Department of Health & Social Care

The medical technology strategy:

One year on

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Ministerial foreword

Time and time again innovative medical technology (medtech) has advanced our quality of care. As we look ahead to the next 75 years of the NHS and social care system, medtech has never been so important as a catalyst for change to improve patient outcomes.

That is why, in February 2023, we published the government's inaugural medtech strategy. This set out how, over the next 5 to 10 years, we will ensure the health and social care system can reliably access safe, effective and innovative technologies. These technologies will enable the delivery of high-quality care, outstanding patient safety and excellent health outcomes, while making the best use of taxpayer money.

One year into delivery of the medtech strategy, we are pleased to present an update on our achievements towards establishing an innovation pathway, to realise our vision of right product, right price, right place.

Medtech is integral to tackling our major health challenges, with the ability to transform care and improve both productivity and patient outcomes. It plays an important role at each point in a patient's care pathway from prevention through to diagnostics, treatment and aftercare.

Medtech is a vitally important industry for the UK economy. Building on the Life Sciences Vision, this government is committed to creating an environment for innovators to thrive and grow.

As we look forward, our ambition is to provide patients with faster access to the right products, wherever they are in the country, by streamlining the end-to-end innovation pathway. This takes products from initial concept through to use in the NHS to support patient care. To do this, we are providing clearer signals to industry on the innovation patients need, reforming the regulatory framework for medical devices, expanding our assessments of product categories, improving clarity over funding routes and making procurement an enabler for innovation, not a barrier.

We know there is still much to do. Streamlining the innovation pathway is a complex task involving targeted initiatives requiring leadership from across the health system, and we need all parts of the sector to play their part. As we continue this journey, we would like to thank colleagues from across the health and social care system, devolved administrations, industry and patient groups for their support and wider work, in alignment with the medtech strategy, to make this ambition a reality.

We are encouraged by the progress made and excited by the opportunities that lie before us. We look forward to continuing to work with patients and partners in further delivering the ambitions of the medtech strategy.

Andrew Stephenson
Minister of State (Minister for Health and Secondary Care)

Lord Nick Markham
Parliamentary Under Secretary of State (Minister for the Lords)

Enhancing the innovation pathway

Entry Point | Approvals | Funding & commercial | Adoption

This government remains committed to achieving the vision of right product, right price, right place for medtech. We cannot do this alone. Industry, patient groups, clinicians and the wider health and social care system in England and across the devolved administrations are integral to our shared success.

The message from our partners has been simple: to achieve our vision, we need to streamline the innovation pathway by ensuring the steps from entry to adoption are joined up and clear.

The department's role is to set policy direction and governance that enables a more cohesive and aligned environment, ensuring patients have access to the right technology for their needs, in line with the fast pace of technological advancements.

Our intention is to create a thriving hub for all innovation, from diagnostics, to treatment, to aftercare.

Figure 1: medtech industry in the UK figures

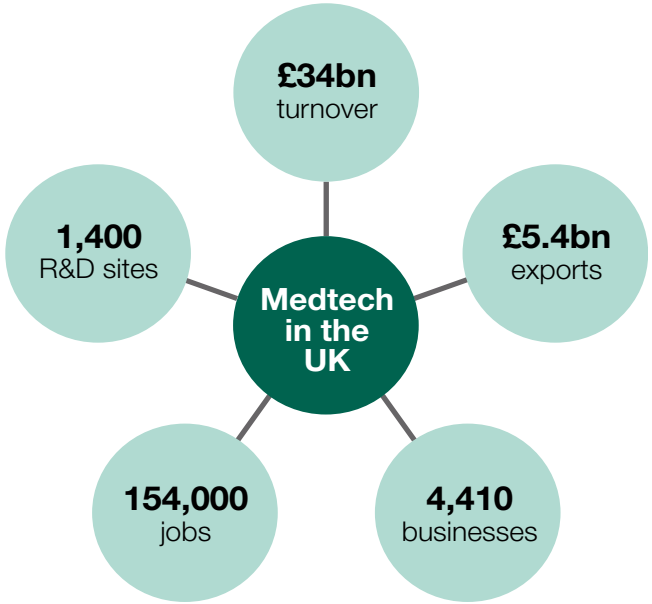


Figure 1 illustrates the UK medtech industry figures. This includes:

- £34 billion turnover
- £5.4 billion in exports
- 4,410 UK businesses
- 154,000 UK jobs
- 1,400 research and development sites

Source: Office for Life Sciences, Bioscience and health technology sector statistics 2021 to 2022

This one year on report highlights what we have achieved over the last 12 months and what we see as the next steps to deliver an innovation pathway, which is the backbone of our implementation plan.

Building on the priorities of the strategy and the Accelerated Access Collaborative's health technology pathway, we have structured the report into the 4 overarching stages of the pathway that government is seeking to improve:

- entry point
- approvals
- funding and commercial
- adoption

Across this pathway we have made good progress over a relatively short period of time with the delivery and launch of a range of initiatives.

Beyond the medtech strategy, there is work across the health and social care system to streamline and integrate the pathway. We remain committed to aligning activity, as we progress towards our collective goal.

Entry point

We know that for innovators and the NHS, consistency and clarity on what and how to bring innovative products to market is essential.

In September 2023 we launched the **Innovative Devices Access Pathway (IDAP)** pilot. For the first time for medtech, we brought together regulatory, assessment and NHS partners to provide enhanced support through a sequential pathway. The first 8 novel technologies to be selected were announced on 14 February 2024.

In April 2024, we published the **medical technology innovation classification framework (the framework)** to introduce a single version of truth for innovative language. This will help industry and the health and social care system clearly express and understand the nature and benefits of innovation compared to what already exists on the market. We will keep the framework under review with feedback from stakeholders.

In 2024, we will launch the next phase of the **Design for Life programme** to support a move towards a circular economy for medtech, as part of our wider strategic resilience planning.

In February 2024, NHS England published **a small and medium enterprise (SME) action plan**. This plan sets out how the NHS will help to deliver on its commitment to SMEs and enable the NHS to benefit from their significant value and contribution to patient care.

Approvals

We want to create an environment in which products identified at entry point efficiently progress through the regulatory requirements for safety and efficacy, and the assessment of cost effectiveness and affordability.

Alongside the work led by the Medicines and Healthcare products Regulatory Agency (MHRA) to reform the regulatory framework and more than double the UK approved body capacity, we have commissioned the National Institute for Health and Care Excellence (NICE) to undertake **late-stage assessments (LSAs)** of existing medtech categories, with the first category recommendations due to be published by autumn 2024. This complements NICE's early value assessment programme piloted in 2023 to 2024. This programme assesses promising new technologies at an early stage and forms part of NICE's new lifecycle approach to technology evaluation, that ensures NICE has the ability to look at any technology at any stage across the product lifecycle, to ensure best use of taxpayers' money.

Funding and commercial

As a short-term intervention, we launched the £30 million **Health Technology Adoption and Acceleration Fund (HTAAF)** in October 2023 to enable integrated care systems (ICSs) to invest in medtech to support winter pressures. It is recognised that further work is needed this year to review the available reimbursement routes for medtech and this remains a core area of focus.

To provide a fast-track procurement route for innovation, NHS Supply Chain launched their first **Medical Technology Dynamic Purchasing System (DPS) for Innovative Products** in January 2024.

We are committed to launching a **value-based procurement methodology** later this year to provide central guidance on how value-based procurement should be applied to support greater consistency and reduce the burden to industry.

Adoption

Many proven innovations and best practice tend to spread slowly and unevenly in the NHS, leading to unwarranted variation and health inequalities. We want to support the innovation which has progressed through the pathway to spread across the system at scale.

Last year, the NHS mandate included a requirement for all NHS trusts to submit data into the new **Outcome and Registries Programme** by March 2024. Going forward, the expansion of the national registries covering surgical activity will support adoption of the most effective medtech and reduce unwarranted variation.

For medtech prescribed in the community, we launched a targeted consultation in October 2023 to propose changes to the **Part IX Drug Tariff** and for the first time put the patient at the centre of decision making over what products should be listed. We remain on track to respond to the consultation in spring 2024. This is the first step in a wider review of Part IX to ensure products which are of good quality and demonstrate value to the NHS are listed and address variation in prescribing practice.

Enabling infrastructure

A data driven approach underpins our work to improve the innovation pathway. Our objective is to build a trusted and connected medtech data ecosystem.

In January 2024 we launched a procurement process to build a national **Product Information Management (PIM) database** as a first step to establish a single version of truth.

Meanwhile NHS Supply Chain are building a **National Equipment Tracking and Inventory System (NETIS)** to provide visibility over equipment assets.

Figure 2: Medtech strategy initiatives within the innovation pathway

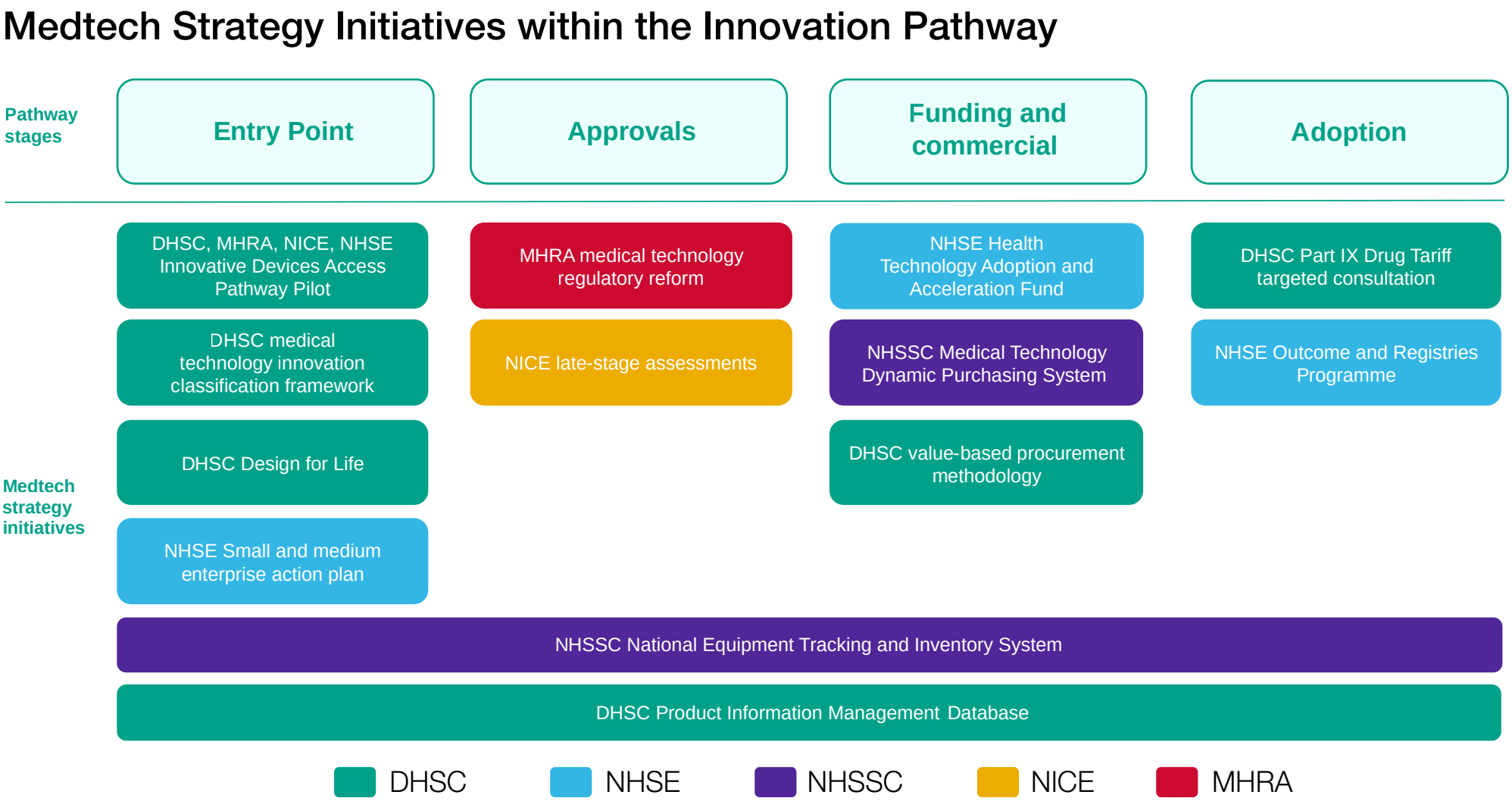


Figure 2 summarises the medtech strategy initiatives within the innovation pathway stages:

- entry point:
  - Department of Health and Social Care (DHSC), MHRA, NICE, NHS England Innovative Devices Access Pathway Pilot
  - DHSC medical technology innovation classification framework
  - DHSC Design for Life
  - NHS England small and medium enterprise action plan
- approvals:
  - MHRA medical technology regulatory reform
  - NICE late-stage assessments
- funding and commercial:
  - NHS England Health Technology Adoption and Acceleration Fund
  - NHS Supply Chain Medical Technology Dynamic Purchasing System
  - DHSC value-based procurement methodology
- adoption:
  - DHSC Part IX of the drug tariff targeted consultation
  - NHS England Outcome and Registries Programme
- across the pathway:
  - NHS Supply Chain National Equipment Tracking and Inventory System
  - DHSC Product Information Management database

Health equity in medical devices

We are committed to maintaining the highest standards of safety and effectiveness of medical devices available for all patients. Throughout the innovation pathway, we are dedicated to ensuring equitable medical device practices, spanning from design through to use.

In March 2024, we published the Equity in medical devices: independent review alongside the government's response to the independent review. We welcome and acknowledge the importance of the recommendations.

Strategic resilience

Prior to the medtech strategy publication, our focus on medtech resilience had largely been driven by ensuring preparedness for Brexit and COVID planning and risk mitigation. We remain committed to increasing the resilience of medtech supply chains and have begun shifting towards a more pro-active, longer-term approach to resilience. NETIS and Design for Life are 2 core strategic projects in this area.

Diagnostics

Medtech products play a vital role in diagnostic services, which are crucial to supporting preventative care and delivery of world leading, safe and effective treatment.

We remain committed to integrating innovative technologies into diagnostic services to transform patient outcomes. Technologies selected for the IDAP pilot include a blood test to support diagnosis of Alzheimer's disease, and artificial intelligence to determine risk of chronic obstructive pulmonary disease. Technologies funded by the HTAAF include an at home testing kit for chronic kidney disease.

The NHS is also investing in a range of innovations to improve early diagnosis, including the largest ongoing trial of multi-cancer early detection tests through the GRAIL-Galleri trial.

Beyond this,155 community diagnostic centres (CDCs) are currently operational, and the programme is on track to deliver the ambition of opening 160 by 2025.

Entry point

Entry point

The NHS is a large and complex system. Introducing new products and technologies can be challenging. Innovators must navigate a complicated environment with multiple front doors, divergent pathways and stakeholder signals. For the NHS, finding innovations that meet its evolving needs can be equally difficult.

As outlined in the medtech strategy, our ambition is to build well understood mechanisms for companies to enter the pathway, accompanied by clear, co-ordinated, national signals on innovation. This is so the health and social care system can prioritise what technology enters the medtech pipeline.

To pilot initial pathway improvements, we launched the **Innovative Devices Access Pathway (IDAP)** in September 2023, in partnership with:

- Health Technology Wales (HTW)
- MHRA
- NICE
- NHS England
- Scottish Health Technology Group (SHTG)

IDAP provides an integrated and enhanced regulatory and access pathway for innovative medtech that meet an unmet need in the NHS and offer the potential to be transformative to patient outcomes.

Eight technologies were announced on 14 February 2024. One device aims to destroy liver cancer tumours using ultrasonic waves, offering a safer alternative to radiotherapy. Other technology selected supports earlier diagnosis of Alzheimer's disease and stroke through novel blood tests. Another device uses artificial intelligence to predict patients at risk of hospitalisation for chronic obstructive pulmonary disease.

To bring greater clarity for industry and the system on how we collectively define innovation, we published **the medical technology innovation classification framework (the framework)**.

In the immediate term, the framework will support the system to use a shared language for different types of innovation and explore use cases on how the framework can be deployed across the pathway.

The framework will be kept under review to understand the applicability and utility of the language and will be adjusted in consultation with the wider health system.

In the long term, use cases for the framework may include how different technologies are considered across the innovation pathway, suitability for funding, assessment of cost effectiveness and qualification for national framework agreements.

To address resilience challenges, we want to lead a sustainable transformation of product supply, usage and disposal – in part – via targeted innovation. In March 2023, we launched the **Design for Life programme** which is a collaboration between government, industry, the healthcare sector and academia, to identify practical actions that address the challenges of resource efficiency.

A roadmap is due to be published in 2024, to outline the necessary actions to ensure the move forward to reuse, remanufacture and materials recovery by default across medtech systems.

In February 2024, NHS England published a small and medium enterprise (SME) action plan, as the culmination of its first year working with the SME Advisory Group.

Over the past 12 months, the SME Advisory Group has advised the Chief Commercial Officer, the NHS Commercial team and the wider system on their challenges and worked with NHS colleagues to improve the opportunities for SMEs to engage with and compete for business.

Entry point

The plan outlines how the NHS will:

- better engage, communicate with and learn from the SME community
- improve visibility of the NHS opportunities and encourage SME's participation in commercial activity
- leverage the innovation power of SMEs for the benefit of the NHS
- maximise the SME opportunity arising from social value

The plan aims to progress making the NHS a place where SMEs can thrive, for the benefit of our patients.

Case study: the Innovative Devices Access Pathway pilot

The aim of the Innovative Devices Access Pathway (IDAP) pilot is to reduce uncertainty in the route to market for technology developers. It stems from the Life Sciences Vision, published in July 2021, which set out the government's intention to create an outstanding environment for life sciences businesses to start, grow and invest and strengthen access and uptake of innovation.

The pilot will streamline the pathway for innovative products that address an unmet clinical need and align with the Life Sciences Vision healthcare missions. These missions will help the NHS to solve some of the biggest healthcare problems of our generation. Those considered in the pilot were:

- **improving translational capabilities in neurodegeneration and dementia**
- **enabling early diagnosis and treatments, including immune therapies such as cancer vaccines**
- **treatment and prevention of cardiovascular diseases and its major risk factors, including obesity**
- **reducing mortality and morbidity from respiratory disease in the UK and globally**
- **addressing the underlying biology of ageing**
- **increasing the understanding of mental health conditions, including work to redefine diseases and develop translational tools to address them**

It is the first example of system partners working together to provide tailored support along a single pathway. This will include advice on regulation, assessment and access considerations into the NHS through a tailored Target Development Profile roadmap with input from patient and public representatives throughout the pathway. This roadmap is informed by Target Development Profile meetings with the IDAP partners to discuss the maturity of their technology and determine the nature of support and advice they will receive from the pilot tools.

This is a unique offering, as the pilot enables direct interaction with partners in an innovative approach to support the safe, timely and efficient generation of evidence to underpin both regulatory approval and Health Technology Assessment (HTA) of innovative medical devices.

The pilot was 10 times oversubscribed. Applications covered a wide array of health and wellness areas such as cardiac health, oncology, ageing and geriatrics, long-term condition management, mental health, early diagnostics innovations and remote monitoring technologies.

Our assessment of the applications was comprehensive and collaborative, involving experts from across our partner organisations and patient and public representatives. Scoring of applications focused on their effectiveness in addressing critical health issues, the novelty of the technologies and the broad advantages they offer to the healthcare system.

Selection for the pilot also aimed to include a variety of technologies in different stages of development, disease area and company size to enable testing of the full pathway. Through this approach, we identified 8 technologies with promising capability to transform patient outcomes and service delivery.

The pilot is scheduled to run until March 2025 with the aim to establish IDAP as an ongoing programme beyond 2025. We will evaluate the successes and lessons learned as we move through the pilot to leverage the insights and feedback to establish an ongoing programme. This future programme will be focused on identifying and nurturing innovative solutions, with the aim of streamlining their progress through the pathway.

More widely across the innovation landscape, the pilot acts as a trailblazer to test elements of the end-to-end innovation pathway.

Technoleg Iechyd Cymru
Health Technology Wales

Medicines & Healthcare products Regulatory Agency

NHS England

NICE National Institute for Health and Care Excellence

Healthcare Improvement Scotland | SHTG Advice on health technologies

Case study: Design for Life

In March 2023, we launched the Design for Life programme with an event bringing together over 60 organisations to consider steps needed to reach the overarching vision: medtech systems that support reuse, remanufacture and materials recovery by default.

What do we mean by reuse, remanufacture and materials recovery? These definitions are taken or based on those from the Ellen Macarthur Foundation:

- reuse: the repeated use of a product or component for its intended purpose without significant modification for example, sterilisation
- remanufacture: re-engineer products and components to as-new condition with the same, or improved, level of performance as a newly manufactured one
- materials recovery: transform a product into its basic components, materials or substances to be used again or reprocessed into new materials

Over 2023, in partnership with the National Interdisciplinary Circular Economy Research programme, we held numerous workshops with expert stakeholders in industry, the health and social care system and academia. By the end of 2023, we had received over 90 distinct recommendations that can be used to develop a roadmap of activity towards reaching the programme's vision. These spanned from new systems of purchasing, to training for clinical staff, to realising groundbreaking innovations that could enable widespread improvements.

These recommendations are being combined into:

- a roadmap for the sector with a vision, a clear articulation of problem statements and sub issues
- a set list of actions that we'll begin exploring how to deliver with our collaborators
- an areas of research interest document that communicates our evidence gaps

With regards to the areas of research interest, we and our collaborators will soon be looking to set out fundamental research on areas such as digital enablement, behavioural insights and sterilisation infrastructure.

We envision this will include a safe delivery of in situ pilots with participating organisations such as hospitals, manufacturers and material processors.

Resource efficiency benefits many areas of the medtech system. Our 4 objectives show the breadth of the expected benefits:

improve supply chain resilience

grow UK economy and jobs

realise NHS cost savings

contribute to sustainability targets

Enabling and adopting innovation is a core theme that runs throughout our planned activity, with 2 areas of focus being:

exploration of 'commercial incentives'

improving leadership and collaboration for 'transformative innovation'

To support these areas, Design for Life will develop closely with the medtech strategy's other initiatives.

Approvals

Regulations

Regulation is the cornerstone of patient safety and market access. It is a central enabler to deliver the ambitions of the medtech strategy. The MHRA is taking forward an ambitious reform of the regulatory framework for medical devices and diagnostics. This will allow us to take advantage of the huge advances in life sciences and diagnostics and is being developed with patient safety at its heart.

Figure 3: number of medical products registered with the MHRA, 2022 to 2024

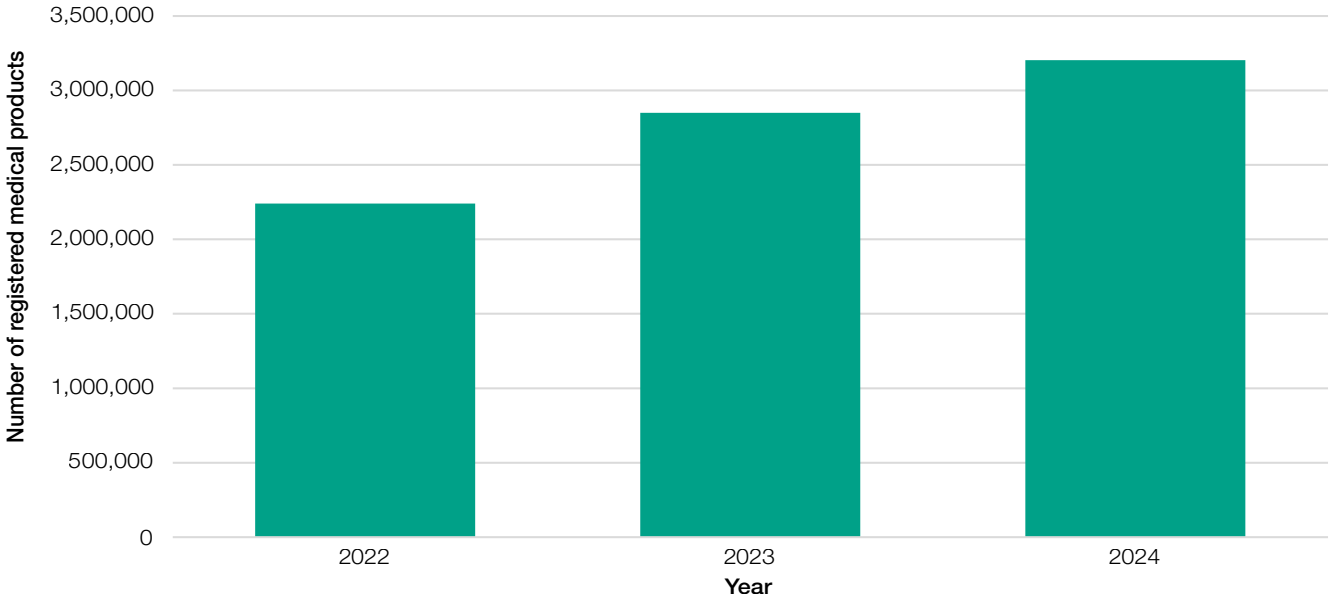


Figure 3 shows the increase in the number of registered medical products with the MHRA from 2022 (around 2.25 million) to 2024 (around 3.25 million).

Source: MHRA (internal data).

The MHRA recently published a roadmap towards the future regulatory framework for medical devices, giving clarity on the next steps in the development of the regulatory regime. The roadmap commits to stakeholder discussions on the regulatory regime, ensuring that those impacted by the changes understand them and can practically implement them. The core regulatory changes are expected to be laid in Parliament in 2025, with a 6-month implementation window before taking effect.

A core achievement of 2023 and early 2024 has been the designation of 5 additional approved bodies, bringing the total number to 9. These organisations assess whether manufacturers and their medical devices meet the regulatory requirements. Approved bodies play a critical role in the supply of medical devices, and expanding capacity will support manufacturers to bring their products to the UK faster.

Looking forward, we will introduce an international recognition framework for medical devices as part of the core regulatory changes. This will mean that medical devices with approval from trusted overseas regulators are able to access the Great Britain market more easily, while ensuring patient safety is protected. This will ensure patients have access to medical devices that best suit their needs, speed up patient access and reduce duplication on regulatory effort for industry.

Assessment

In the medtech strategy, we reflected that a lack of consistent specifications and standards for detailed evaluation can lead to inefficient use of resources and duplicated evaluation processes. The variation in individual approaches means clinicians are unable to meaningfully compare product quality and value across classes.

In 2023, NICE introduced its early value assessment programme that rapidly assesses products early in the lifecycle that need further evidence to support wider adoption. In March 2024, NICE published 13 early value assessments and evidence generation plans incorporating more than 70 technologies. These focus on areas of critical unmet need such as new digital therapies for depression and anxiety disorders with the combined potential to help more than 7 million people, and digital programmes for delivering multidisciplinary weight management services with the potential to save thousands of hours of clinicians' time.

As part of NICE's ongoing transformation work, and the development of its lifecycle approach to the evaluation of health technologies, NICE is now introducing multi-tech assessments of existing product categories, referred to as **late-stage assessment (LSA)**. LSA aims to assess technologies that are in widespread or established use in the NHS to inform commissioning and procurement decisions. Over time, technologies in use often undergo continuous or incremental innovation and adaptation. NICE will assess which technologies, or features of a technology, in a category represent value for money and whether price variations are justified by the incremental differences and advancements.

The evaluations will lead to published recommendations that empower NHS decision makers to identify the right products for the right price. The evaluation will harness the perspective of healthcare professionals, patients and the NHS. It will refine and tailor NICE's existing guidance methods and processes. LSA will also develop additional approaches, as needed, to fully capture the value of technologies already in established use in the NHS.

Product evaluations will consider a broader range of comparators than before, such as patient preference and usability, and will incorporate real-world evidence and expert input. NICE published the interim methods and process statement in February 2024.

NICE will undertake 8 LSAs during 2023 to 2024 and 2024 to 2025. These LSAs will focus on priority areas that are either high cost and more clinically complex, or lower cost areas with high use in the system. The first LSA launched in October 2023 and is reviewing transcatheter aortic valve implantations. The second launched in February 2024 and is evaluating colostomy bags. Throughout the rest of the year, NICE will evaluate coronary stents, continence products, beds, slide sheets and 2 areas within wound care.

LSA is a central element of the lifecycle approach to evaluation, valuing incremental innovation in transformative and radical products once they have become established or widely available to the NHS. It forms a core component of the medtech innovation pathway, and we will work closely with NICE in reviewing these topics to develop a sustainable 'business as usual' approach to LSA.

By ensuring the NHS is supported with clear recommendations on the value that different products offer, we are reducing the administrative burden on health and social care professionals, ensuring patients have access to the right products for their needs, and securing better value for taxpayer money.

Funding and commercial

Funding

In November 2023 we provided £30 million of new investment through the **Health Technology Adoption and Acceleration Fund (HTAAF)** to provide ICSs with immediate funding to support winter pressures. Local areas have received funding to implement some technologies, including:

- Healthyio is an at-home early detection device for kidney disease
- BRAVE AI being used in primary care to identify patients who may be at risk of their wellbeing declining to the point of needing to go to hospital
- Docobo is a telehealth system which supports people to monitor and maintain their own physical health at home
- Whzan supports the set-up of virtual wards enabling the capture of critical health metrics like oxygen levels and heart rates

Commercial

The procurement process in the NHS can be complex. As outlined in the NHS England commercial strategic framework published in October 2023, we seek to leverage NHS collective buying power and provide clear, consistent guidance on how to contract with the NHS.

NHS Supply Chain have launched a new **Medical Technology Dynamic Purchasing System (DPS) for Innovative Products**, allowing public sector organisations access to buy goods and services compliantly from a range of innovative medtech categories.

Unlike traditional frameworks for the supply of goods and services, the DPS simplifies and overcomes barriers to entry that small and medium sized enterprises (SMEs) face when tendering to supply NHS trusts. Current barriers to SMEs are due to the complexity of a traditional open process, which includes the requirement for them to provide detailed award questions which can be confusing and time consuming and are expensive. Timing of renewals can be a barrier to SMEs who may have to wait up to 4 years before the opportunity becomes available.

The DPS for medtech process is streamlined, with clear entry requirements and assessment within 15 days of submission.

We are working to develop a **value-based procurement methodology**. This is to ensure a consistent approach is applied for the procurement of medtech in which important factors such as the impact on the patient pathway, patient safety and productivity can be assessed.

The guidance includes a proposed passport model to enable a product to be assessed once centrally to simplify the procurement process for industry. In particular, to avoid additional burden to SMEs and support them in accessing and negotiating with the NHS.

A draft version of the methodology is being circulated with procurement, industry and patient groups with the aim to have a finalised version ready for launch by the end of 2024. We are working to align with the NHS England commercial strategic framework so that it can be embedded into business as usual.

Case study: Medical Technology Dynamic Purchasing System for Innovative Products

As the procurement partner for the NHS Innovation Service, NHS Supply Chain is uniquely positioned to quickly scale access to innovations across the NHS, enabling new ways of delivering care, improved patient outcomes and cost savings.

NHS Supply Chain were asked to provide a compliant route to the NHS market for innovative and game changing medtech products, reducing the barriers to entry and the time to market, while still maintaining patient safety and improving patient care.

The introduction of a Medical Technology DPS for Innovative Products was proposed to meet this need and significantly ease the burden on suppliers and shorten time for the products to reach patients. This DPS will ensure innovative products are available to improve patient outcomes whilst ensuring the highest levels of regulatory approval for patient safety.

The DPS was launched in January 2024 and will run for up to 7 years. The NHS trusts will have an easy and efficient route to access innovative products for patient care.

See further information from NHS Supply Chain on the required criteria and instructions on how to use the new Medical Technology DPS for Innovative Products.

Adoption

Many tried and tested innovations spread slowly and unevenly in the NHS, leading to unacceptable variation in quality, cost and patient environment. Adoption is impacted by the cumulative impact of earlier stages in the innovation pathway. Our work to improve the effectiveness in these upstream elements will support our ambition to enable greater spread of the best innovations and reduce unwarranted variation in adoption. Clinicians are central to effective adoption on innovations. As outlined in the NHS Long Term Plan, upskilling the workforce is key to unlocking the potential of science, research and technology to deliver the care of the future.

Devices in primary care

As the use of medtech outside of hospitals increases, further clinical and patient input on the devices available for prescribing in primary care is integral. In October 2023, we consulted on proposals to modernise the tariff system for the £1.3 billion of medical devices available for prescribing in the community in England and Wales. The mechanisms of the tariff system have been subject to very minimal amendment since it was established, during which time the world of medical devices has evolved dramatically.

The aim of the proposals is to ensure that devices are of good quality and demonstrate value to the NHS, and to update application processes to support the adoption of innovation that can improve patient outcomes and quality of life. The proposals therefore focus on options to implement a more rigorous process for assessing and comparing technologies. We will formally respond to the consultation in spring 2024 and we continue to collaborate with industry and partners on developing the proposals.

Figure 4: medtech spend in community care in England in 2022 by category

Figure 4 shows that of the total medtech spend in community care in England in 2022 (£1.3 billion):

- £604 million was spent on appliances
- £383 million was spent on stoma appliances
- £166 million was spent on dressings
- £131 million was spent on reagents
- £61 million was spent on incontinence appliances

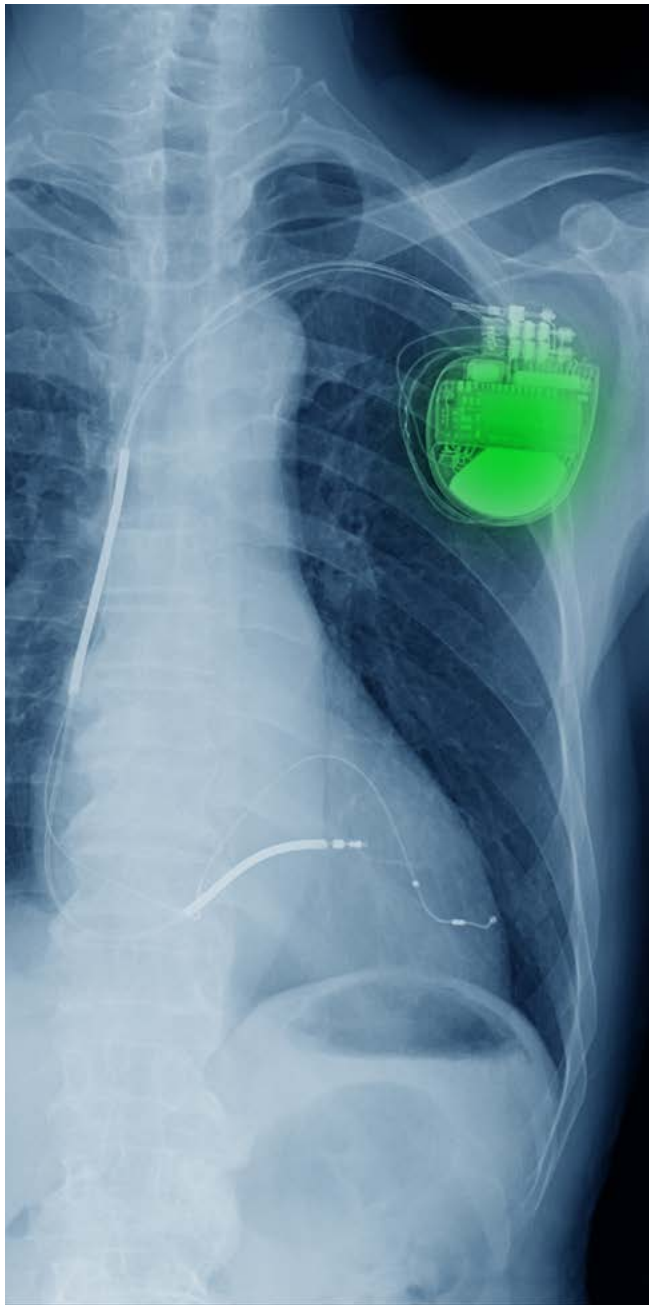
Source: NHS Business Services Authority

Devices in Secondary Care

The NHS England Outcome and Registries Programme was established in 2022 and is delivering a number of core workstreams to fulfil the recommendations of the 'First do no harm: the report of the Independent Medicines and Medical Devices Safety Review', chaired by Baroness Julia Cumberlege and the Paterson Inquiry report. Our intention is to unify the fragmented governance, access, financial and technical landscape of registries and audits.

The programme has established speciality clinical steering groups with patient representation, developed the national mandatory Medical Device Outcome Registry Platform and obtained new Secretary of State directions to require NHS providers and request the independent sectors to submit device and non-device data, for the purposes of improving patient safety and patient outcomes. It is onboarding priority registries to the Outcome Registry Platform, in addition to delivering a new national major trauma registry solution. The scope of the programme is to cover 100% of surgical activity and once in place will provide visibility over product use to reduce unwarranted variation and support the consistent adoption of cost effective medtech.

New workstreams under the Outcome and Registries Programme include digital patient reported outcome measures and patient reported experience measures developments across prioritised specialities and conditions, shared decision making and consent. The programme will establish a patient advisory panel to further increase patient involvement in practical areas such as assuring patient data security and programme transparency, development of public and patient information, and appraising website and technical developments. It will continue to monitor compliance of providers submitting high-risk device, patient and clinician data via barcode scanning across all specialties and advance its commitment to establishing a research and innovation capability to improve the clinical trial infrastructure within the UK.



Enabling infrastructure

Our objective is to build a trusted and connected medtech data ecosystem. Medtech data is currently inconsistent and fragmented across multiple systems, making it difficult to build a national and transparent outlook.

To underpin the innovation pathway, we are working in collaboration with industry and the health system to improve existing datasets by enhancing the data quality, coverage, structure and access. Having higher quality, joined up, comprehensive data for medtech will make it easier to compare products, reducing search time and making it easier to make informed choices to select the right product, at the right price, in the right place.

We launched a project to build a single, online and national **Product Information Management (PIM) database**. PIM will become the central reference system for core medical product information, aligned to national standards. This will create efficiencies across the system by improving the exchange of quality data between NHS trusts and suppliers to inform delivery of objectives including purchasing decisions.

A procurement exercise was launched in January 2024 to appoint a supplier to take forward the initial alpha phase. In spring 2024, the alpha phase of delivery for PIM will commence to explore the practicalities of developing, maintaining and using a PIM. This will include building and iteratively designing prototypes, informed and tested by users to begin developing a system that best delivers on user needs. This will develop a more holistic view of the supplier landscape so that risks can be proactively spotted and mitigated.

The new regulatory framework that MHRA is developing aims to mandate products having a unique device identification which will further enhance traceability, as well as introduce implant cards to provide improved patient information.

In partnership with NHS Supply Chain, we are building a **National Equipment Tracking and Inventory System (NETIS)** to consolidate multiple data sets to provide a single and coherent view of medical assets across the NHS landscape.

Case study: Product Information Management (PIM) database

The medtech strategy committed to building a trusted data picture to enable the delivery of the vision of the right product, at the right price, in the right place. A central element of delivering this is the medtech PIM database. PIM will be a centralised database that consolidates, manages and displays standardised information on all medtech products.

We have completed the discovery phase of the PIM programme to understand the user requirements in detail. We consulted over 25 stakeholders from across the health system, including trusts, medical device manufacturers and data standards bodies. Through this collaboration we were able to better understand the problems caused by the currently lacking data picture and refine the requirements for the solution.

Using this, we identified that PIM should aim to:

- improve patient safety, by making data more accessible so that healthcare providers can make informed decisions about medical products
- streamline procurement processes, by providing instant access to complete and necessary information required for purchasing medical products
- increase efficiency of data sharing, by reducing the need for further information requests
- improve our strategic understanding of medtech

To achieve these aims, we will use the existing wealth of data from the medical device registrations. This supports the ‘collect once, use often’ approach.

In April 2024 we will launch the alpha phase of PIM delivery. This will develop and test ideas to solve the identified problem and deliver the aims, including:

- exploring data flows, to identify what data is required, by who and at what stage
- examining incentives and barriers to using PIM, to ensure that the solution will be used in practice
- developing data standards, to identify and address gaps in the scope and quality of data
- continuing to engage with stakeholders, to ensure that developments in PIM focus on user needs

Once alpha phase has identified the optimal solution for PIM, we will start the beta phase later in the financial year 2024 to 2025, which will develop a proof of concept to test with users.

Case study: National Equipment Tracking and Inventory System (NETIS)

NETIS will consolidate multiple data sets to provide a single and coherent view of medical assets across the NHS landscape.

Improving visibility of our assets and how they are being used will lead to enhanced system resilience through data driven procurement, improved asset sharing across the NHS and greater system coherency.

During the COVID pandemic there was an urgent need to know what equipment was available across the NHS to ensure the locations that most needed the equipment had sufficient capacity. Due to the independent way each trust procures and manages equipment, this wasn't easily viable.

We identified an information gap that needed to be resolved, which was the genesis for the national equipment tracking inventory system: NETIS.

The NHS Supply Chain also needed to understand the national install base of Medical Equipment to support the NHS with efficient replacement of equipment – to add value into the NHS and support patient pathway outcomes.

As a result, the NETIS project was initiated under the medtech strategy to generate efficiencies and savings across the NHS network, and empower procurement decisions through data interpretation, insights and visualisation.

The NHS Supply Chain will develop NETIS in 2 stages. Engagement has been conducted with various stakeholder groups both internal and external to NHS acute trusts.

Phase 1 will bring together existing NHS Supply Chain data into a single version of the truth. We will present a comprehensive picture of assets across the NHS, covering a specified range of products, by collating and normalising accessible data on equipment sales, maintenance contracts and combining this dataset with imaging data already collected from trusts. The primary focus will be 'fixed' medical equipment, such as imaging equipment and other portable diagnostic and monitoring equipment.

Phase 2 will enhance the product coverage, on a 'real-time' basis to strengthen the resilience of the NHS network. The NHS Supply Chain will continue to build and manage a robust asset management system by amalgamating data to the existing asset dataset. This will be developed to provide better understanding of assets and their utilisation by using procedure data, matched to assets. The system will be a bespoke build to provide access to all NHS colleagues that need it, on a platform that is accessible and pragmatic to the user.

NETIS will be a visualisation tool that will allow easy access to insight and data extraction at local, regional and national level. This will provide multi-level context and accessibility to different levels of stakeholders, based on varying requirements and use case scenarios.

Diagnostics

Government has made progress to improve diagnosis rates, bring diagnosis closer to the patient and integrate innovative technology to transform the pathway.

Improve diagnosis rates

Over the last year, the NHS has been delivering record levels of diagnostic tests, including MRI and CT scans, with each month in 2023 setting a record. The monthly diagnostics data can be found on the NHS England website.

We have reformed cancer waiting time standards, in line with the recommendations of clinicians within the 'Clinically led review of NHS cancer standards'. This included replacing the 2-week wait standard with the Faster Diagnosis Standard (for patients to receive a cancer diagnosis or all clear within 28 days) so that there is a greater focus on improving the speed of diagnosis for patients with suspected cancer. Performance against the Faster Diagnosis Standard has shown a steady year-on-year improvement over 2023 to 2024.

To improve early diagnosis, the 2019 NHS Long Term Plan introduced an ambition for 75% of people with cancer to be diagnosed at stage 1 or 2 by 2028 and 55,000 more people to survive their cancer for 5 years or more. At the time, the proportion of patients diagnosed stood at 54% to 55% and had not changed for some time. However, the latest rapid registration data shows that this has now improved over the last year to 58%. This is the first significant improvement in early diagnosis rates, although we know there is much more to do to reach our ambition.

NHS England is deploying a range of interventions to meet its ambition, such as the expansion and targeting of screening programmes. This includes the roll-out of the national lung cancer screening programme, which is diagnosing 76% of lung cancers at an early stage (against 30% historically), and trials for prostate screening targeted at those at high risk. The NHS continues to run its 'Help Us Help You' programme to encourage timely presentation to support earlier diagnosis.

Diagnosis closer to the patient

The NHS is on track to deliver its public commitment in the elective recovery plan to rollout 160 community diagnostic centres (CDCs). There are currently 155 operational CDCs. Since July 2021, CDCs have delivered over 7 million diagnostic tests.

The NHS has successfully worked with private providers to deliver elements of the CDC programme, in line with the recommendations in the Sir Mike Richard's review into diagnostic recovery and renewal. The NHS South West region has pioneered an independent sector and NHS partnership CDC network across the region, including 5 independent sector-led CDCs and a fleet of independent sector mobile units using a managed clinical service model approach.

Acute imaging and endoscopy capacity

The NHS is also on track to deliver its commitment to increase acute imaging and endoscopy capacity and continues to invest in improving digital diagnostic capability and strengthening the imaging and pathology networks.

In August 2023, the NHS published guidance on turnaround times for reporting of imaging services, developed in consultation with and supported by the Royal College of Radiologists and the Society of Radiographers. This was a key recommendation from the 2018 Care Quality Commission's review of NHS radiology services in England.

The NHS national diagnostic programme successfully piloted phase 1 of the general practitioner (GP) direct access programme, with a focus on increasing GP direct referral to imaging services for patients who have concerning symptoms, but do not meet the threshold for referral to a specialist or for urgent direct access testing under cancer recognition and referral guidance.

In November 2023, phase 2 was launched, which will focus on increasing direct referrals to support faster diagnosis of asthma, chronic respiratory conditions (including chronic obstructive pulmonary disease) and cardiovascular diseases.

Digital and technological transformation

The NHS is using improvements to pathways to diagnose cancers faster. As of January 2024, 77.8% of referrals for suspected lower gastro-intestinal cancers now use faecal immunochemical testing, a test that looks for microscopic amounts of blood in a stool sample and can identify patients at risk of bowel cancer, up from 22% in April 2022. This means patients at higher risk can be prioritised for endoscopies, whereas other patients can be given the all-clear without an invasive procedure.

The NHS is investing in a range of innovations to improve early diagnosis, including the cytosponge and colon capsule endoscopy trials.

Milestones

Quarter 1 2024 to 2025 (April, May and June)

Milestones include:

- Outcome and Registries Programme
  - support providers to submit high-risk medical device procedure data by barcode scanning across all specialties
  - establish clinical leadership for programme clinical steering groups
  - develop an electronic patient reported outcomes service within the Outcome Registry Platform with patient and clinician input and endorsement
  - facilitate broad patient and patient group involvement in the development of the Outcome Registry
  - Align the Acute Data Alignment Programme (ADAPt) with Outcomes and Registries Programme
- Part IX of the Drug Tariff – response to the targeted consultation expected to be released
- Design for Life – draft roadmap expected to be circulated
- Product Information Management database – alpha stage delivered with assessment
- National Equipment Tracking and Inventory System – phase 1 delivered
- value-based procurement methodology – engagement with industry and the wider health and social care system on the methodology
- Medical Technology Dynamic Purchasing System for Innovative Products – first products available for the NHS to purchase

Quarter 2 2024 to 2025 (July, August and September)

Milestones include:

- Medical Technology Dynamic Purchasing System for Innovative Products – begin phase 2 roll-out to expand medtech category scope
- Outcome and Registries Programme – develop a robotic assisted surgery registry implementation plan

Quarter 3 2024 to 2025 (October, November and December)

Milestones include:

- National Equipment Tracking and Inventory System – digital application piloting wider data sources for enhanced capability
- medical technology innovation classification framework – expected evaluation of usage
- Outcome and Registries Programme:
  - onboard all NHS and independent sector providers to the Medical Device Outcome Registry Platform
  - unification of additional 22 NHS England registries
  - run a public consultation on digital patient reported outcome measures and digital shared decision making during calendar year 2024
- late-stage assessments – publish first category recommendations

Quarter 4 2024 to 2025 (January, February and March)

Milestones include:

- Innovative Devices Access Pathway – pilot phase completed and agreement over ongoing programme
- Product Information Management database – proof of concept built and tested with selected number of users
- late-stage assessments – all NICE late-stage assessments expected to have been launched and draft publications available online

Financial year 2025 to 2026

Milestones include:

- regulation – core medical device regulatory framework including alternative routes to market expected to be in place

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