensuring the needs of the local community are met.

Innovate UK

Innovate UK[10] is the UK's innovation agency. It drives productivity and economic growth by supporting businesses to develop and realise the potential of new ideas. Innovate UK has a strong business focus and funds business and research collaborations to accelerate innovation and drive business investment into research and development. It helps turn ideas into commercially successful products and services by connecting businesses with partners, customers and investors through two innovation networks - the Knowledge Transfer Network (KTN) and Enterprise Europe Network (EEN).

Knowledge Transfer Network (KTN)

A network partner of Innovate UK, the KTN[11] links innovators with expertise, markets and finance through a network of business, universities, funders and investors. The Health KTN provides in-depth knowledge and an established network with the added advantage of being able to connect innovators in this space with peers from other sectors.

Knowledge Transfer Partnership (KTP)

Development of a KTP[12] has been shown to increase profitability for business partners as a direct result of the partnership through improved quality and operations, increased sales and access to new markets. The three-way partnership also includes a qualified graduate who supports the company for the duration of the programme, an arrangement which typically lasts between 12 and 36 months.

Innovation Exchanges

The AHSN Network operates innovation exchanges[13] to link ideas with existing local healthcare system challenges, to ensure the local needs of the Sustainability and Transformation Partnership (STP) and Integrated Care Systems are met. Funded by the Office for Life Sciences (OLS), the innovation exchanges bring people and organisations together, speeding up the spread of innovation in the local area, saving the NHS money, generating economic growth and getting technologies to more patients faster.

NIHR Applied Research Collaborations (ARCs):

In July 2019, NIHR announced a £135 million investment in 15 new ARCs[14], which will join up some of the country's best universities, leading innovators and local authorities, universities, private companies, charities and academics to solve some of the biggest issues facing health and social care in their region over the next five years.

Industry associations

Various industry associations and trade bodies e.g. ABHI[15], BIVDA[16] and TechUK[17] support the innovation of medical technologies in the UK and the wider EU market.

Development (Prototype)

Once the value proposition and other fundamentals have been defined, a MedTech concept can advance through to product development in readiness for regulatory submission and market launch. The development step of the innovation pathway is formed of two phases: Prototyping and testing through clinical trials

Q: How is a MedTech prototype product developed?

A: Development of a product prototype is an iterative process with multiple versions often developed, refined and tested until a final 'market ready' product is developed. Facilitation of a close working relationship between the engineering team and the manufacturer during the design phase, with a clear focus on the needs of the end user, is critical to delivering a successful viable end product. This collaboration builds value into the product and ensures that the product can be manufactured in a cost-effective manner, providing evidence to support the product's value proposition. Catapult centres[18], the NHS Innovator Accelerator programme[19] and SBRI Healthcare[20] all provide innovation opportunities at this step of the pathway.

NHS Innovation Accelerator (NIA)

The NIA[19] supports the uptake and spread of high impact, evidence-based innovations across the NHS and wider healthcare system, benefiting patients, populations and staff. An NHS England initiative, delivered in partnership with AHSNs, it currently supports over 30 'Fellows' representing an equal number of innovations. Since its inception in 2015, the NIA has raised over £80m of external funding, and supported over 50 innovations to scale nationally, with just under half of these selling internationally. Over 1800 NHS organisations currently use NIA innovations.

Catapult centres

Catapult centres[18] facilitate UK businesses, scientists and engineers to work side by side on late-stage research and development. There are 11 Catapults in total including cell and gene therapy, digital, high value manufacturing and medicines discovery.

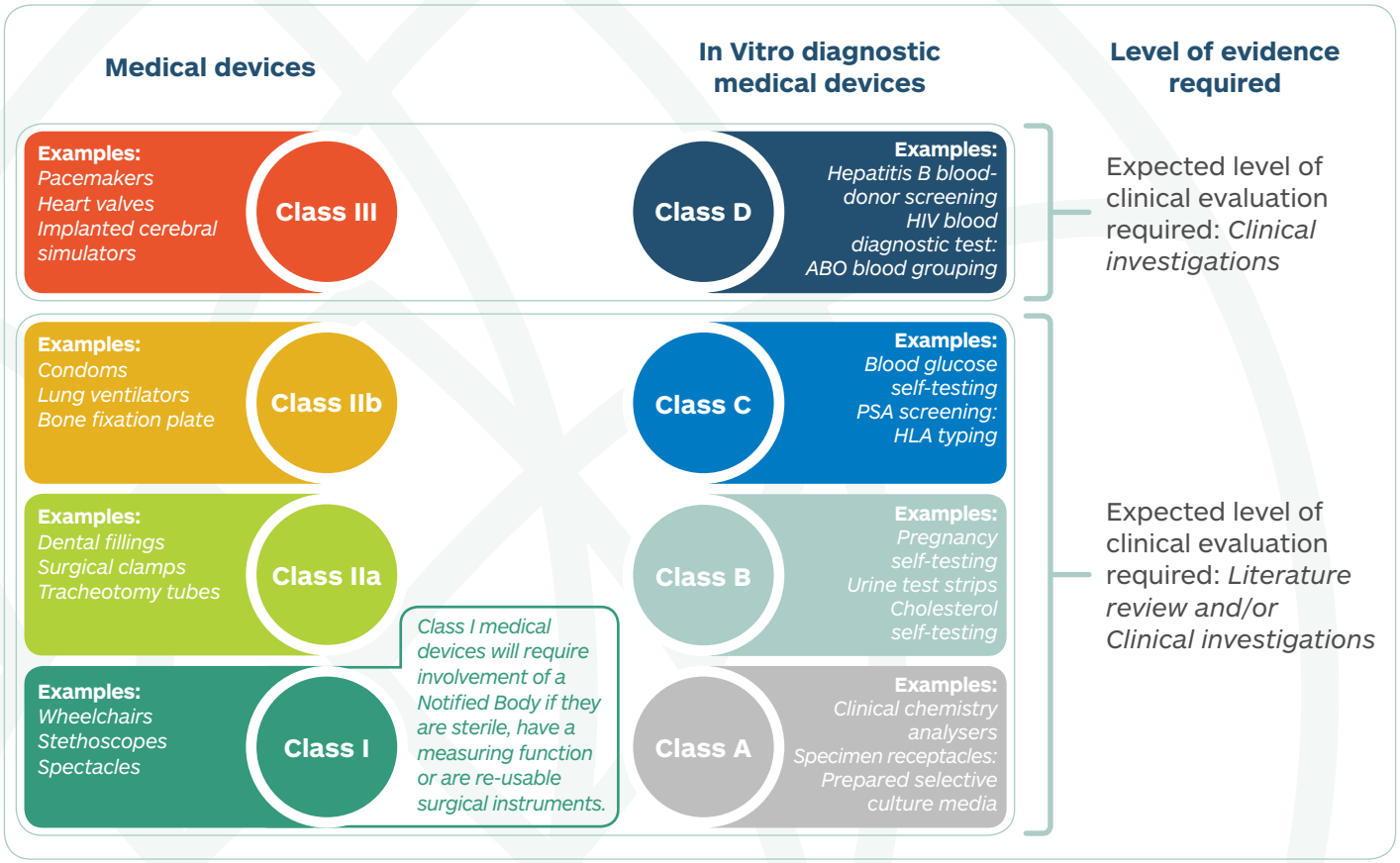
SBRI Healthcare (SBRI)

Supported by the AHSN network, SBRI Healthcare[20] is a programme jointly funded by NHS England and NHS Improvement which seeks to improve patient care and drive efficiency of delivery. Through research and development, SBRI Healthcare acts as an enabler for the NHS to accelerate access to new innovations in their early stages of maturity, to help solve identified healthcare challenges and unmet needs. The programme also aims to support economic growth by boosting wealth creation through the adoption of UK-sourced innovations. The programme has been running since 2013 and has awarded around £10million annually through contracts for development awarded to innovators, including a recent investment of £5.6 million to support 6 pioneering HealthTech innovations in the fields of mental health and surgery.

Development (Clinical evaluation)

Q: What evidence is required to clinically evaluate MedTech products?

A: Whilst the clinical trial protocol for pharmaceutical drugs has long been established, the level of clinical evaluation required to gain regulatory approval for MedTech products is less mature. The clinical data required by the regulators to demonstrate that a MedTech product performs as intended and is safe to use is dependent on the class of technology (outlined on the Medicines & Healthcare products Agency (MHRA) website)[21], with higher risk MedTech products requiring more extensive clinical evaluation before they can be launched onto the market. This is summarised below:



MedTech classes and level of clinical evaluation required

Medicines and Healthcare products Regulatory Agency (MHRA)

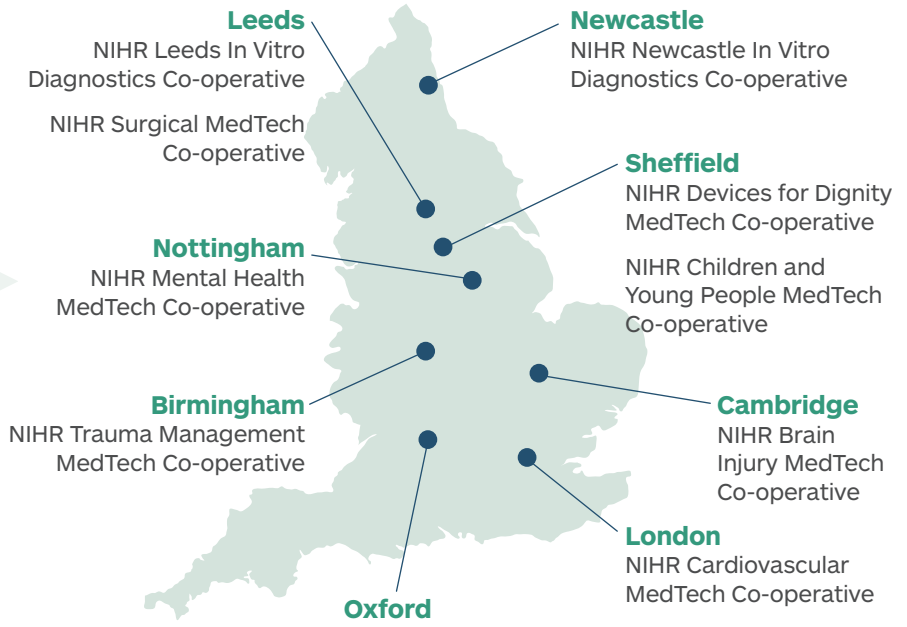
The MHRA[22] regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care.

Q: What support is available to innovators during this phase?

A: A number of initiatives are in place to support innovators during the clinical development phase of their MedTech product. The MedTech and In vitro diagnostic Co-operatives (MICs)[23] offer an alternative to the contract research organisation clinical testing route, whilst the recent launch of the Digital Innovation Hubs will provide innovators with access to real world patient data. NICE operates a number of tools and services including the NICE Scientific Advice consultancy[27], the MedTech Early Assessment (META) tool[29] and the HealthTech Connect[28] 'horizon scanning' database. Support in this phase of development has been enhanced through the recent launch of the NIHR Clinical Research Network Health Services Research Toolkit[30] and Invention for Innovation (i4i) programme[31].

MedTech and In Vitro diagnostics Co-operatives (MICs)

The newly-formed MICS[23] act as centres of expertise, bringing together patients, clinicians, researchers, commissioners and industry to support the development and evaluation of MedTech products in a clinical setting. Each MIC has a specific theme and is hosted by an identified lead NHS organisation.



Geographical locations of MICs across England

Patient Data for Research

The landscape for accessing 'real world' patient data for both retrospective and prospective research is changing incredibly quickly. Supported by £37.5m of UKRI Industrial Strategy Challenge Fund (ISCF) funding, Health Data Research UK (HDR UK)[24] is leading the delivery of the Digital Innovation Hubs – a UK-wide initiative to enable the safe and responsible use of health-related data at scale for research and innovation.

In the meantime, the Clinical Practice Research Datalink (CPRD)[25] facilitates observational studies, clinical trial feasibility and protocol optimisation by making de-identified patient data available from a network of GP practices across the UK.

Contract Research Organisations (CRO)

Partnership with a CRO or another authorised clinical testing body for the completion of the clinical testing of MedTech products will ensure that the process is completed to a standard sufficient to meet regulatory requirements. Information is available through the Clinical and Contract Research Association[26]

NICE Scientific Advice (NICE SA)

NICE SA[27] is a fee-based consultancy service available to developers of MedTech, working with innovators during the early stages of product development to encourage consideration of relative clinical and cost effectiveness of products. NICE- appointed experts support the development of evidence that demonstrates product value and provide detailed feedback on clinical, economic development and evidence generation plans.

HealthTech Connect

HealthTech Connect[28] (previously known as MedTechScan), a new 'horizon scanning' database of MedTech products at any stage of development, was launched in February 2019. This secure online system replaces and unifies existing sources of MedTech information, improving the identification and tracking of new and emerging MedTech in development across the UK. Developed by NICE, with NHS England funding, and supported by local AHSN systems, it will reduce the duplication and complexity involved in getting health technology to market in the UK. Access to this database will permit improved NHS planning around introduction and adoption of new technologies, including those through the Accelerated Access Collaborative (AAC), and encourage early engagement of innovators with the industry. Although not mandatory, market access may be delayed if an innovation is not on the HealthTech Connect database.

MedTech Early Assessment (META) Tool

The META tool[29] is an online service that helps medical technology developers optimise their development plans for their medical technology. It provides a structured framework to help identify potential gaps in product development plans and the next steps to bring a product to market.

NIHR Clinical Research Network Health Services Research Toolkit (NIHR CRN HSR toolkit)

Launched as a national resource in July 2019, the toolkit[30] is designed to bring together ideas, guidance and practical support together in one place, helping researchers undertake clinical studies in both the NHS and the wider health and social care environment.

NIHR Invention for Innovation (i4i) Programme

This funding programme[31] supports the pre-clinical and clinical development of medical devices in areas of existing or emerging patient need. Its main aim is to de-risk early stage projects that have demonstrated proof-of-principle and have a strong potential for adoption and commercialisation, making them attractive to follow-on funders and investors.

Regulation

Q: What are the regulations for MedTech products?

A: As stated previously, there are a number of regulatory requirements that must be met before a technology can enter the UK and EU market. Until recently, this conformity was in the form of alignment to one of three EU Medical Device Directives (MDDs).

In May 2017, new EU regulations for medical devices were put into force to overcome perceived flaws and divergences in the existing MDDs, increasing patient safety via a robust, transparent and sustainable regulatory 'fit for purpose' framework.

Directives (OLD)

- The Active Implantable Medical Devices (AIMD) Directive (90/385/EEC)
- The In Vitro Diagnostic (IVD) Medical Device Directive (98/79/EC)
- The Medical Devices Directive (93/42/EEC)

Regulations (NEW)

- The Medical Device Regulation (MDR) (2017/745)
- In Vitro Diagnostic Medical Device Regulation (IVDR) (2017/746)

Regulation of MedTech products

EU member states have been given a 3 to 5-year transition window, with the new regulations (MDR and IVDR) expected to be fully implemented by 26 May 2020 and 26 May 2022 respectively[32]. The implementation of these new regulations have introduced additional responsibilities for the European Medicines Agency (EMA)[33] and national competent authorities (MHRA in the UK) During this transition period, MedTech can be placed on the market under either the current EU MDDs or the new regulations. However, MedTech devices placed on the market after the transition period will need to fully comply with the new regulations, unless they wish to make use of the extended period of CE certificate validity. Manufacturers with a product already on the market will need to update their technical documentation and processes in order to meet the requirements of the new regulations by the dates above.

In the UK, regulation of medicines, medical devices and blood components for transfusion is overseen by the MHRA[10].

Increasing risk

Devices class		Notified body approval required?
Medical Devices	In Vitro Diagnostic Medical Devices	
I	A	No
IIa	B	Yes
IIb	C	Yes
III	D	Yes

MedTech conformity assessment routes

Conformity assessments

Manufacturers need to demonstrate that their MedTech product meets the requirements in the MDR or IVDR by carrying out a conformity assessment. The conformity assessment route depends on the classification of the device (and the risk class determines whether or not a conformity assessment is required). Undertaken by notified bodies, conformity assessments include the review of clinical and scientific data, manufacturing processes and the quality management system. Manufacturers can certify their products with any notified body in the EU. The MHRA retains an up to date list of notified bodies for MedTech[34].

Most class I medical device and Class A in vitro diagnostic devices do not need to pass a conformity assessment. However, they will still need to be registered with the MHRA.

Manufacturers will be issued with a CE certificate which can be placed on their product to show that it has passed the conformity assessment.

Quality Management System (QMS)

Companies submitting a MedTech product for regulatory approval in the UK will need to demonstrate alignment to the ISO Standard 13485[35] and other applicable standards. This is facilitated by the development of a QMS, a repository of business processes, policies, documented information and resources relating to the development and manufacture and procurement of the MedTech product.

Compliance

Manufacturers are required to have at least one person available with responsibility for regulatory compliance who possesses expert knowledge in the field of MedTech.

Post-market monitoring and surveillance

Once a MedTech product has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the MHRA, to ensure the technology is safe to use.

Custom-made devices

NHS organisations often produce diagnostic tests in-house or modify MedTech to allow clinical teams to respond rapidly to new or emerging threats, and to promote the development of more innovative solutions through collaboration by medical researchers with peers. Guidance on compliance requirements for custom-made devices can be found on the UK Government website[36].

Traceability

Manufacturers complying with the new regulations will be required to assign a Unique Device Identification (UDI) to the label and/or packaging of their product to enable traceability within the global market, improving the effectiveness of the post-market safety of MedTech products and security of the supply chain[37]. Manufacturers will also be required to register their organisation and technology, upload relevant information, apply for clinical investigations and performance studies, and upload post-market surveillance documentation to the European databank on medical devices (Eudamed)[38].

Q. How are products marketed outside of the EU regulated?

A. Manufacturers planning to launch their product in markets outside of the EU will need to ensure regulatory requirements for each of the product destinations are met. The regulatory burden for market access to some countries has been alleviated by Mutual Recognition Agreements (MRAs) between the EU and third-country authorities concerning the conformity assessment of regulated products. These trade agreements facilitate market access through greater harmonisation of compliance standards, and reduced need for duplicated inspections upon importation of products. The EU has MRAs with United States, Australia, Canada, Israel, Japan, New Zealand and Switzerland[39].

Q. What is the implication of Brexit on MedTech regulation?

A. The EMA moved its headquarters from London to Amsterdam in March 2019. At the time of writing this guide, it is unknown whether the UK will leave the EU with a deal. The effect of Brexit on HealthTech regulations in the UK will be largely dependent on the deal agreed, if any.

Further information on the implications of Brexit on the UK HealthTech industry can be found in the MedTech Europe position paper[40]. Contingency planning guidance for the event of a no-deal Brexit has been developed by the Government and shared with HealthTech manufacturers[41].

Evaluation and reimbursement

Once a MedTech product has received a CE mark, the manufacturer is free to sell, lease, lend or gift the product across Europe. Although not mandatory, it is widely accepted that the case for reimbursement of MedTech products in the UK (and wider field) is made fundamentally easier through evaluation and endorsement of the health and economic case by the National Institute of Health and Care Excellence (NICE)[42].

National Institute of Health and Care Excellence (NICE)

NICE[42] is an executive non-departmental public body of the Department of Health in the UK, responsible for providing national guidance on medicines and MedTech products and advice to improve health and social care, highlighting a product's potential to improve patient outcomes, reduce costs and provide whole system benefits. NICE helps the NHS to adopt effective and cost-efficient technologies through a review of evidence and advice from experts and patients, leading to the publication of market briefings, guidance and guidelines relating to the technologies/topics of interest.

Q. How does NICE evaluate MedTech products?

A. It takes approximately 38 weeks to develop a piece of HealthTech guidance. NICE is informed of new MedTech products requiring evaluation, either through notification from a sponsor (manufacturer, clinician, patient or other interested party) or through sources (for example, the National Institute for Health Research Innovation Observatory (NIHRIO) which identify technologies likely to have the most benefit to patients and the health and social care system. Notified MedTech products are initially assessed by the NICE topic oversight group, who determine if a topic briefing on the technology and/or MedTech Innovation Briefing (MIB) should be produced. NICE will only review technologies which have a CE mark or equivalent, or if it is expected within one year.

If selected, the topic oversight group route the product through one of three NICE programmes for full assessment to ensure that guidance is appropriate for the value proposition offered by the technology and evidence available.

MedTech products likely to result in an overall increase in resource costs to health and social care are routed through either the Technology Appraisal Programme (TAP) or the Diagnostics Assessment Programme (DAP), depending on product type. Those products likely to deliver a cost saving or to be cost neutral are routed through the Medical Technologies Evaluation Programme (MTEP).

MedTech product journey through the NICE evaluation pathway

An overview of the NICE evaluation programmes is shown below:

Clinical performance	Better		Non-inferior
Cost	Higher		Less overall
Evaluation method	Cost effectiveness (QALY)		Cost consequences
NICE guidance programme	Technology Appraisals Programme (TAP)	Diagnostics Assessment Programme (DAP)	Medical Technologies Evaluation Programme (MTEP)
Technologies	Devices	Diagnostics	Devices Diagnostics

NICE evaluation programmes for MedTech products

NICE assesses a product on both a benefits and cost basis:

- How well does the technology work compared to standard practice in the NHS?
- How much does this course of action cost compared to standard practice in the NHS?

External Assessment Centres (EAC) are employed by NICE to critique the submission and undertake any further technical evaluations. Recognising the limited evidence base available for MedTech products, a permissive approach is adopted to allow consideration of unpublished as well as published information. The outcome of the EAC assessment is collated into a report which is reviewed by the Medical Technologies Advisory Committee (MTAC), which is responsible for making the final decision on NICE recommendations for use of MedTech products. Draft guidance recommendations are subject to public consultation before being finalised and published on the NICE website. In collaboration with NHS England and others, NICE has recently implemented, an Evidence Standards Framework for digital health technologies[43]. Aligned to the recently updated Government's Code of conduct for data-driven health and care technology[44], the framework describes standards for the evidence that should be available or developed to demonstrate the technology's value to the health and care system.

MedTech Innovation Briefings (MIBs)

Commissioned by NHS England, MIBs[45] provide evidence-based advice to those considering the implementation of new medical devices or diagnostic technologies. By making this information available, NICE helps to avoid the need for NHS organisations to produce similar information for local use. MIBs are designed to be fast, flexible and responsive to the need for timely information on innovative technologies.

The National Institute for Health Research Innovation Observatory (NIHRIO)

The NIHRIO[46] is hosted by the National Innovation Centre for Ageing, National Institute for Smart Data Innovation, and Newcastle Academic Health Partners (a collaboration involving Newcastle University, Newcastle Upon Tyne Hospitals NHS Foundation Trust and Northumberland, Tyne and Wear NHS Foundation Trust). It undertakes 'horizon scanning' identifying topics and aims to inform NICE of new MedTech early in development to enable NICE to publish guidance as close as possible to product launch.

Q. How are MedTech products reimbursed?

A. One of the most common mistakes made by companies is the assumption that, by assigning a price and successfully gaining market entry, a product will be bought and reimbursed fully in that country. It is imperative to consider a product's pricing strategy, reflecting the different market drivers and reimbursement policies at this stage of the process to ensure the attractiveness of product in the market and maximal market uptake.

To understand how reimbursement works, it is important to understand how the money flows. In the UK, MedTech manufacturers sell their products broadly through three channels:

- To an NHS or private healthcare provider to use in the secondary care services, either directly, through wholesalers or the NHS Supply Chain;
- To a company who uses the MedTech product in the delivery of their service to a healthcare provider.
- Directly to patients (private sale, prescriptions);

UK NHS reimbursement

Clinical Commissioning Groups (CCGs) are clinically-led statutory NHS bodies responsible for the planning and commissioning of healthcare services in their local area. Responsible for approximately two thirds of the total NHS England budget, CCGs exert a significant influence over the prescribing and reimbursement of MedTech products for use by their population.

NICE- approved products are not reimbursed until individual CCGs grant access to the product in their region. NHS funding and reimbursement for products recommended by the NICE Technology Appraisal Programme, however, is obligatory within three months of guidance being published. Typically, CCGs will go to tender to select formulary devices. Progressively CCGs are forming larger regional decision-making groups for evaluating devices for inclusion on formulary, and for devices which are used in both hospital and out of hospital.

High-Cost Tariff-Excluded Devices (HCTEDs) programme

The prices paid by the NHS for the same high cost MedTech products can vary up to 50% between Trusts. The High-cost Tariff Excluded Devices HCTED programme[47], commissioned by NHS England, centralises the procurement of a range of specialist commissioned high-cost MedTech products through NHS Supply Chain to achieve national transparency of pricing and combine future purchasing power through aggregation. The programme expects to release over £100 million that can be reinvested back into NHS services. Operated through the new NHS Supply Chain OM, providers are now able to procure HCTEDs at zero cost, with reimbursement by NHS England. HCTEDs included in this programme are set out in the National Tariff.

Innovation and Technology Payment (ITP)

In light of the findings from the Accelerated Access Review, NHS England launched a programme to support innovative MedTech products in the penetration of the NHS market. The ITP programme[48] supports the NHS to adopt innovative market-ready MedTech which have demonstrated improvements in the quality and efficiency of patient care, by removing financial or procurement barriers to uptake. Each year, NHS England carefully selects a number of cost-effective innovations that have already proved their clinical effectiveness and are ready for nationwide spread. Recognising the concerns of the sector, NHS England is committed to funding CCGs to implement these innovations for a fixed one-year period, which maximises the spread of these innovative products in the NHS market.

Q. What is the Accelerated Access Collaborative?

A. The new umbrella organisation for UK health innovation, the AAC[49] will act as the front door for innovators looking to get their products funded by the NHS, and identify and support the best new innovations to benefit patients, driving their uptake and adoption within the health and care system. The Collaborative, commissioned in 2018 by NHS England and NHS Improvement in response to the findings of the Accelerated Access Review[50], brings together leaders from across the healthcare landscape, including government, NHS, industry and AHSNs. The AAC, hosted by NICE, utilises existing platforms including HealthTech Connect and the NIHRIO, to identify innovations appropriate for acceleration through the scheme. As it matures, the AAC will support innovators through the innovation pathway by signalling the needs of clinicians and patients so innovators understand the problems to be addressed and by establishing a testing infrastructure to support innovators in the generation of evidence required to enable product adoption. The AAC will draw on the capabilities of the AHSN Innovation Exchanges to enhance the spread of products over the established supply chain channels.

Since its inception, the AAC has selected and supported 12 Rapid Uptake Products (RUPs)[51] to increase their use within the NHS. These include a blood test for early pre-eclampsia diagnosis and an implant to alleviate the lower urinary tract symptoms of benign prostatic hyperplasia. This £2 million investment is estimated to save the NHS up to £30 million and improve the lives of around 500,000 patients. A selection of these Rapid Uptake Products are outlined further on in this report.

HeartFlow: A non-invasive diagnostic test for heart disease[52]

Artery blockage is currently measured in the NHS by an angiogram, an invasive procedure where a tube is inserted into the heart of the patient to measure arterial pressure. HeartFlow has engineered a unique computer programme that can determine the severity of artery blockage by analysing CT scans of the heart. The doctor can use this non-invasive NICE approved computer programme to accurately determine which treatment a patient needs, avoiding the need for an invasive procedure or unnecessary stent treatment.

UroLift: A minimally invasive alternative treatment for the lower urinary tract symptoms of benign prostatic hyperplasia[53]

Enlarged prostates are an extremely common condition that occurs with age, leading patients to have difficulty passing urine. The NHS currently delivers Transurethral Resection of the Prostate (TURP) surgeries to relieve a patient's symptoms. This is an invasive surgery that can damage nerves and surrounding tissue. UroLift is a medical device which anchors the enlarged prostate in place using a 25-minute technique, reducing invasiveness and risk for patients. This alternative procedure offers a number of benefits to the patient including a reduced hospital stay, quicker recovery and fewer post-operative complications.

A pre-symptom diagnostic test for pre-eclampsia[54]

Pre-eclampsia is a condition by which the placenta does not develop properly, leading to barriers for the normal development of the foetus. The main symptoms of pre-eclampsia are high blood pressure and proteinuria, which are also experienced by healthy pregnancies, making it a very difficult condition to diagnose. A new blood test developed by Roche and Quidel can predict with 99% accuracy whether a pregnant woman will develop pre-eclampsia before the occurrence of symptoms. Early diagnosis means that the NHS can accurately identify high-risk pregnancies and redirect money to prevention rather than treatment.

Commissioning and adoption

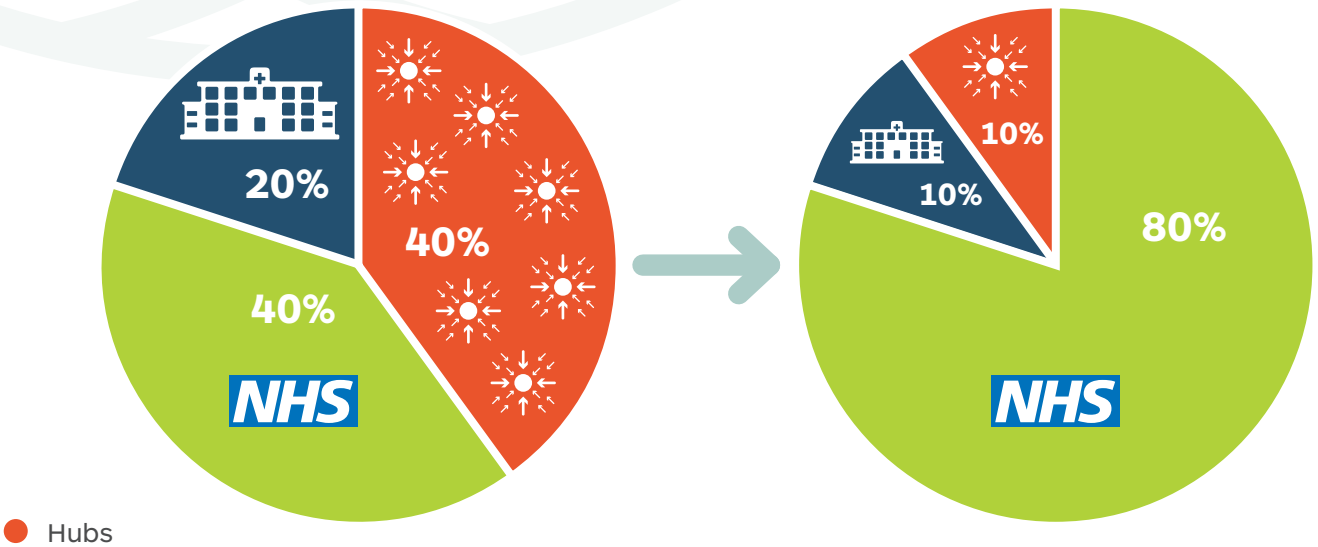
Q: How does the NHS supply chain operate?

A: The NHS Supply Chain has a new operating model that has been introduced to deliver improved procurement and logistics support to the NHS. In a strategic response to the findings outlined in the Carter report[55], the new operating model will enhance procurement efficiency and effectiveness across the NHS, delivering clinically safe, high quality products for the best possible value.

Transformation and re-procurement of the NHS Supply Chain is expected to achieve significant benefits for the NHS through:

- Increasing uptake/volume of products purchased via the national route to market in order to aggregate national demand, and secure value for money for the NHS and taxpayers;
- Increasing use by the NHS of a standard range of clinically appropriate products to reduce unwarranted variation in the system; and
- Using increased buying power to affect purchasing behaviours and deliver the best products at the best value for the NHS.

Currently only 40% of the NHS's £6bn spend on everyday hospital consumables, common goods, high value healthcare consumables and capital equipment goes through NHS Supply Chain. Implementation of the new operating model is expected to double this to 80%, releasing an estimated £2.4bn of savings in its first five years of operation, which can be used by the NHS for reinvestment in front line services.



Changes to the NHS procurement landscape

The procurement function of the NHS Supply Chain is managed through 11 Category Towers. These towers are operated by a Category Tower Service Provider (CTSP) who has specialist knowledge of that product category to enable them to undertake the clinical evaluation of products, run compliant procurement processes on behalf of the NHS and create strategies that sustainably provide the NHS with clinically assured products that drive the best value.

Category towers	
Tower 1	Ward Based Consumables
Tower 2	Sterile Interventions and Associated Consumables
Tower 3	Infection Control and Wound Care
Tower 4	Orthopaedics, Trauma and Spine, and Ophthalmology
Tower 5	Rehabilitation Disabled Services, Women's Health and Associated Consumables
Tower 6	Cardio-Vascular, Radiology, Audiology and Pain Management
Tower 7	Large Diagnostic Capital Equipment including Mobile and Consumables
Tower 8	Diagnostic, pathology and therapy technologies and services
Tower 9	Office Solutions
Tower 10	Food
Tower 11	Hotel Services

NHS supply chain procurement category towers

Fourteen separate contracts have been awarded to service providers that will manage the Category Towers, and the procurement of logistics, transactional services and IT services for the NHS for a three-year period. Oversight and operational management of the new contracts and services along with customer engagement activities will be delivered by the management function of the NHS Supply Chain, The intelligent Client Coordinator.

The NHS supply chain is centrally funded and the price of goods are passed onto trusts with no additional margin.

The new operating model is expected to promote a number of opportunities for suppliers when selling to the NHS:

- Aggregation of demand could offer suppliers larger volume opportunities than the current NHS Supply Chain;
- Lowered sales and marketing costs by reducing the number of interactions with Trust procurement teams, as the NHS Supply Chain can act as a single point of contact for supplying into the NHS;
- Clinical assurance that products are being procured on the basis of user requirements, not simply unit price;
- Sales commitment making business and production planning easier for suppliers;
- CTSP incentivisation to reduce total cost in the system, not just reduce unit price; and
- A streamlined procurement landscape will reduce the burden of multiple tenders.

Q: How are MedTech products commissioned by the NHS?

A: There are six main routes to market for companies interested in supplying their MedTech product directly to the NHS:

- Selling direct to trusts or primary care organisations;
- Selling through the new NHS Supply Chain;
- Selling through collaborative purchasing arrangements;
- National framework collaborations and contracts;
- Government tenders and contracts;
- Selling to a company which then uses the MedTech product in the delivery of their service to an NHS provider.

Q. How can innovators increase market adoption of their MedTech product?

A. MedTech innovators often refer to a 'Valley of Death'. This is part of the pathway where products have been developed but take anywhere between 5 and 10 years to navigate regulation, endorsement and procurement hurdles before they have the opportunity to generate significant revenues. The timeframes are often longer than typical investors are prepared to wait for returns. Successful navigation of these hurdles does not automatically guarantee market adoption. Innovators need to achieve replication at scale to exploit the full potential of a product, requiring a significant investment of time, skill, resource and finances, with the innovation itself sometimes undergoing substantial revision and refinement in the process.

A recent report by the Health Foundation highlights the complexities of replicating even simple, well-designed innovations between sites[56]. More often than not, successful market diffusion of innovations requires the design of programmes to spread them in more sophisticated ways. This is particularly important for those complex innovations that lead to a domino effect, triggering a series of changes to diagnosis, treatment and the roles of staff and patients and revealing new patient needs, all of which impact on the wider health system. This set of consequences is likely to be true of the most disruptive – and hence potentially the most beneficial innovations.

The challenges of getting HealthTech products to market in a timely manner has been nationally acknowledged with the publication of the Accelerated Access Review by the Office for Life Sciences[50]. Since then, significant strides have been made through investment in HealthTech-specific procurement initiatives which aim to simplify and speed up adoption of promising HealthTech products. These include the HCTED[47] ITP[48] and HealthTech Connect[28] programmes and recently launched AAC which has the appropriate capabilities, partnerships and infrastructure to support a large volume of innovations access the market at an accelerated pace, significantly increasing the number of patients that will benefit from these products at an earlier stage of their condition.

CTSPs will be designing category strategies through engaging with the market and horizon scanning upcoming innovative products. Manufacturers of innovative MedTech products that can demonstrate proven whole system value to the NHS will be able to discuss these with the relevant CTSP.

The NHS Supply Chain is designed to provide the infrastructure for adoption of transformative products through its customer engagement function. Working with the AHSNs, NHS Supply Chain has been exploring ways in which it can help with the early stages of the innovation pathway.

Q. What role do the AHSNs play in supporting market adoption and diffusion?

A. The importance of AHSNs in the successful spread of innovations has been documented in a recent King's Fund study[57], and is highlighted in the following case study, where the AHSN network is supporting the distribution of over 6,000 MedTech devices to detect atrial fibrillation in primary and community care settings.

Healthcare teams using a new MedTech product will often need to adapt their existing ways of working, develop new skills and potentially change their culture or build new relationships to ensure optimal use of the technology in their organisation. There is work to be done to support market adoption through the development of standardised User Guides/ Standard Operating Procedures for prioritised innovations that can be used at a local level by healthcare providers to support implementation, thus reducing duplication of effort across organisations.

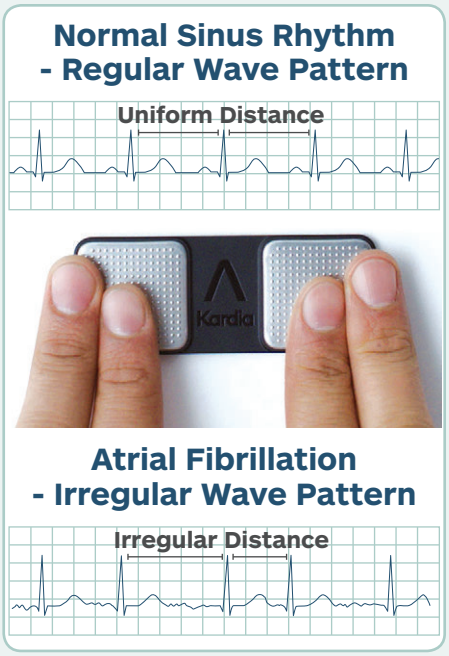
The AHSN Network will maintain a view of MedTech adoption and diffusion nationally, by tracking uptake of products by individual healthcare providers.

Case study:
Atrial Fibrillation

Atrial Fibrillation (AF) is an irregular heart rhythm that causes one in five strokes. AF is often asymptomatic and can occur intermittently, which makes diagnosing it a challenge. It is estimated that 400,000 people in England are unaware that they have the condition. Furthermore, there are currently in excess of 140,000 people who have a confirmed diagnosis of AF and hence are at risk of stroke, who are not receiving anticoagulation therapy. This would reduce their chance of experiencing a stroke by at least one third, depending on whether they are already taking either aspirin or another anti-platelet drug, or not on medication.

The traditional method of detecting AF is with manual pulse palpation. However, the effectiveness of this can be limited, as it does not detect all cases of AF and many patients with an irregular pulse on palpation do not in fact have AF. The diagnosis is then confirmed using a 12-lead ECG. Given that manual pulse palpation is not 100% effective, this can lead to unnecessary 12-lead ECGs being undertaken.

However, this is an area where the introduction of new mobile technology, followed by a clearly-defined anti-coagulation pathway, is starting to revolutionise the way in which AF is detected in primary care and to give rise to significant reductions in the incidence of strokes through better detection and treatment. The AF programme is one of the seven two-year programmes being rolled out nationally by all 15 AHSNs on the basis of research which showed the benefits of anti-coagulation. The programme is an excellent example of proven mobile technology, strong national commissioning and a national implementation pathway, which is being rolled out with local variation where necessary.



The mobile technology is a portable or pocket-sized ECG device which enables a pulse rhythm check for AF to become an everyday part of patient assessments in a variety of settings where it may not have been considered previously; for example, community pharmacies, optometrists and podiatry clinics and 'Safe and Well' checks carried out by the fire service. Since January 2018, all 15 AHSNs have been distributing over 6,000 of these devices (of five different types) to primary and community care settings in order to understand how best to diffuse and encourage adoption of this technology at scale. Evidence suggests that, for primary prevention of stroke in AF patients, about 25 strokes and about 12 disabling or fatal strokes would be prevented yearly for every 1,000 AF patients given OACs[58].

Although the introduction of the mobile ECG devices has provided a valuable contribution to the number of people being diagnosed with AF, their health outcomes will not change and strokes will not be avoided unless individuals with newly identified AF at risk of stroke are prescribed anticoagulation therapy and are supported with long-term adherence. The mobile ECG devices are therefore only a small part of the much wider pathway change that is required in AF stroke prevention. Notwithstanding this (and the programme is still underway), it is an excellent example of the effectiveness of new technology being implemented in tandem with awareness campaigns and changes to the clinical pathway, resulting in improved health outcomes.

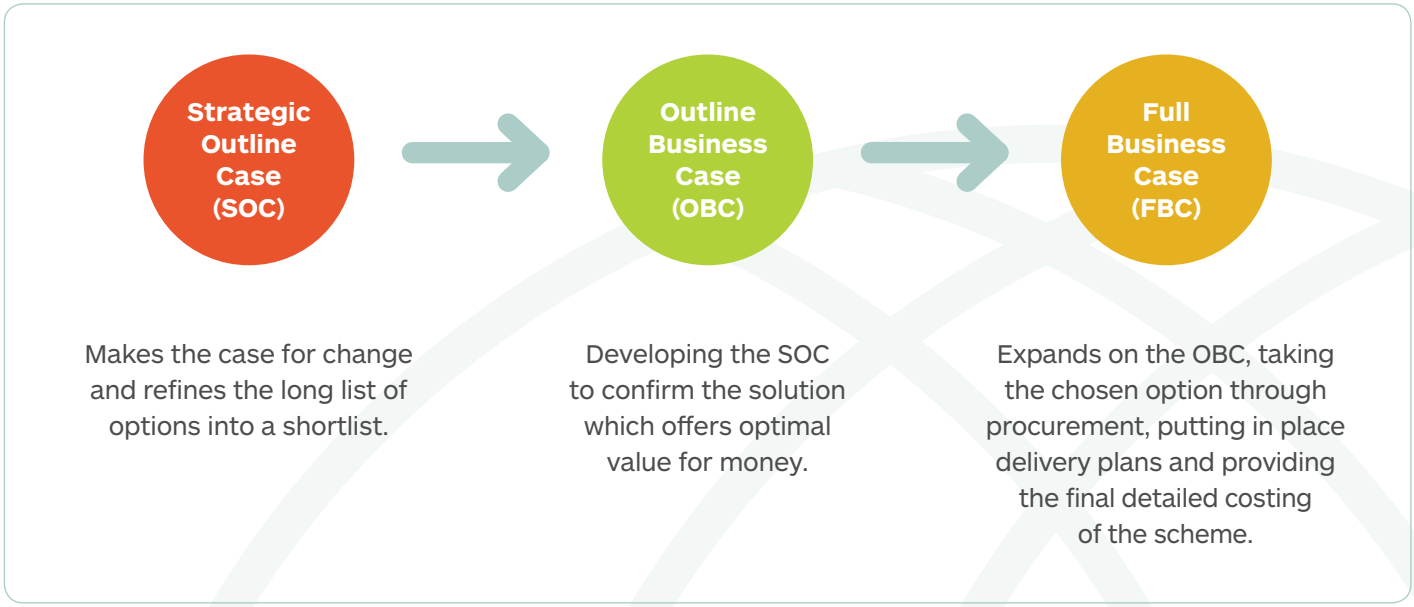
Q. What type of business case will be needed for NHS procurement?

The Five-case model

A. The NHS has a standard approach to business cases which can be adapted to support marketing of an innovation. The Five-case model is the UK government's best practice approach to public sector business cases. Sharing an 'example case' can help reduce the time and workload involved for NHS buyers.

The Five-case model

Large, complex proposals are developed in three iterations:



Business case iterations

Further information on the Five Case model can be found on the UK Government website[59, 60]. Utilising their network functionality, AHSNs are well placed to support manufacturers in the development of their business case, for example de-risking the process through the identification and engagement of appropriate reference sites.

Assessing benefits in NHS business cases

NHS England has defined a 'triple aim' to guide the development of a high quality, financially sustainable service, seeking to achieve better outcomes, better experiences for patients and staff and better use of resources. Within this, a range of benefits may arise from the use of a MedTech innovation, and there are many different ways they can be reported. When it comes down to the business case, the focus will be on defining cost-benefits, so the sponsors will look to understand how each benefit can be monetised and reported. The standard categories for defining benefits in UK business cases are shown below:

Cash releasing	Financial, non-cashable	Non-financial	Qualitative
Resulting in 'cash in the bank' through avoided spend	Benefits that can be monetised but don't result in 'cash in the bank'	Benefits that can be counted but are very difficult to monetise	Benefits that cannot be monetised, but are often a significant driver of change
Reduced headcount Reduced cost per test	Value in £ of hours saved that will be dedicated to front line duties	Improved patient satisfaction Faster turnaround time for a diagnostic test	Improved patient journey

Typically, a business case will look to ascribe a financial value to non-financial benefit so that the overall benefit to the public is presented. This can include the value of economic growth and improved health and wellbeing. Any anticipated downsides should also be stated. These are outcomes of the change that could be perceived as negative by a stakeholder such as an increase in workload for frontline staff.

Innovator checklist for successful market access

Having walked through the innovation pathway, there are number of things that manufacturers can do to maximise their chances of their MedTech product being adopted into the NHS market:

1. Ensure the **product meets the need of the end user and aligns to national priorities** to maximise market value;
2. **Engage with stakeholders including clinical and academic teams and service users as early in the pathway** as possible to ensure the product is designed appropriately for use;
3. Undertake an **early review of regulatory requirements and NICE evaluation criteria** to ensure testing and clinical trials undertaken in the development phase address requirements;
4. Develop a **clear and concise business case aligned to the Government's Five Case Model** (see page 38 of this guide), outlining the ROI and articulating the economic and health benefits to the population served by the targeted NHS organisation(s). Note the frequent importance of being able to generate short-term financial savings in the NHS, which often runs counter to the long-tern nature of innovation;
5. **Ensure full comprehension of commissioning, pricing and reimbursement approaches** of the market in which the product is to be adopted;
6. **Share concept and development intentions with NHS procurement teams and national bodies to raise profile of the product** being innovated (and capture via early scanning platforms e.g. HealthTech Connect) and to permit end user planning for adoption;
7. **Secure an appropriate level of investment** to ensure cash flow throughout the pathway;
8. **Maintain an up-to-date QMS** to address regulatory and evaluation requirements in a timely manner;
9. Develop a **comprehensive communication and engagement plan** that serves throughout the innovation pathway, with a clear view on benefits, engaging stakeholders e.g. clinicians, procurement teams, AHSNs, national bodies, advocacy groups, service users through carefully selected channels e.g. marketing and communication strategies, advertising campaigns, governmental lobbying, market engagement events and publishing of clinical papers.

Identifying and developing regional strengths

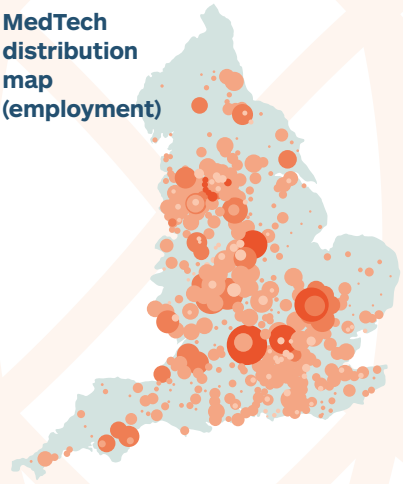
The original Life Sciences Industrial Strategy notes that future growth "is likely to emerge from clusters where strong scientific activity is adjacent to small and emerging companies and which are attractive places for large companies to also collocate".

MedTech is already a UK-wide endeavour[61]. The MedTech workforce has a broad spread throughout England but, in some areas, there are particular pockets of high concentrations of employment.

"Clustering" is the tendency of firms in related lines of business to concentrate geographically. The recent Science and Innovation Audits highlight a range of regional strengths that provide a platform for future growth. There is no single formula for successful regional development and the journey to develop a globally significant cluster can take different paths.

For instance, there is a cluster effect in Leeds/Sheffield based around orthopaedics (see insert). Cambridge is also a cluster based on early stage innovation that draws on a broad science and engineering base, a number of very successful incubator sites and an established service and supply sector for early stage developments providing legal, financial design and other related services. The Midlands Engine, Greater Manchester and Leeds are developing opportunities drawing on regional legacies in manufacturing to develop a thriving MedTech sector. Finally, Oxford is a place which has seen heavy investment in diagnostics companies such that it is a clear leader in this respect.

MedTech distribution map (employment)



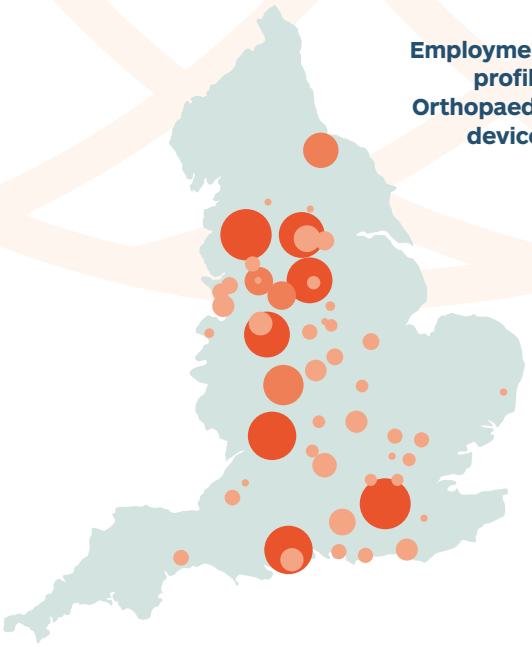
Orthopaedics

– An example of regional clustering

There is a cluster of orthopaedic activity around Leeds/ Sheffield where research strengths in materials coupled with access to leading NHS orthopaedic researchers and supported by a high-tech manufacturing supply chain have contributed to the development of an ecosystem with both large and small companies.

The employment for the core orthopaedic devices sector shows that the activity is not solely focused on Leeds/Sheffield, and there could be further opportunities for companies elsewhere across the UK to access the specialist capabilities available in the Leeds/Sheffield region.

Employment profile: Orthopaedic devices



Maps: courtesy of OpenStreetMap contributors

Successful clusters support companies right along the innovation pathway. Increasingly, there is an emphasis on accelerating the translation of clinical needs through research and development into cutting edge MedTech products. The UK can compete globally by offering an ecosystem with closer links between industry, clinicians and regulators, including NICE to make this happen.

The NIHR has designated 11 MICs to build expertise and capacity in the NHS to develop new medical technologies and provide evidence on commercially-supplied IVD tests. Leading NHS organisations act as centres of expertise, bringing together patients, clinicians, researchers, commissioners and industry. The MICs may become the focus for regional clusters, they are also national assets which can be accessed by companies located anywhere in the UK.

Many regions are looking to further support the development of local MedTech clusters. To achieve this, Government, local partners and industry need to work together to ensure the right infrastructure is in place to support the growth of life sciences clusters and networks.

There is a growing network of over 100 science and technology parks in England that provide an environment for innovative companies to grow. As well as offering access to high-tech space and specialist laboratory facilities, they provide a community for companies to exchange ideas, a focal point for service and supply companies as well as space to expand. An attractive wider environment for staff is an important factor in developing a wider regional skills base. Some areas are developing regional strengths where strong scientific activity is adjacent to small and emerging companies and which become attractive places for large companies to also co-locate.

There is no single formula for a cluster. A look at where successful early stage companies are based shows that many have benefited from co-location in incubator sites alongside other innovative companies, including companies in related sectors such as bio-tech and digital. There are a number of features common to successful MedTech clusters, as shown in the diagram to the right of this page. Equally, some regional groupings play to particular strengths and may be part of a wider ecosystem.

- Incubators with concentrations of life science businesses
- Access to specialist facilities including test labs
- Space to grow
- Distinctive local capabilities such as advanced manufacturing

- World-leading academic expertise in physical sciences and engineering
- Ready access to a range of research disciplines
- Ability to operate in fields of convergence (e.g. connected medical devices and AI)

- Access to leading research clinicians – ideally aligned to MICs
- Access to patient populations for trials – typically needing large and diverse populations, test beds
- Access to clinical data – particularly for generating 'real world evidence'

- A structured approach to networking
- Legal advice – IP and regulatory
- Specialist design consultancy
- Specialist manufacturing
- Access to investors

A pool of specialist expertise which can include

- Based on legacy industries
- Experienced leadership of innovative companies

- Concerted commitment of regional leadership to support the development of the MedTech industry
- Attractive environments including housing, schooling and transport
- Funding for re-location and supportive business rates

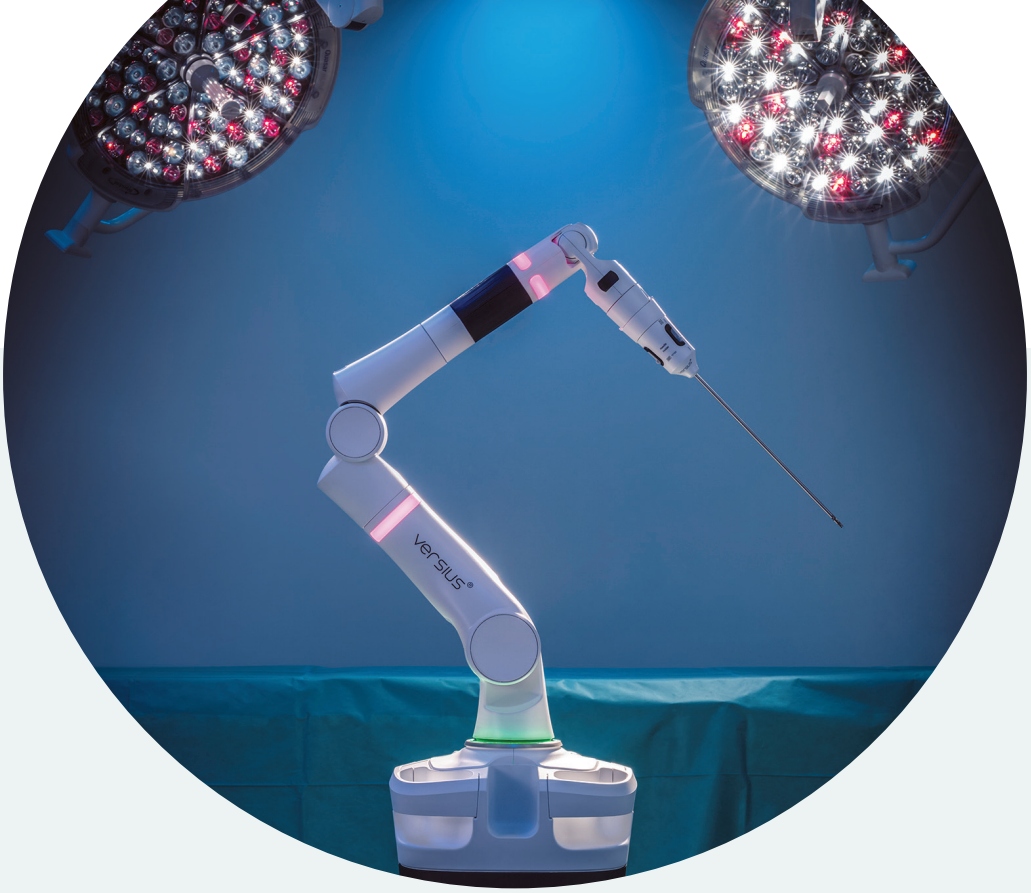
- The ability to attract inward investment from research intensive arms of global players
- Effective business networking bringing together both large and small enterprises

Features common to successful MedTech clusters

Achieving growth

A thriving MedTech sector would see innovative companies growing successfully as a receptive health and care system moves to adopt and diffuse innovation. Such a progression would close the gap between the small number of multi-national MedTech companies with a presence in the UK and the large number of SMEs and start-ups.

In recent years, the most common route to growth has been for start-ups to use traditional financial instruments such as government grants and contracts, angel investors and venture capital (VC) before seeing an exit through listing on a stock exchange or trade sale. Notwithstanding the recent controversy around the two Woodford funds[62], the patient capital model still works, with our Oxford Nanopore Technologies case study on the following page, testament to this. However, the long timeframes involved in the adoption and diffusion of HealthTech innovation have tended to work against organic growth as investors look for early returns, leading to early exits and trade sales where the IP and onward development is transferred overseas. In some cases, companies are unable to raise sufficient funds to continues development and fail as a result[63]. While the VC route will remain a component of the route to growth, many companies are growing successfully by using a range of alternative strategies. The case studies on the following pages highlight some of these routes.



Case study:
CMR Surgical – Agile development

CMR Surgical[64] from Cambridge has developed a next generation surgical robotic system that aims to transform minimal access surgery (MAS). The system, named Versius, is designed to be portable, transportable and affordable.

The CMR vision is to make MAS universally accessible where currently only half of people who could benefit from this surgical technique do. By unlocking the potential of MAS, the company wants to enable millions of patients worldwide to get the benefits that include reduced scarring, less blood loss, reduced risk of surgical site infections and reduced length of stay in hospital. The Versius system, which was awarded a CE mark in March 2019 is specifically designed to meet this vision.

The surgical robotic market is highly competitive with an established global leader and emerging competition from several companies whose backing includes the likes of Google and Johnson & Johnson. Global annual revenues for robot assisted minimal access surgery are presently approximately $4 billion and are anticipated to reach $20 billion by 2025. The Versius system is modular, portable and versatile and is intended to be cost effective when it comes to market.

CMR recently attracted $100m in the largest ever Series B investment deal raised by a European medical device company.

Commenting on the growth of CMR, Martin Frost, CEO, said “Typically, medical device development from idea or design through to commercialisation is normally a 10-year journey and we will have done that in around five. You can only do that by having clear focus on what you want to deliver and why, recruiting excellent people and creating a culture that facilitates creative, responsive thinking.”

In commenting on how the company has achieved this backing to grow in the UK, Martin Frost says: “We identified an unmet need – 95% of minimal access procedures are not yet done robotically. We then looked at why this was the case and what we could do to address that need. My advice is to any new start-up company is to go and look for the unmet need and then find investors who will be prepared to overlook the risks for the potential return.

From the very beginning we had a plan of how we would get our product to market and our commercial advantage – our success is having the ‘big idea’ the expertise and technology to deliver a solution.”

Case study:
Oxford Nanopore Technologies – Patient capital

Oxford Nanopore Technologies Ltd[65] was founded in 2005 as a spin-out from Oxford University to develop a disruptive, electronic, single-molecule sensing system based on nanopore science.

The management team, led by CEO Dr Gordon Sanghera, brought a track record of delivering disruptive technologies to the market. Two elements of this past experience have been central to their successful growth:

- IP – ensuring that the company owned a comprehensive portfolio of Intellectual Property to create and maintain a strong position with respect to potential competition. Early on, this included securing IP licences from a range of universities internationally.
- Ambition – recognising the truly disruptive potential of the technology and being committed to retaining the value of the technology by growing the company rather than seeking a traditional VC- funded route involving an early exit once the technology was de-risked.

The Company is growing from its Oxford base with a new high-tech manufacturing facility now opened on the Harwell Innovation and Science Campus. The commitment to Oxford recognises the value of keeping close links between its manufacturing and R&D operations. At the same time, it has expanded a global presence with satellite offices in Cambridge (UK), New York, Cambridge, San Francisco (US), Beijing, Shanghai, Singapore and a broader commercial presence that includes Japan, Germany, France, India and France. Growing locally also provides stability for its more than 450 employees who bring a wide range of expertise including nanopore science, molecular biology and applications, informatics, engineering, electronics, manufacturing and commercialisation.

Patient capital fulfils a vital role in supporting university start-ups because of its ability to take a lengthy and systemic view that accords with the diversity, dynamism and risk of solving complex problems. Oxford Nanopore has successfully attracted investments of £451 million to date, including two recent rounds each raising £100 million. It has not followed a traditional Venture Capital investment; instead, the investor profile more closely mirrors those of publicly listed companies. All its shares are Ordinary, without the traditional preferences seen in more complex VC style fundraising.

Case Study:

SurePulse Medical Ltd – Securing long term value through an exciting collaboration between academia and industry

SurePulse Medical Ltd[66] is committed to developing innovative and user-centric solutions to unmet clinical needs, which will ensure that new-born babies get the best care possible. 10% of new-born babies need resuscitation at delivery - they are born not breathing and need support transitioning from the womb to the outside world. In these critical first few minutes accurate heart rate assessment is essential in guiding optimal care. Current heart rate monitoring approaches are insufficiently quick, reliable or accurate leading to uncertainty in how to optimise care and regularly leading to the undertreatment or overtreatment of new-born babies.

SurePulse VS is a wireless heart rate monitor which provides early, accurate and continuous information to guide the stabilization process, enabling confident decision making. The device is the only heart rate monitor designed specifically for new-born babies. The SurePulse VS technology was developed at the University of Nottingham (UoN) who have an impressive track record in technology transfer, in collaboration with the Nottingham University Hospitals NHS Trust. SurePulse Medical Ltd was established in 2014 as a joint venture between the UoN and Tioga Ltd, thereby combining the academic strength of the University with the expertise of one of the UK's premier contract manufacturers.

SurePulse VS received CE approval in 2019 and has been launched into the UK and European Neonatology markets. Further research into additional applications for the technology are under way with an exciting clinical trials programme that should expand the opportunities to support optimal care for new-born babies.

Other partners have been hugely important through the development and commercialisation phases including the East Midlands AHSN, CHEATA (The Centre for Healthcare Equipment & Technology Adoption), Innovate UK, Medilink East Midlands, and the Department for International Trade.

SurePulse Medical Ltd is one of a growing number of companies linking academia with industry, benefiting from the complementary expertise of both, in parallel with the all-important investors – to date they have raised over £3 million in research and development funding. SurePulse Medical Ltd is well prepared to scale-up for volume sales with excellent UK suppliers and looks forward to a bright future both commercially and, critically, clinically, in improving the care of hundreds of thousands of new-born babies around the world.

Case study:

QuantuMDx – Focusing on alternative markets to secure early returns

QuantuMDx Group[67] has developed Q-POC™, a simple-to use, portable DNA analyser capable of providing lab standard molecular diagnostic (MDx) testing anywhere, anytime in a matter of minutes.

The company's highly innovative and disruptive technology converts DNA into binary codes - the code of computers - and is ideally suited to help address the humanitarian health burden by offering MDx at a fraction of the price of traditional testing, at the patient's side and providing results within 10-30 minutes. Currently in field studies in South America, South Africa and the UK, the first portfolio of tests - including HPV genotyping and TB/MDR-TB - are targeted for soft launch next year, followed by an STI and drug resistance panel.

QuantuMDx was founded over a decade ago by CEO Elaine Warburton and CSO Jonathan O'Halloran in Jonathan's garage in Sussex and later settled on Newcastle's Quayside, following an invitation from Chair Prof Sir John Burn. The Founders took a conscious decision to design Q-POC™ for use in decentralised low resource settings where there is intermittent electricity, no water, extremes of temperature and altitude and minimal technical training amongst health professionals. From incorporation, an offensive and defensive IP strategy was put in place and supported by IP attorneys in the US, Europe and Asia.

A business strategy was developed to work with NGO's, such as Global Good/Intellectual Ventures, Bill & Melinda Gates Foundation and Clinton Health Access Initiative, and allow for funding and leverage in high volume markets within low to middle income countries. To do so, they were determined to drive down the COG's of their technologies. This has resulted in QuantuMDx being in a unique position: they can enter into the low-cost high-volume markets described but are also able to compete on pricing, speed and a comprehensive test menu within the high margin High Income Countries (HICs). In HICs, purchasers and providers, such as the NHS, more readily offer greater investment returns and enhanced partnering opportunities with multi-national companies with established global sales and distributor networks.

The Founders' funding and partnering strategy has been unique within the MedTech industry. Mindful that it takes at least 10 to 12 years to develop a novel and disruptive technology, a frugal funding approach was adopted. Rather than seeking institutional funding from the get-go, they took the decision to 'drip feed' angel, family office, philanthropic and strategic investment to fund an iterative approach to developing Q-POC™ and - at all times - testing the technology with end users.

In addition, the Founders leveraged equity funding with non-equity diluting grants from sources such as Innovate, NIHR i4i, Biomedical Catalyst, EU and others, whose profits covered some of their overheads and payroll in the early days. To date, they have raised over £55m, with £40m from equity and £15m from non-equity diluting sources. This patient investment strategy has given the company time to fully develop Q-POC™ before needing to access more traditional venture capital funding, to scale up.

Elaine Warburton OBE said: *"Developing a medical technology is a long journey. At QuantuMDx we had to plan for what the market will be like in 30 years' time and developed Q-POC™ accordingly. We have an ambitious vision, so the discipline of designing our technology for use in a low resource setting has meant we have had to be highly creative with the small amounts of funding we have raised."*

About the AHSN Network and the MedTech initiative

Academic Health Science Networks (AHSNs)

AHSNs are pioneering new ways to spread and adopt innovations in healthcare. First licensed in 2013, they have become a vital part of the country's health economy, connecting and brokering partnerships between health and care, academia, the third sector and industry. AHSNs have a dual regional and national perspective – providing a link into the regional health and care community and understanding patient needs while also operating as part of a national network. The AHSN licence was renewed in 2018 and has increased the emphasis on achieving an impact on the NHS from the adoption of innovation.

The AHSN Network will seek to champion game-changing technologies that combine cutting-edge science from our universities and leading clinical research from the NHS with innovative companies seeking to grow in England. These are the innovations with greatest potential to scale and address global market needs. AHSNs are empowered at a local and national level to:

Convene

- Bring the right people together to create the right conditions for collaboration
- Facilitate access to high tech manufacturing advice and research and development experts
- Share diverse perspectives to shape the future of health and care
- Build lasting partnerships to deliver maximum benefits for all

Develop

- Provide the know-how to take ideas forward in complex health systems
- Develop compelling value propositions and evidence
- Match the brightest people with the smartest ways to make an impact
- Create a culture where good ideas come alive
- Unlock funding to make change happen

Deliver

- Adopt and spread national AHSN programmes
- Import ideas and creativity from other industries
- Encourage health services to embrace the future
- Mobilise leaders to champion change
- Build a lasting legacy for health and care

The MedTech Initiative

The AHSN network has established the MedTech Initiative to support innovation in the MedTech sector in England. Led by the Eastern AHSN, the MedTech initiative is one of nine initiatives supporting development in areas of national priority, including digital, genomics and personalised medicine.

Government policy in England is on increasing the emphasis on achieving an *impact* from innovation on the health and care system, rather than just sponsoring the development of the innovations (although this clearly continues). A particular focus for the Eastern AHSN, and the wider AHSN network, will be on identifying and supporting MedTech innovations with the potential to scale and achieve significant population-level impacts in the NHS within the next 5-10 years. This means working with industry associations such as Association of British HealthTech Industries (ABHI)[2] and The British In Vitro Diagnostic Association (BIVDA)[3] and the new launched AAC[x] to accelerate the development of a flourishing market by pulling through successful innovations into mainstream use. Potential will be judged by considering both the demand and supply sides of the innovation cycle. It will include consideration of:

- The technology maturity – what is the scientific basis of the innovation and what more must be done to demonstrate a mature solution?
- The degree of innovation – what is the health economic value proposition?
- The dynamics of adoption – does the technology require a wholesale change to care pathways and reimbursement, or can it be deployed into existing services?
- The competitive landscape – how unique and protectable is the innovation?

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