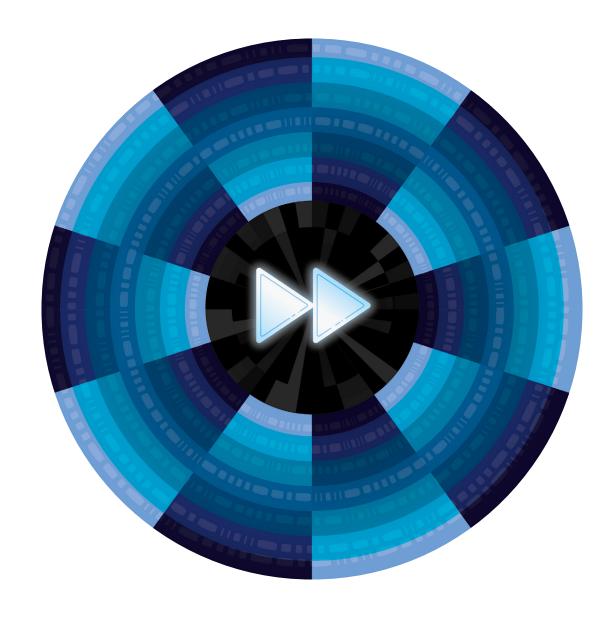
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The future unmasked

Predicting the future of healthcare and life sciences in 2025

Prediction Six

MedTech and the IoMT are crucial drivers
of value-based care

Foreword

Welcome to our sixth prediction *MedTech and the loMT are crucial drivers of value-based care* from our report, *The future unmasked: predicting the future of healthcare and life sciences in 2025*. This is the sixth of ten predictions, all of which have been informed by emerging evidence of the impact of the COVID-19 pandemic on society and the health ecosystem. They have also been shaped by our research insights including our global 2040 Future of Health campaign. This sixth prediction considers what the world in 2025 looks like for MedTech companies whose connected medical devices and advanced data collection capabilities have enabled them to become both a service and product provider.

The COVID-19 pandemic has rapidly accelerated the use of connected medical devices, especially in support of remote patient monitoring, telemedicine and connected assistance. This has enabled individuals to monitor their activities and behaviour, get an online diagnosis and manage their health more efficiently, without having to leave their homes. Telehealth has been scaled dramatically, helping HCPs to work differently and patients to access services whilst reducing the risk of infection. The IoMT has played a crucial role in track and trace to curb the spread of COVID-19. At the same time Al-enabled MRI and CT scanners and *in vitro* diagnostic tests have increased the accuracy and speed of diagnostics.

In 2025 the role of MedTech has been transformed to become a key enabler of 4P medicine. MedTech companies have partnered with consumer-focused technology companies benefiting from their experience of brand development, customer engagement and advanced analytics. Connected medical devices have helped close the loop between patients and HCPs by augmenting HCP skills. In addition, MedTech companies have a crucial role in driving value-based healthcare (VBHC), helping reduce medical costs, optimise surgical performance, and improve patient outcomes.

Our sixth prediction is brought to life through a series of portraits imagining the experience of individuals in 2025, with reference to the evidence today to predict what the future might look like tomorrow.

Stay tuned for the subsequent predictions in our series of ten.

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MedTech and the IoMT are crucial drivers of value-based care

Data from connected medical devices is enabling population health management

Prediction: In 2025, MedTech companies are actively driving the future of health, focusing on the use of transformative technology to enhance products and services and enable 4P medicine. Companies have access to sophisticated data analytics capabilities through in-house skills development and partnering, working closely with end-users and leveraging new cognitive and robotic technologies to improve outcomes. MedTech companies have also partnered with consumer-focused technology companies to benefit from their experience of brand development, customer engagement and advanced analytics. Where once MedTech companies were traditionally focused on developing hardware (surgical equipment, joint replacements, diagnostic equipment, etc.) many more now use software and sensors and deploy advanced analytics, to become Software as a Service (SaaS) providers, targeting preventative care at specific patient populations. Companion diagnostics have become a crucial tool for personalising patient therapy with MedTech playing a major role in driving VBHC, helping reduce medical costs, optimise surgical performance, and improve patient outcomes. Connected medical devices have helped close the loop between patients and HCPs by augmenting HCP skills.

The world in 2025

- Government and other funding models have expanded to provide wide-scale telehealth coverage including telemedicine and other breakthrough technologies to deliver efficiencies and proactive care.
- Most MedTech companies have robust strategies and transparent policies for generating and publishing peer-reviewed evidence on efficacy of outcomes including HTA cost-effectiveness analyses.
- Providers, clinicians and patients use connected medical devices at scale to monitor health, improve efficiency and patient outcomes. Business models use RWE from connected medical devices, to enable companies to transition from a provider of products to an insightful partner, delivering evidence-based value for stakeholders across the clinical pathway.
- Companies developing services use the generation and transmission of patient data and FAIR data sharing principles to help increase the trust of patients and confidence in using devices.
- MedTech companies have entered into long-term VBHC arrangements that differentiate products which offer protection from price erosion, create stickier relationships with customers, and increase market share and revenue by being a preferred product.
- Established collaborations between stakeholders have enabled the transmission, aggregation, analysis and management of data, improving their understanding of patient needs.
- MedTech companies have developed a better understanding of the clinical context in which their devices are used, creating VBHC solutions to deliver preventative wellness solutions.

Conquered constraints

- Skills and talent: MedTech companies recruit talent with advanced digital, cognitive and analytical skills and have established partnerships with academia, tech companies and innovative start-ups, to obtain access to data scientists and bioengineers.

 Six new MedTech roles have emerged (see figure) with leaders acquiring new skills and capabilities.
- Funding: Companies' new payment models use innovative contracting and value-based arrangements such as risk sharing. Payment pathways encourage adoption of VBHC payments at scale, as data quality has improved. Payer funding has been extended to remunerate RPM, digital therapeutics etc. using flexible models such as 'per-patient per use'. A new evaluation framework has been agreed for the reimbursement of *in vitro* diagnostics (IVD) aimed at improving health outcomes in a sustainable way.
- Regulations: Regulatory teams use a
 'Regulation by Design' approach from
 design to manufacturing to after care,
 including validated software updates.
 Companies have robust systems for
 compliance with the raft of regulatory
 changes introduced over the past five
 years, including MDR, IVDR and GDPR.
 They also collect and publish RWE on
 outcomes to satisfy safety and efficacy
 requirements and expedite approval of
 innovative medical devices.
- Data and interoperability: MedTech has adopted FAIR data principles and protocols for the exchange and use of data, a governance framework and eConsent systems. Manufacturers have adopted a 'security by design' approach (adopting key data encryption and authentication mechanisms), working with providers to manage Al-ethics, data privacy and cyber security, enabled by cloud, edge computing and blockchain technologies.

Imagine the world in 2025

The use of RWE to smooth regulatory medical device submission and expedite approval

Amen is the market access lead for a new medical device aimed at transforming the management of diabetes. In gathering the information needed for regulatory approval, he first piloted its use in a small patient pool to refine the technology and collect efficacy data. He then partnered with the university hospital and research institute to run a clinical trial. In this second phase, Amen collected efficacy and safety data from early adopters to qualify the solution for certification as a medical product. He also worked with the university to develop a health economic model to support reimbursement discussions with payers. The platform collected a large amount of RWE, increasing confidence in the validity of the results, which Amen used to start early dialogue with the regulator and payers about a reimbursement model. He decided to follow the centralised approval process which has stricter technical and efficiency criteria than local agreements; and once the the device is approved for use on a countrywide basis, it is likely to be recommended as a standard part of the diabetes care pathway with an agreed nationwide reimbursement model. This ensures patients will be able to get access to the device across the country more quickly. This is a win-win for the company, for patients and for Amen's own performance evaluation.

Recent technology developments streamlining stroke care and dramatically improving outcomes

dramatically improving outcomes Mike is at high risk of having a stroke, having had two mini strokes. Knowing that stroke was the third main cause of death and disability, he and his wife Mary had recently attended an online support group training session on recognising the signs of a stroke. Mike was in the kitchen making a cup of tea when his wife noticed he was slurring his speech and one side of his face had sagged. She knew that if this was a stroke, 'time lost was brain lost', so she called immediately for an ambulance. The ambulance call centre reviewed Mike's EHR and despatched their specialised stroke ambulance fitted with 5G-enabled video communication, monitoring and consultation technology. Mike was moved quickly into the ambulance and using a new smart camera ML-algorithm, the paramedic Alex confirmed the likelihood of a stroke. Using the video Alex shared the results and a mobile CT scan (taken in transit to the hospital) with the stroke consultant, who confirmed an ischaemic stroke (a blocked blood vessel). Under supervision, Alex, administered a clot-busting intravenous thrombolytic drug as Mike was well within the 3-4 hour window from the onset of the stroke. A cerebral angiogram at the hospital confirmed that there was no evidence of further clots stroke. Mike was discharged from hospital two days later with only minor after-effects and a set of RPM tools to support his rehabilitation.

Digital therapeutics successfully treating chronic back pain

SBTech has a reputation for its strong innovation and product development (I&PD) strategy which has helped it to develop and deliver the right products to market at the right time using agile development methodologies and advanced IT tools that support engineering and clinical development. SBTech has recently launched a new digital therapeutic solution to treat back pain which includes an Al-enabled triaging and monitoring tool, an education and training app about back pain, mindfulness practices, and a range of physiotherapy developed physical exercises. SBTech's solution was initially developed through a partnership between the company and a neighbouring Technical University to demonstrate how such a digital therapy can provide effective, cost-effective standard care for back pain. An independent review of SBTech's digital tool provided compelling evidence of improved outcomes and this led to a number of partnerships with payers to trial a way of paying for the therapy in the same way as for conventional treatments. This resulted in inclusion of the technology in the standard patient pathway. A recent randomised control trial demonstrated that SBTech's technology was more efficacious than physiotherapy and online education, the current standard of care.

Note: All elements on this page are from a perspective of 2025 and are fictional

Evidence in 2020

NICE Evidence framework for MedTech products

The UK's National Institute of Health and Care Excellence (NICE) Evidence launched a standards framework in 2019, HealthTech Connect to make it easier for innovators and commissioners to identify the evidence that should be available, or developed, for digital health technologies in order to demonstrate their value. This includes evidence of effectiveness relevant to the intended use(s) of the technology and evidence of economic impact relative to the financial risk. This initiative aims to help companies develop health technologies to identify routes to national evaluation programmes, as they seek to move from inception to adoption in the health and care system.^{71,72}

Digital therapeutics for the treatment of Substance Abuse in the US

Pear Therapeutics is a leading prescription digital therapeutics (PDTs) company with the first three FDA-authorised PDTs. Pear's products are clinically validated software-based therapeutics that directly treat diseases. Its lead product, reSET®, treats Substance Use Disorder (SUD), the first PDT to receive FDA marketing authorisation to treat SUD. It's second, reSET-O®, for the treatment of Opioid Use Disorder, was the first PDT to receive Breakthrough Designation. Pear's third product, Somryst™, for the treatment of chronic insomnia, was the first PDT submitted through FDA's traditional 510(k) pathway while simultaneously reviewed through FDA's Software Precertification Pilot Program. Its products collect RWE, have been tested in RCTs with results published in peer-reviewed journals. The products, are adjuncts to outpatient counselling, providing patients with algorithm-driven CBT, fluency training, and contingency management, while clinicians receive access to clinical dashboards to inform in-office and tele visits.73,74

Launch of a Digital Health Centre of Excellence by the FDA to advance digital health technology

In September 2020, the FDA announced the launch of the Digital Health Centre of Excellence within the Centre for Devices and Radiological Health (CDHR). Its aim is to boost the advancement of mobile devices, software-as-medical-device (SaMD), wearables when used as a medical device, and other technologies. The Centre is responsible for providing advice and coordinating and supporting the work being done across the FDA in advancing best practices and reimagining digital health device oversight. Through the Center, the FDA intends to modernise digital health policies and regulatory approaches to ensure access to 'the most cutting edge, digital technologies are rapidly developed and reviewed'.75

Deloitte crowdsourcing simulation with MedTech stakeholders

Deloitte conducted a crowdsourcing simulation, to understand what the MedTech company of the future might look like. It found that companies that traditionally focused on developing hardware (e.g. surgical equipment, joint replacements, diagnostic equipment, infusion pumps, pacemakers, etc.) are shifting their focus to software, data collection, and advanced data analytics. MedTech companies that focus on developing acquiring or partnering to access sophisticated data analytics capabilities can better address changing patient and clinician needs. The top technologies cited were Al (80%), robotics (53%) and nanotechnology (47%). The research noted that the MedTech company of the future will face intense competition from consumer technology companies. Beyond product offerings, MedTech companies are also positioned to help hospitals and health systems make the transition to the future of health through services.76

Evidence of new payment models in MedTech

Medtronic-Tyrx antibacterial sleeve has 1,000 contracts that require the company to reimburse hospitals for certain costs if its antibacterial sleeve fails to prevent infection in patients receiving cardiac implants.

J&Js has developed a Thermocool' catheter ablation procedure whereby if a repeat procedure is needed within a year of treatment the company guarantees a discount on the cost of its device for the second procedure.

Bruin Biometrics has developed a hand-held wireless scanner that detects pressure ulcers (bed sores) and helps caregivers or providers prevent the formation of pressure ulcers. The company has been developing a variety of risk sharing agreements with providers in the UK which may involve payment tied to early detection and prevention of ulcers.

Philips and the Jackson Health System have entered into an 11-year enterprise-monitoring-as-a-service (EMaaS) partnership. Under the terms of the agreement, Jackson Health will use remote patient monitoring systems, such as wearable biosensors, for a per-patient fee and adopt standardised patient monitoring for each care setting across its network. Philips own the hardware, software, and networking solutions to patient monitoring technologies, Jackson pays only for hours of monitoring usage.⁷⁷

The COVID-19 impact

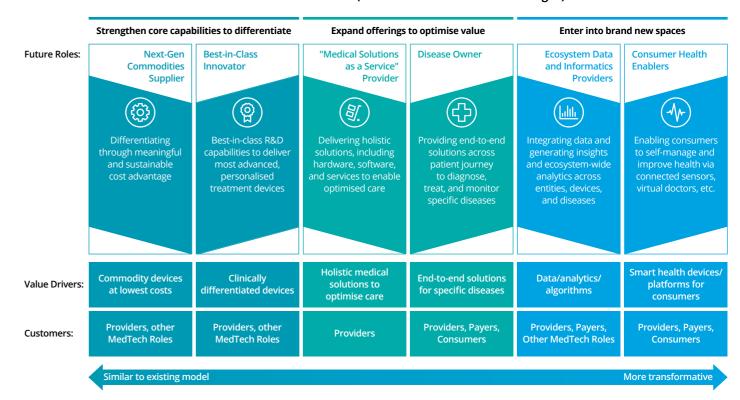
Deloitte view on the impact of COVID-19

The COVID-19 pandemic has accelerated the use of MedTech devices enabling individuals to record their behaviour, get an online diagnosis and manage their health more efficiently, without having to leave their homes. Virtual consultation technologies have been scaled dramatically to help HCPs diagnose, monitor and care for patients remotely while reducing the risk of infection. Wearable technology has magnified the added value provided by IoMT technology, giving patients, carers and HCPs with numerous real-time data points about the patient's activity and vital signs. The IoMT has also played a crucial role in 'test, track and trace' to curb the spread of COVID-19 by creating a virtual perimeter using GPS, RFID, Wi-Fi, Bluetooth signal, and cellular network. Al-enabled MRI and CT scanners and IVD tests have also increased the accuracy and speed of diagnoses. The pandemic has highlighted the importance of large-scale partnerships to mobilise and coordinate public and private efforts to tackle global public health threats.

Philips' IoMT solution for critical care patient monitoring

Philips has a comprehensive portfolio of solutions to help support the care of COVID-19 patients. Solutions include secure, connected and intelligent approaches to diagnosis, treatment and predictive monitoring in hospitals, plus screening, RPM and care at home. Philips' telehealth and Al-enabled data analytics help support HCP's workflows, facilitate remote collaboration and help optimise the use of resources, being designed for rapid deployment and scalability. In June 2020, Philips received Emergency Use Authorisation (EUA) from the FDA for it's IntelliVue Patient Monitors and Active Displays, for use during the COVID-19 health emergency. These solutions support infection-control protocols and provide critical patient information remotely when caring for hospitalised COVID-19 patients. Updated features, include enhancements to monitor and assess clinical and network device performance, and additional functionalities to strengthen cybersecurity.78

MedTech and the IoMT are crucial drivers of value-based care (six new MedTech roles have emerged)



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