

The AHSN Network



MedTech landscape review

March 2019



Office for Life Sciences



This guide has been produced because the AHSN national network thought that there might be an opportunity to adopt a systematic and coordinated national approach to supporting MedTech innovation, building on the support provided by the 15 Academic Health Science Networks (AHSNs) to the NHS and to industry. There are opportunities to do this throughout the innovation journey by focusing on the following potential themes:

- Robustly assessing and prioritising game-changing technologies for national support;
- Facilitating access to cutting-edge R&D, spanning regional boundaries to complement the work of AHSNs;
- Connecting companies to high-tech manufacturing advice;
- Partnering with leading NHS providers seeking to adopt game-changing innovations;
- Offering guidance to AHSNs as they support MedTech innovators through market access activities.

This guide is the first step. It focuses specifically on the MedTech innovation pathway and opportunities in England. It builds on the work done by the Office for Life Sciences in the Accelerated Access Review by incorporating recent changes. This guide provides signposting to some key organisations who can offer up-to-the-minute advice. In the future the AHSN Network intends to look at the innovation landscape in Europe to understand what aspects we can learn from and import here.

Acknowledgements

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Foreword

This is an exciting time for the Medical Technology (“MedTech”) industry. Healthcare systems around the world are increasingly looking for innovative solutions that will address pressing needs, while advances in science and technology are opening up new possibilities. Often these advances sit at areas of convergence: between different clinical disciplines and between industries. The boundaries of MedTech are increasingly blurred by convergence with biotechnology, telecommunication, artificial intelligence and even consumer health and wellness.

It is right to look some way into the future, as the new ideas of today will enter the market to address the pressing needs of some years hence. Companies with game-changing innovations that incorporate cutting-edge science have the potential to achieve significant population-level health impacts. These are the innovations with greatest potential to scale and address global markets. In particular

the NHS, in common with many other health systems, is looking for solutions that will enable earlier diagnosis of disease, address unmet needs in mental health, offer new solutions to cancer and rare diseases, and for complex multi-morbid patients. Some of these needs are more obvious candidates than others for MedTech innovations and all are likely to involve new devices of some sort for diagnosis, drug delivery or as aids to support independent living.

The sheer diversity of the MedTech sector means that, while there are common aspects to the innovation pathway, there is no standard approach that all can follow. Some innovations provide immediate patient outcomes and financial benefits that make them readily adoptable, while other highly promising scientific ideas will require significant market-making activities through service change and financial reforms before they can sustain company growth.

In terms of finance, patient capital has emerged in recent years as one solution that could help companies survive through the long process of securing regulatory approvals and economic endorsements based on real-world clinical evidence. Patient capital is a very long-term form of investment that offers a support mechanism for highly promising scientific ideas. The prize for companies able to access patient capital is the potential for large, long-term returns from servicing global markets for their products.

But the goal to support the MedTech industry to thrive is not just about finance. The recent Life Sciences Sector Deals take forward ambitions set out in the Accelerated Access Review to make the entire MedTech innovation pathway work better for patients, clinicians and innovators and for UK plc.

Piers Ricketts
Chief Executive at Eastern
Academic Health Science Network

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1 What is MedTech?

The MedTech sector comprises businesses developing, manufacturing and selling medical devices, supported by an extensive network of service and supply businesses¹. The sector sits within Life Sciences alongside Bio-Tech 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. The diversity of MedTech has resulted in an innovation pathway that is less clearly defined than that for pharmaceuticals.

This guide sets out key features of the industry, the innovation pathway, some regional clusters and some examples of UK companies who have achieved successful growth.

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 treatments and improved patient experience, such as the ability to take high quality care closer to home. Significant trends in recent years include the evolution of drug-device combinations,

the convergence of digital and medical devices 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. More generally, medicine is moving towards a more preventative and personalised approach, and MedTech has a crucial role in this.

Medical devices remain central to understanding the scope of the medical technology sector, and the World Health Organisation (WHO) definition serves as a useful guide to what is covered by this wide-ranging sector:

“An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose”

In keeping with this broad definition, the MedTech sector covers technologies ranging from single-use consumables to complex hospital equipment and including both digital health and In-Vitro Diagnostics (IVD) products.

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

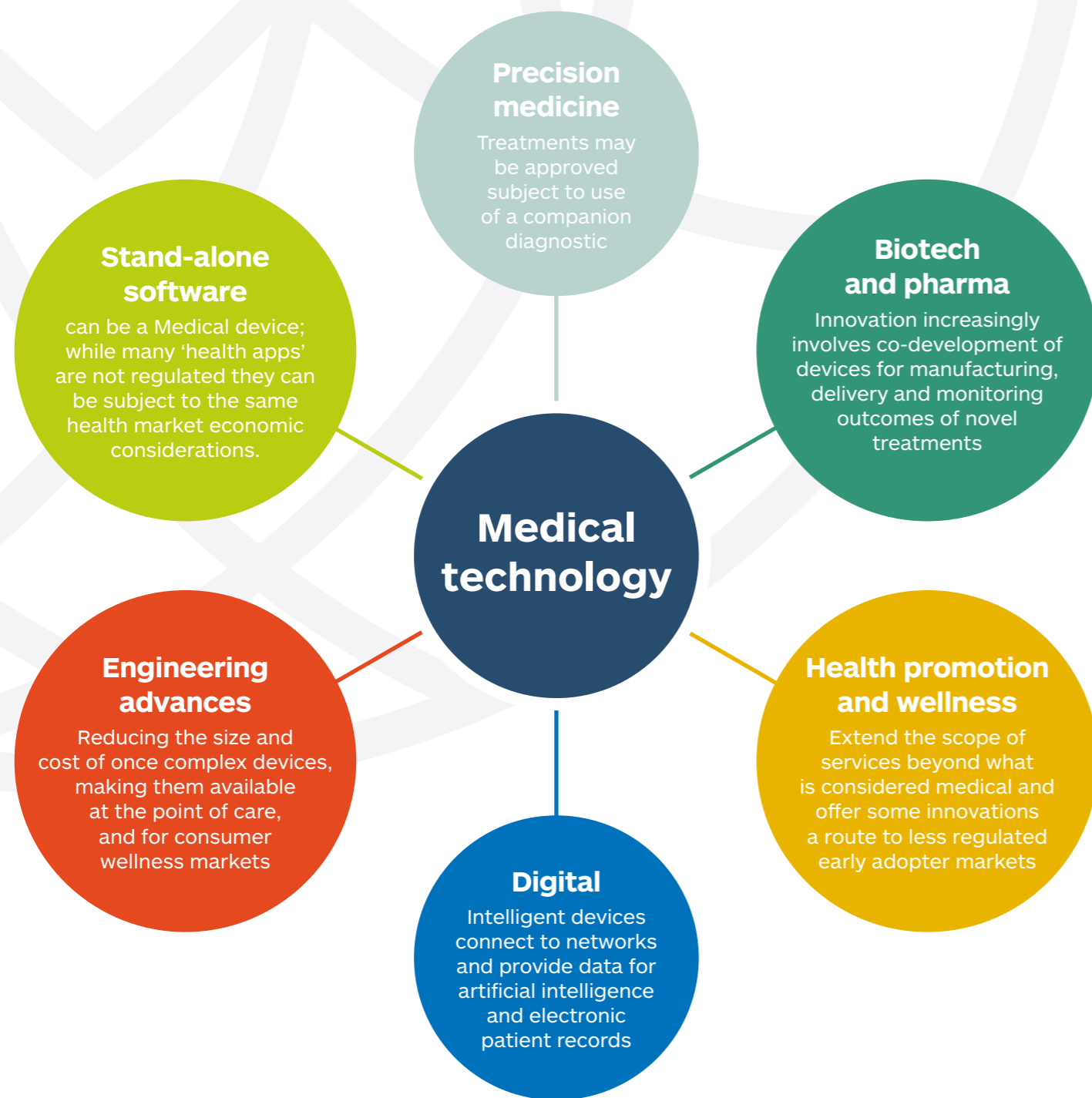
“Core” MedTech

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.



What matters most for our current purposes is the impact that innovations will have on health and care systems. While a definition such as the above is helpful, it should not be used to discourage innovators working at the boundaries with other sectors. Indeed, the MedTech market is evolving rapidly as convergence enables many innovations to exploit the synergies between traditional sectors, as highlighted in the diagram above.

Academic Health Science Networks

Academic Health Science Networks (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 MedTech Innovation National Network

The AHSNs have established a MedTech Innovation National Network (INN) to enhance the awareness and support given to the MedTech sector in England by the AHSN Network to accelerate the development of innovations and their adoption by the NHS. It is one of nine 'networks of networks' to support developments in areas of national priority. These nine include INNs for Digital and for Genomics and personalised medicine. The specific focus for the MedTech INN is therefore on physical devices and in-vitro diagnostics, i.e. excluding the more consumer-focused digital technologies at one end and large devices such as MRI scanners at the other.

Ultimately the AHSN Network – through the INN or more generally – 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 markets. We will do this by facilitating access for the relevant parties to:

- Cutting-edge R&D
- High tech manufacturing advice
- Leading NHS providers seeking to adopt game-changing innovations.

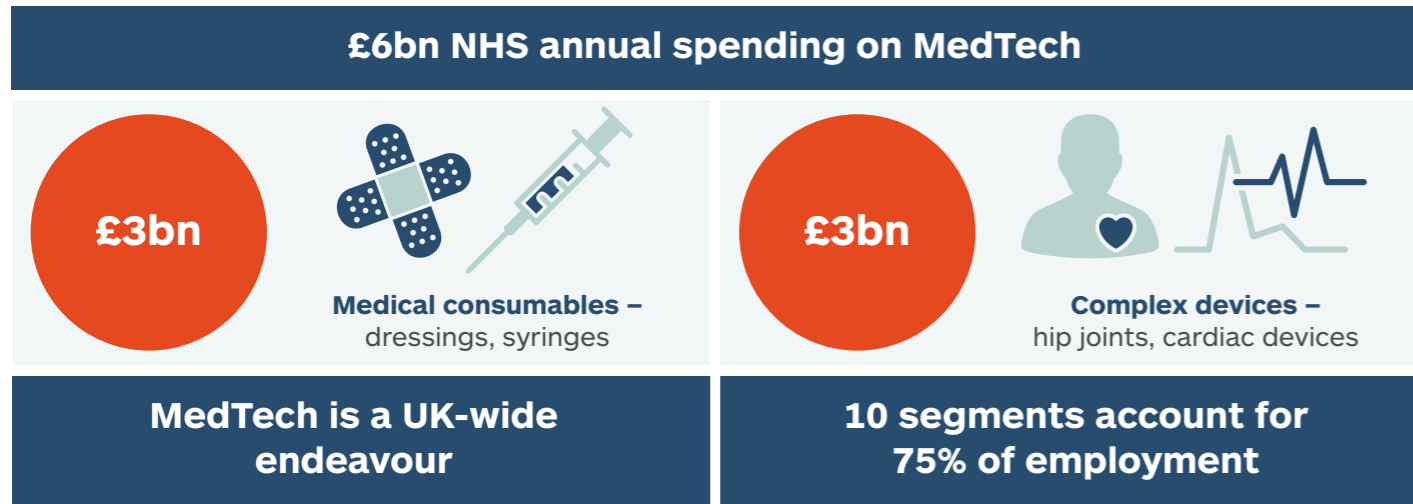
Government policy in England is on increasing the emphasis on achieving an *impact* from innovation on the health and care system, rather than just sponsoring the development of the innovations (although this clearly continues). A particular focus for the AHSN Network will be on identifying and supporting 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 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?

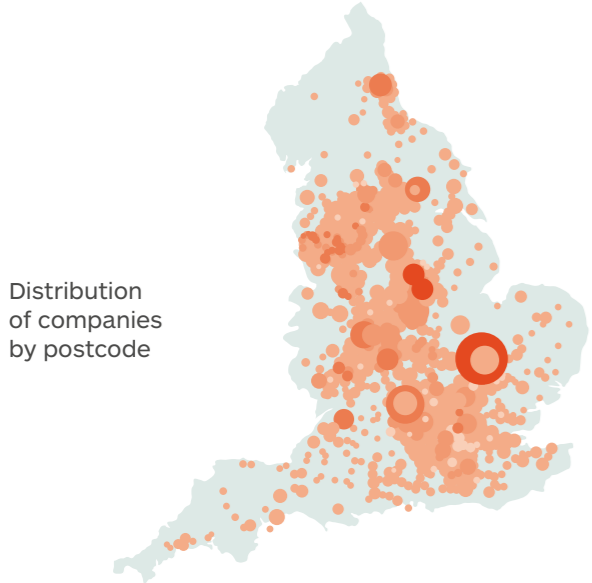
2 The MedTech industry in England

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.

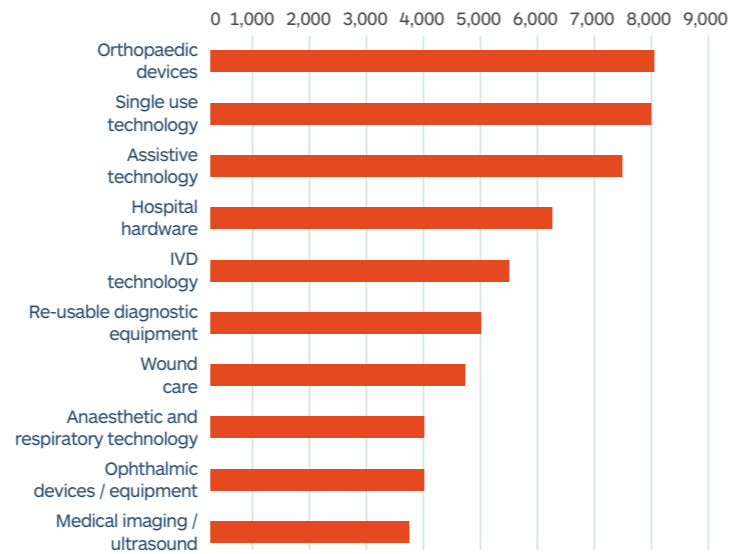


MedTech sector company distribution

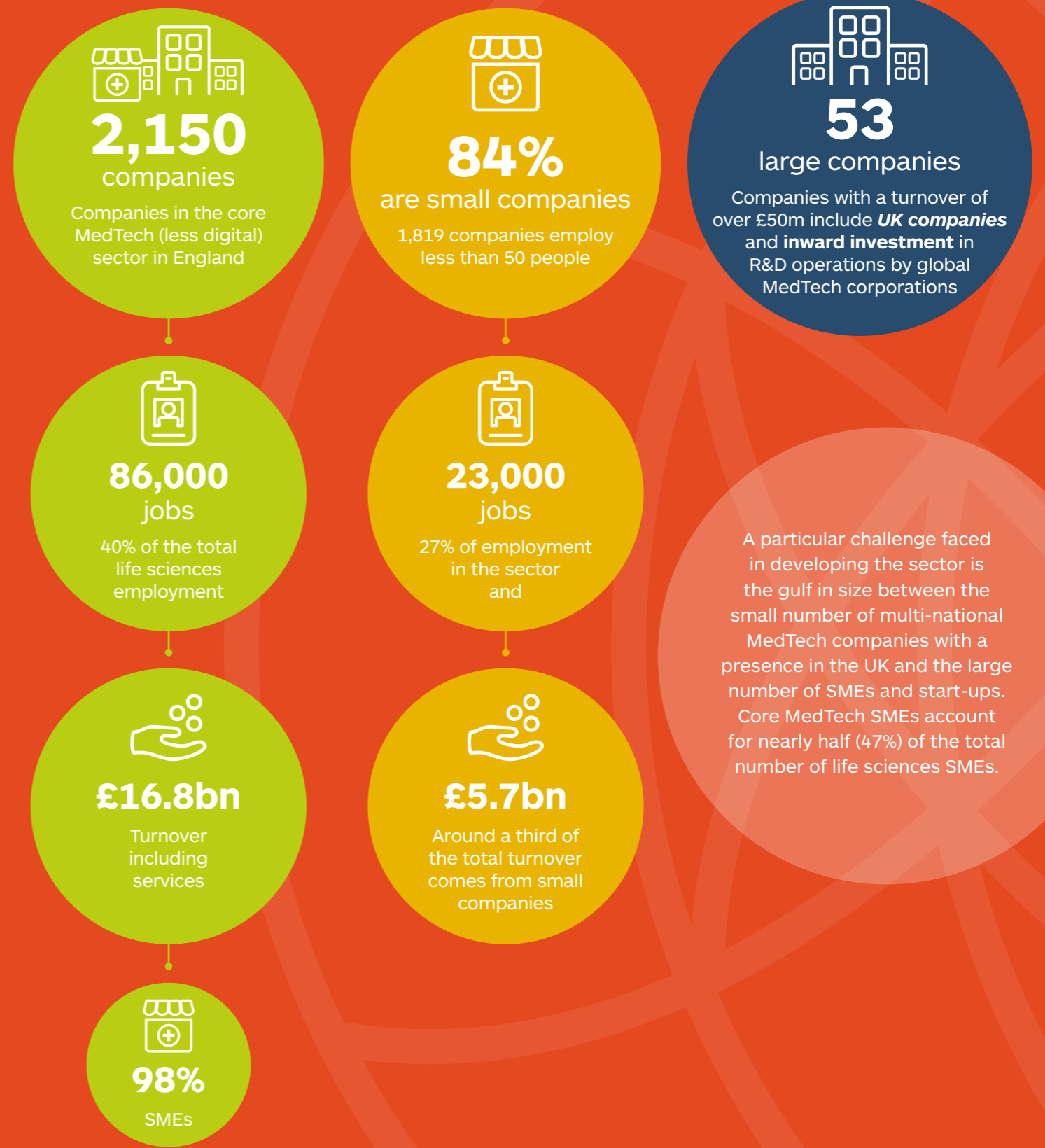


Distribution of companies by postcode

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

3 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 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 MedTech innovation pathway

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



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 guidance⁴

3.1 Creation

Before investing a significant amount of effort in developing a MedTech concept, it is important to understand the market in which it will be placed. Considering the market at this early stage will avoid unnecessary investment of time and expense in maturing technologies that offer limited market value.

What is the market value of the product?

Whether offering a MedTech solution to the NHS or a private healthcare provider and its patients, its value to the market must first be identified. Paramount to moving the MedTech concept forward is remembering that it will not be of worth if nobody wants to buy it. 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 technology align to published NHS priorities and/or address an unmet need for providers and patients? The NHS Five Year Forward View⁵ and the recently published NHS Long-Term Plan provide a strong indicator of the focus for NHS investment going forward.

What outcomes will the product deliver?

The health 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 healthcare 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 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.

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 NICE when evaluating 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?

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

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 health 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. We cannot over-stress the importance of understanding how the NHS determines the costs and benefits of a product in order to inform the buying decision.

Are there any barriers to market access?

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. Considering market hurdles 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 on page 24 of this guide.

How will this phase be funded?

Sourcing investment is almost always one of the first problems 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. The National Institute of Health Research (NIHR) 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) 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 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.

www.ukri.org

Innovate UK

Innovate UK 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).

www.gov.uk/government/organisations/innovate-uk

Innovation Exchanges

Each AHSN operates an Innovation Exchange which has the potential to link MedTech solutions with existing local healthcare system challenges, to ensure the local needs of the STP and Integrated Care Systems are met. Funded by the OLS, the Innovation Exchanges are able to 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.

The implementation of innovation exchanges varies from region to region but see www.ahsnetwork.com/innovation/innovation-exchange and for example www.innovationexchangeeast.org.

Patient and user engagement

Patient and user engagement 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. 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.

www.involve.org.uk



Knowledge Transfer Network (KTN)

A network partner of Innovate UK, the KTN 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 with peers from other sectors.

<https://ktn-uk.co.uk>

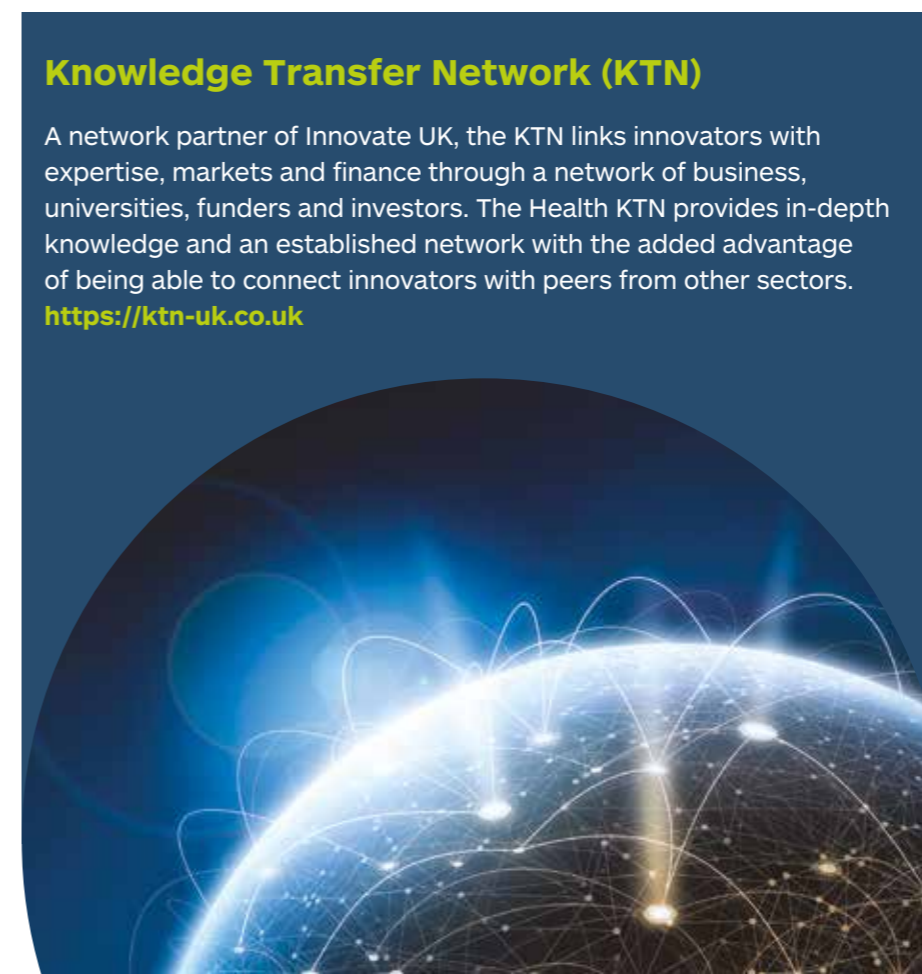
NICE Office for Market Access (NICE OMA)

NICE's Office for Market Access provides expert advice to the life sciences industry, helping innovators to understand the impact on their technology, of initiatives such as the Accelerated Access Review (AAR), and the wider life sciences strategy. NICE OMA helps navigate the differing approaches to market access, considering the implications for the technology offering.

www.nice.org.uk/about/what-we-do/office-for-market-access

Industry associations

Various industry associations and trade bodies e.g. ABHI², BIVDA³ and TechUK⁶ support the innovation of medical technologies in the UK and the wider EU market.



3.2 Development

Once the fundamentals described here have been defined, a MedTech concept can advance through to the development for readiness for regulatory submission and market launch, depending on the complexity of the innovation and its adoption. We have divided this development phase of the innovation pathway into two phases: Prototyping and testing through clinical trials.

Phase 1: Prototyping

As is well known, development of product prototypes is an iterative process with multiple versions often tested and refined until a final product is developed to progress to the market. 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

Support in the design phase is strengthened by the presence of Catapult centres which 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, medicines discovery and precision medicine. www.catapult.org.uk

Knowledge Transfer Partnership (KTP)

Development of a KTP 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. <http://ktp.innovateuk.org>

NHS Innovation Accelerator (NIA)

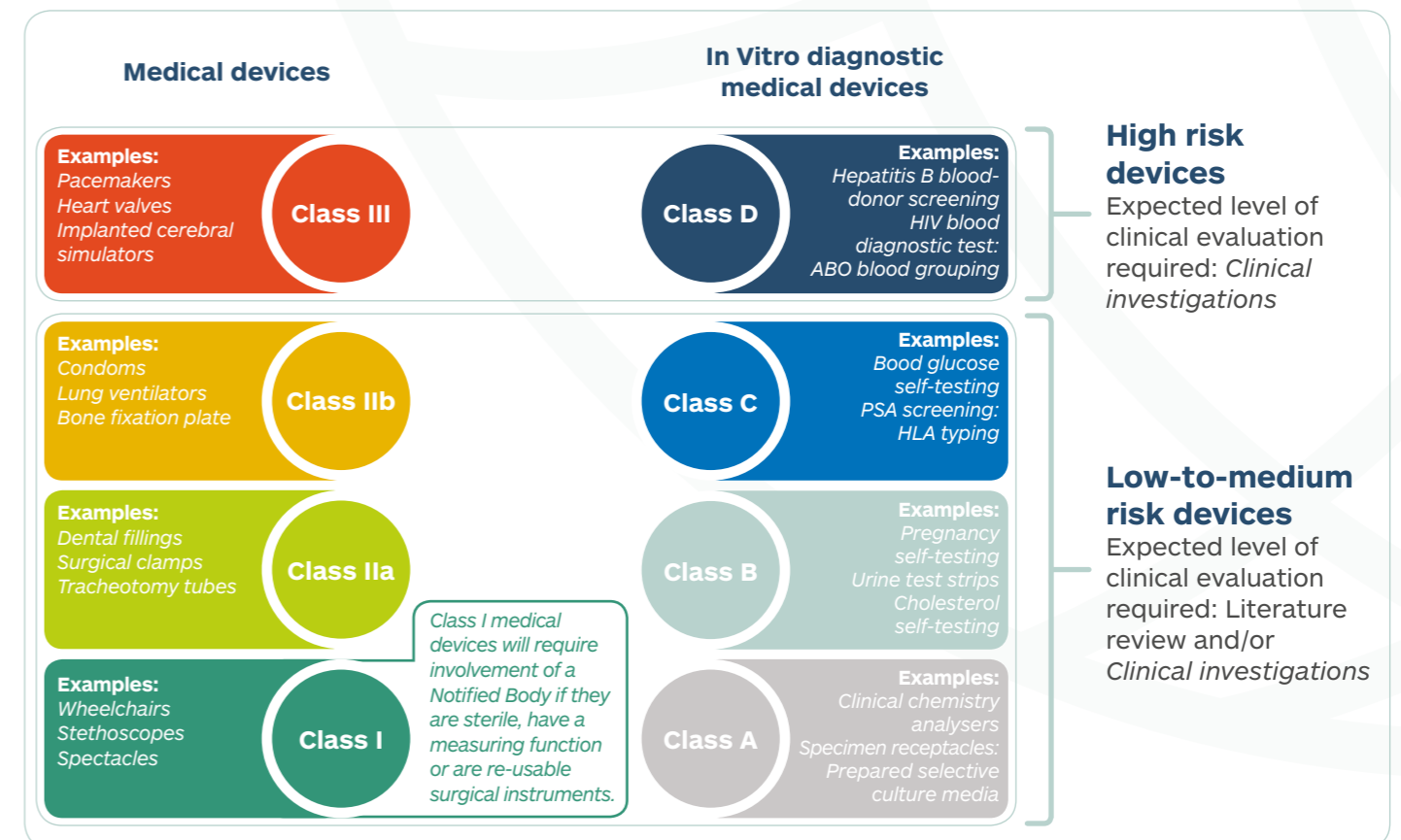
The NIA supports the update and spread of high impact, evidence-based innovations across England's NHS, benefiting patients, populations and NHS staff. An NHS England initiative, delivered in partnership with AHSNs, it currently supports a significant number of 'Fellows' representing over 30 innovations. www.nhsaccelerator.com

SBRI Healthcare (SBRI)

Supported by Innovate UK, SBRI Healthcare is a programme 100% funded by NHS England which both seeks to improve patient care and drive efficiency of delivery. Through research and development, SBRI Healthcare acts as an enabler for the NHS to access 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. www.sbrihealthcare.co.uk

Phase 2: Testing through clinical trials

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 well known. 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) being evaluated⁷, with higher risk MedTech products requiring more extensive clinical evaluation before they can be launched onto the market. This is summarised below with an additional look at In Vitro diagnostic devices:



MedTech classes and level of clinical evaluation required

National Institute of Health Research (NIHR)

Known as the 'research arm of the NHS', NIHR 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. www.nihr.ac.uk

MedTech and In Vitro diagnostics Co-operatives (MICs)

The newly-formed NIHR MedTech and In Vitro diagnostics Co-operatives (MICs) act as a centre 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 organisation⁸.



Geographical locations of MICs across England

Contract Research Organisations

Partnership with a Contract Research Organisation (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 www.ccra.org.uk

MedTech Early Assessment (META) Tool

The META tool 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 potential next steps to bring a product to market; <https://meta.nice.org.uk>

Patient Data for Research

The landscape for accessing ‘real world’ patient data for both retrospective and prospective research is changing incredibly quickly. Health Data Research UK (HDR UK) 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. www.hdruk.ac.uk

In the meantime, the Clinical Practice Research Datalink (CPRD) 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. www.cprd.com

NICE Scientific Access (NICE SA)

NICE offers a fee-based consultancy service 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. www.nice.org.uk/about/what-we-do/life-sciences/scientific-advice

HealthTech Connect

HealthTech Connect (previously known as MedTechScan), a new ‘horizon scanning’ database of pre-launch phase MedTech products, was launched in January 2019. The secure online system will replace and unify 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, digital and face-to-face meetings, it will reduce the duplication and complexity involved in getting health technology to market in the UK. Access to this information will permit improved NHS planning around introduction and adoption of new technologies and encourage early engagement of industry with the NHS. www.healthtechconnect.org.uk

3.3 Regulation

Changes to regulation for MedTech products

As implied 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):

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)

However, 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:

Regulations (NEW)

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

EU member states have been given a 3 to 5-year transition window, with MDR and IVDR expected to be fully implemented by 26 May 2020 and 26 May 2022 respectively⁹. 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 The Medicines and Healthcare product Regulatory Agency (MHRA)¹⁰

Conformity assessments

Manufacturers need to demonstrate that their MedTech 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 MedTech¹¹.

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. →

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

MedTech conformity assessment routes

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.

Quality Management System (QMS)

Companies submitting a MedTech product for regulatory approval in the UK will need to demonstrate alignment to the ISO Standard 1348512 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.

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 chain¹³. 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)¹⁴.

Post-market monitoring and surveillance

Once a medical device 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 website¹⁵

Obtaining regulation for products marketed outside of the EU

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 Switzerland¹⁶.

MedTech and Brexit

At the time of writing this guide, the regulations governing MedTech in the UK were under consideration in light of the planned departure of the UK from the EU. Further information on the implications of Brexit on the UK MedTech industry can be found in the MedTech Europe position paper¹⁷. Contingency planning guidance for the event of a no-deal Brexit has been developed by the Government and shared with MedTech manufacturers¹⁸.

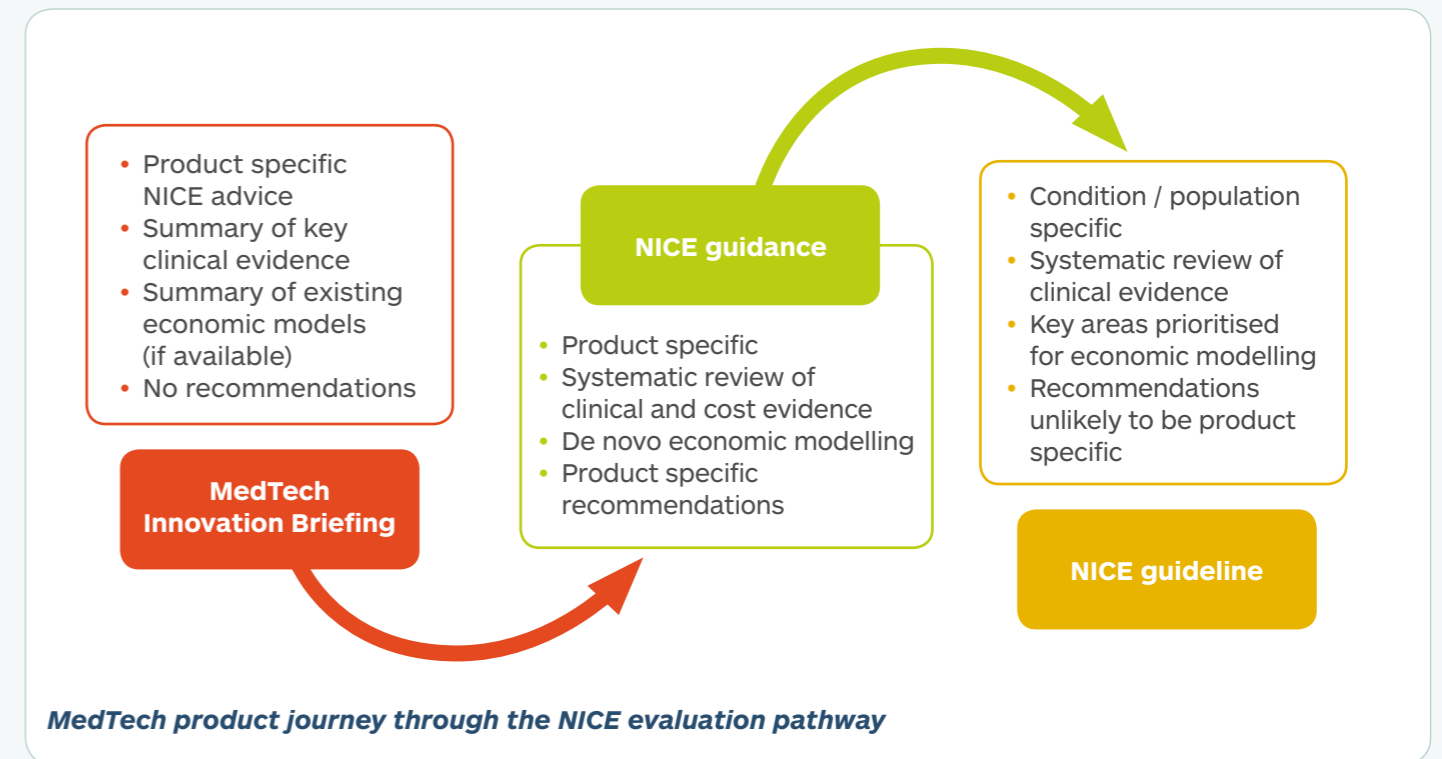
3.4 Evaluation and reimbursement

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)¹⁹.

NICE 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, as outlined below:



The NICE evaluation process

NICE is informed of new medical technologies 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 Diagnostics Assessment Programme (DAP), whilst those products likely to deliver a cost saving or to be cost neutral are routed through the Medical Technologies Evaluation Programme (MTEP). 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). The Committee, comprising of clinicians who develop and use MedTech, scientists and people providing a lay perspective on health and social care issues, 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.

MedTech Innovation Briefings (MIBs)

Commissioned by NHS England, MIBs 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.

See www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/medtech-innovation-briefings

The National Institute for Health Research Innovation Observatory (NIHRIO)

The National Institute for Health Research Innovation Observatory, hosted by the University of Newcastle, 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. www.io.nihr.ac.uk

Product reimbursement

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 with the structure of the reimbursement system of 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:

- Directly to patients (private sale, prescriptions);
- 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.

UK local NHS reimbursement

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.

UK National NHS reimbursement

Some devices associated with specialised services are reimbursed by NHS England at a national level with a funding mandate for specialised commissioners. Classification of a product for specialised commissioning is determined by the following factors:

- The number of individuals who require the product (less than 500 nationally);
- The cost of providing the product and/or associated service for use;
- The number of people able to provide the service;
- The financial implications for CCGs if they were required to arrange for provision of the product and service themselves.

Products are evaluated on clinical effectiveness, finance and activity impact assessments, prior to public consultation and final decision by NHS England. Further information on this process can be found on the NHS England website²⁰.



3.5 Commissioning and adoption

The NHS supply chain

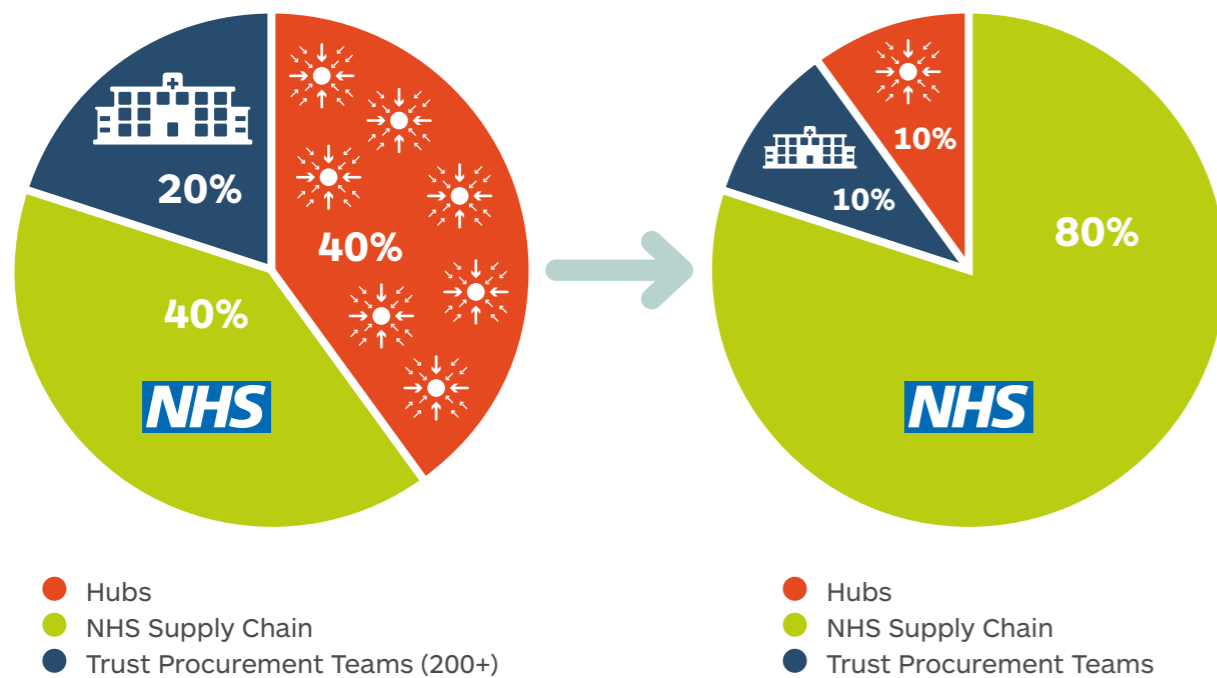
The NHS Supply Chain has a new operating model (herein referred to as the 'NHS Supply Chain') that has been introduced to deliver improved procurement and logistics support to the NHS. In a strategic response to the findings outlined in the Carter report, the new operating model will enhance procurement 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

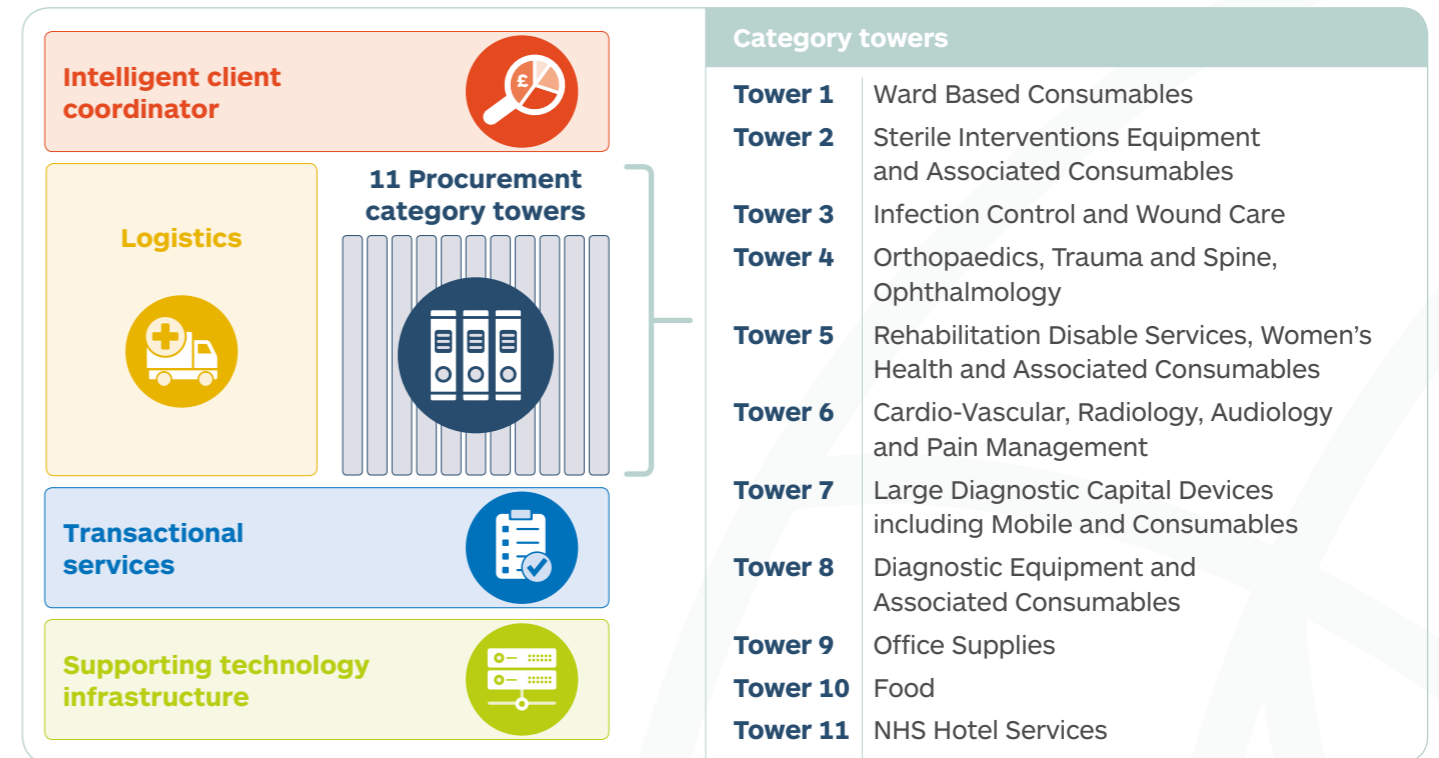
- Using increased buying power to affect purchasing behaviours and deliver the best products at the best value for the NHS.

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.



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 will be centrally funded from 1 April 2019, where the price of goods will be passed onto Trusts with no additional margin.

Commissioning of MedTech products through the new operating model

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.

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.

Increasing market adoption of innovative MedTech products

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 sites²¹. 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 challenge of getting MedTech products to market in a timely manner has been nationally acknowledged with the recent publication of the Accelerated Access Review by the Office for Life Sciences²². Since then, NHS England has invested in MedTech-specific procurement initiatives which aim to simplify and speed up adoption of particular groups of MedTech products. These include the High-Cost Tariff-Excluded Devices (HCTEDs)²⁰ and Innovation and Technology Payment (ITP)²¹ programmes. Whilst these initiatives are encouraging, they are only relevant to a small percentage of MedTech products.

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 and the Accelerated Access Review programme, NHS Supply Chain has been exploring ways in which it can help with the early stages of the innovation pathway.

The role of the AHSNs in supporting market adoption and diffusion

The importance of AHSNs in the successful spread of innovations has been documented in a recent King's Fund study²³, and is highlighted in the following case study. Whilst roll-out is still ongoing, this case study illustrates the impact of how technology needs to be incorporated into a much wider service redesign in order to demonstrate lasting impact on healthcare outcomes.

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.

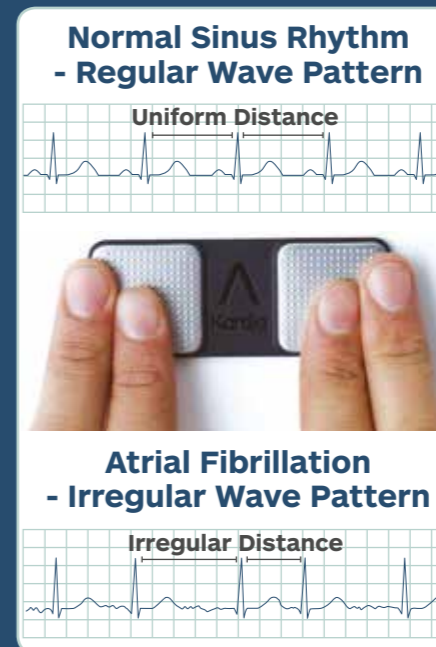
The AHSN Network will maintain a view of MedTech adoption and diffusion nationally, by tracking update of products by individual healthcare providers.

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.¹

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.

¹ <https://www.ncbi.nlm.nih.gov/pubmed/16034869>

Innovator checklist for successful market access

Having walked through the innovation pathway, there are number of things that manufacturers can be doing 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. **Engagement 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. Development of a **clear and concise business case aligned to the Government's Five Case Model** (see page 27 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-term nature of innovation;
5. **Full comprehension of commissioning, pricing and reimbursement approaches** of the market in which the product is to be adopted;
6. **Sharing of 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. **Securing an appropriate level of investment** to ensure cash flow throughout the pathway;
8. **Maintenance of an up-to-date QMS** to address regulatory and evaluation requirements in a timely manner;
9. Development of 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. advertising campaigns, governmental lobbying, market engagement events, opinion articles in the media and publishing of clinical papers.

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 HCTED programme²⁴, 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 £60 million that can be reinvested into specialist care. 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

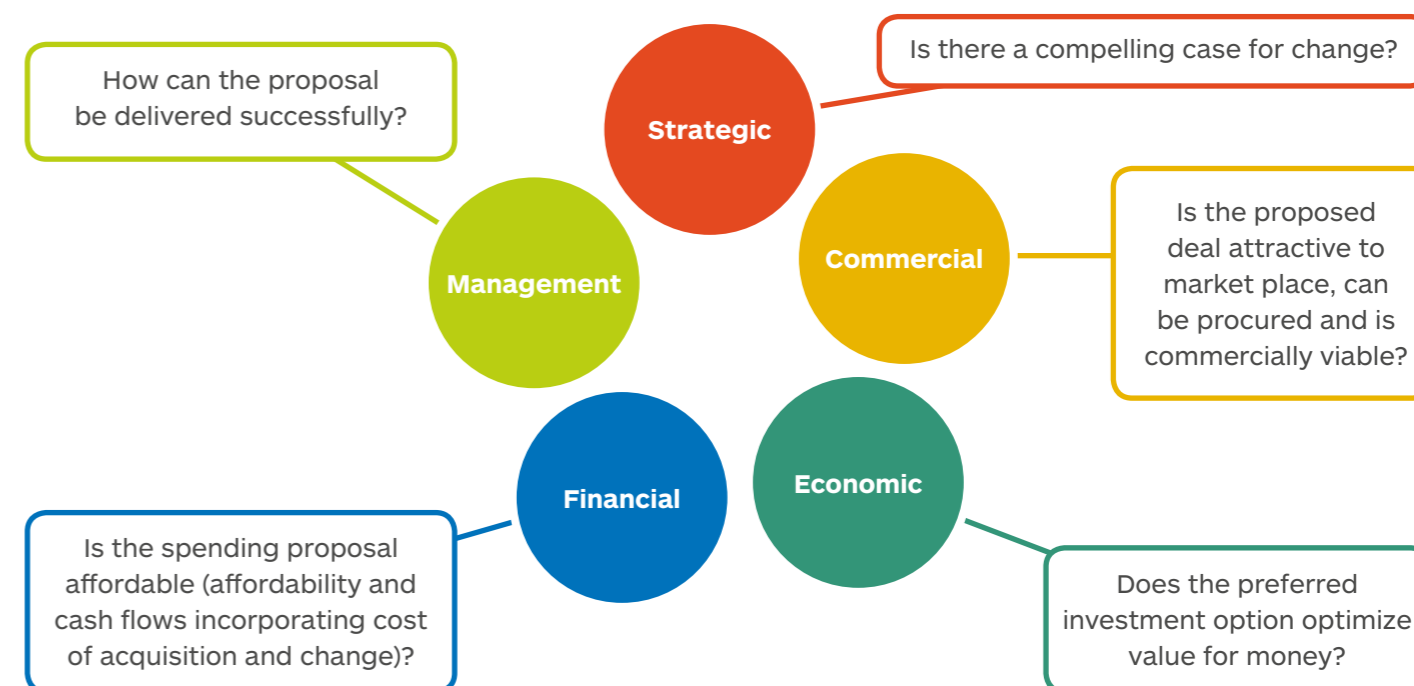
NHS market. The ITP programme²⁵ supports the NHS to adopt innovative market-ready MedTech which have demonstrated improvements in the quality and efficiency of patient care, by removing financial or procurement barriers to uptake. Each year, NHS England carefully selects a number of cost-effective innovations

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.

Developing a business cases for the NHS procurement

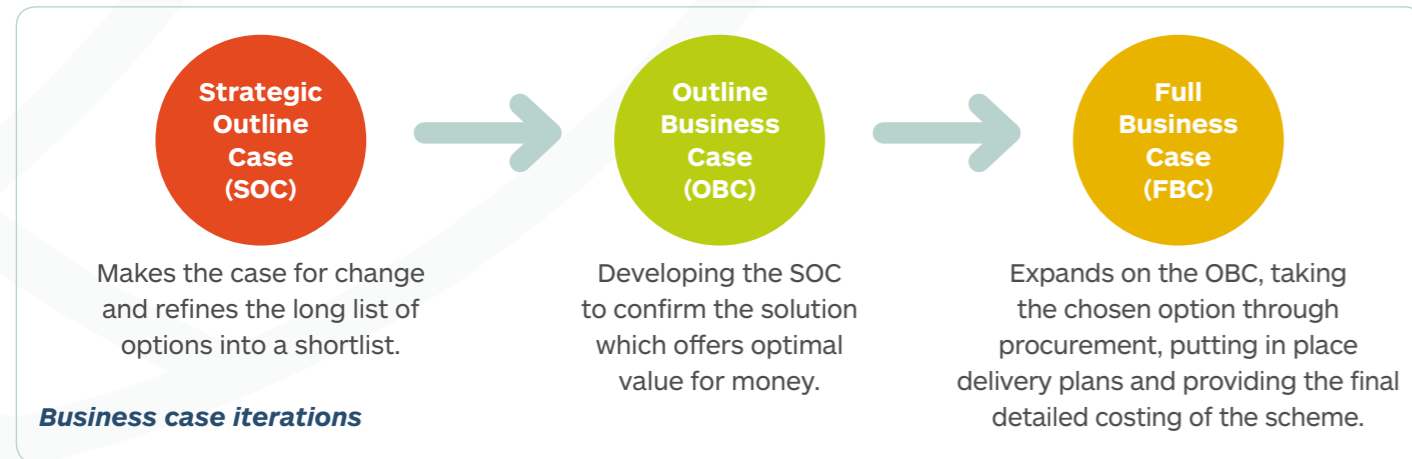
The Five-case model

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.



UK Government Five Case Model

Large, complex proposals are developed in three iterations:



Further information on the Five Case model can be found on the UK Government website^{26,27}. 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	Value in £ of hours saved that will be dedicated to front line duties	Improved patient satisfaction	Improved patient journey
Reduced cost per test		Faster turnaround time for a diagnostic test	

UK Business case benefit categories

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 dis-benefits 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.

4 Identifying and developing regional strengths

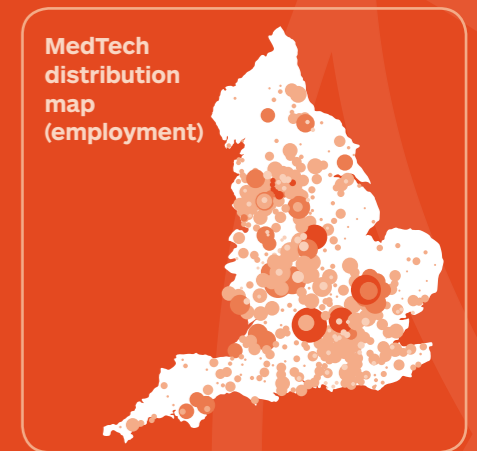
MedTech is already a UK-wide endeavour²⁸. The MedTech workforce has a broad spread throughout England but, in some areas, there are particular pockets of high concentrations of employment.

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".

"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.

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.

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.

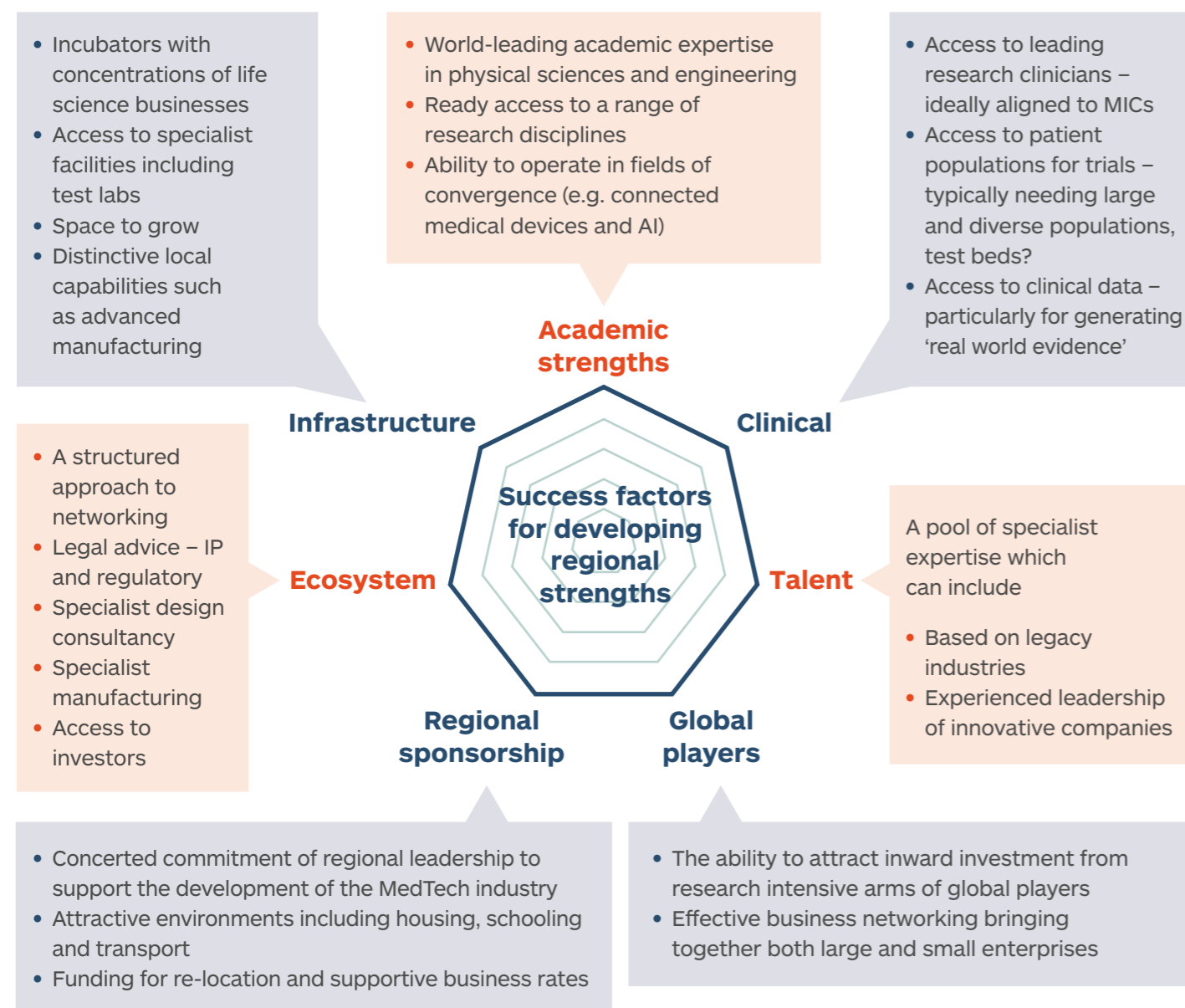


Many regions are looking to further support the development of local MedTech clusters. To achieve this, Government, local partners and industry need to work together to ensure the right infrastructure is in place to support the growth of life sciences clusters and networks.

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 below. Equally, some regional groupings play to particular strengths and may be part of a wider ecosystem.



5 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 multinational 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 a trade sale. The long timeframes involved in the adoption and diffusion of health 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 continue development and fail as a result²⁹.

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 following case studies highlight some of these:

- Using an agile approach to reduce time to market
- Accessing patient capital to secure long-term value
- Technology transfer through a shared equity approach
- Focusing on alternative markets to secure early returns

Case study: CMR Surgical – Agile development

CMR Surgical from Cambridge has developed a next generation surgical robotic system that aims to transform minimal access surgery (MAS) over the next few years. The system, named Versius, is designed to be more portable, versatile and cost effective than existing systems.

The CMR vision is to make MAS universally accessible, thereby improving healthcare outcomes at lower cost. The Versius system is specifically designed to meet this vision.

The medical 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 takes up a smaller footprint, is portable and flexible and is intended to come to market at a significantly lower cost

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 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 being built 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 (US), Shanghai, and a broader commercial presence that includes Japan, Germany, France, India and France. Growing locally also provides stability for its more than 400 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.

“When we started, patient capital was a new concept. We are grateful to be working with global, long term investors who are interested in the rollout of a highly promising disruptive platform which would open up large, global markets.”

Gordon Sanghera,
Chief Executive

Case study: SurePulse Medical – Securing long term value through an exciting collaboration between academia and industry

SurePulse Medical Ltd is committed to developing innovative and user-centric solutions to real clinical needs, which will ensure that new-born babies get the best care possible. Ten percentage 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 undertreatment or overtreatment of new-born babies. SurePulse VS is a head-mounted and 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. 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.

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

Department for International Trade. The latter, as for many MedTech SMEs, is of significant importance for early revenue generation as the UK still lags far behind EU and other overseas markets in technology adoption, despite SurePulse VS speaking directly to many of the themes and

Case study: QuantuMDx - Focusing on alternative markets to secure early returns

QuantuMDx Group 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 20 minutes. Currently in field studies in South America, South Africa and the UK, the first portfolio of tests - including HPV genotyping, an STI panel and TB/MDR-TB - are targeted for soft launch next year.

QuantuMDx was founded 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

objectives of the '5 Year Forward View'. 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

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 NGOs, such as Global Good/Intellectual Venture, 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 COGs 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

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, in improving the care of thousands of new-born babies around the world.

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 £50m, with £30m from equity and £20m 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 develop 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.”*

Next steps

The AHSN Network's work on MedTech is at a very early stage. This publication, and the underpinning work mark the first step in what is envisaged to be an ongoing programme of work, to be coordinated alongside our work on other important areas of innovation such as digital, genomics and personalised medicine. Going forward, it is our intention to champion companies with game-changing innovations that incorporate cutting-edge science, making sure that these inform various routes to market, maximising their potential to achieve significant population-level health impacts. Acting through the AHSN network, we will seek to focus on:

- *Robustly assessing and prioritising technologies for national support.* The AHSNs will continue to provide advice and support to all MedTech companies. The increased need to demonstrate impact on the NHS while also securing long-term potential will require a focus on a balanced portfolio of innovations with the greatest potential;
- *Facilitating access to cutting edge R&D.* We want to make the most of the capabilities in our centres of excellence across the country, regardless of where a company happens to be located. As well as raising awareness of where those centres are, the INN could help focus resources on the most promising projects;
- *Connecting companies to high tech manufacturing advice.* As well as signposting to the national centres which provide world-leading capabilities, the Network can facilitate introductions to companies with experience of similar challenges and also ensure the specific MedTech sector needs are addressed in the development of future national capabilities;
- *Partnering with leading NHS providers seeking to adopt game-changing innovations.* The NHS offers a wealth of opportunities for innovative companies. The Network can match innovations with National improvement initiatives. It can also help with knowledge transfer by sharing business cases and real-world evaluations to accelerate the process of adoption and spread;
- *Supporting MedTech innovators in market access activities.* The Network will provide advice and guidance to AHSNs as they support MedTech innovators during market access activities including due diligence, business case development, and access through the MedTech-specific procurement programmes (e.g. HCTEDs and ITP).

Further information on the work of the AHSN Network in the MedTech sector will be displayed on the Network's website at www.ahsnnetwork.com

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