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Medtech and the Internet of Medical Things

How connected medical devices are transforming health care

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Deloitte Centre *for*
Health Solutions

Contents

Foreword

Welcome to the Deloitte Centre for Health Solutions' report *Medtech and the Internet of Medical Things: How connected medical devices are transforming health care.*

Patient interactions with the health care system often involve interactions with equipment and devices – from syringes and bandages, blood pressure monitors and pregnancy testing kits, to surgical instruments, pacemakers, artificial joints, and MRI and CT scanners. The medical technology (medtech) industry designs and manufactures a wide range of products to diagnose, monitor, and treat patients and is instrumental in helping health care organisations achieve better patient outcomes, lower health care costs, improved efficiency and new ways of engaging and empowering patients.

Major advances in wireless technology, miniaturisation and computing power are driving innovation in medtech, leading to the development of an increasing number of connected medical devices that are able to generate, collect, analyse and transmit data. The data, along with the devices themselves, are creating the Internet of Medical Things (IoMT) – a connected infrastructure of medical devices, software applications and health systems and services. The IoMT is rapidly transforming medtech's role and relationships within health care. More specifically, connectivity between sensors and devices is enabling health care organisations to streamline their clinical operations and workflow management, and improve patient care, even from remote locations. Provided medtech companies can convince clinicians and patients of the value and benefits of connected medical devices, the pace and scale of health care transformation will be exponential.

New regulations, digitisation, data analytics, artificial intelligence, automation and the development of value-based health care represent some of the numerous challenges as well as opportunities facing the medtech industry. Consequently, medtech companies from start-ups to corporates are reinventing themselves to remain competitive. New strategies are needed to harness data provided by digitally-enabled products and make their business and operating models relevant and sustainable. This will help companies develop evidence of better health outcomes at reasonable cost to obtain price reimbursement and gain market access. For some medtech companies this means shifting from a product-based model to a value-based system driven by software-based services and solutions.

Connected medical devices will have a profound impact on patients, clinicians and the life sciences industry. Our report focuses on how the IoMT is transforming medtech's role in health care and the impact of the increased use of connected medical devices on medtech companies' business and operating models. It outlines how medtech companies can get digital transformation right – whether through adapting their existing business models, inventing new ones or both. The industry's future will depend on its ability to demonstrate to providers and payers how connected medical devices contribute to the new value-based paradigm.

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Executive summary

A series of technological and cultural revolutions are allowing technology and people to be better connected to one another, leading to the development of the Internet of Things (IoT) – a network of connected, smart devices and objects that can communicate with each other and automate key tasks.

Medical technology (medtech) companies manufacture more than 500,000 different types of medical devices, including wearable external medical devices (skin patches, insulin pumps and blood glucose monitors), implanted medical devices (pacemakers and implantable cardioverter defibrillator devices) and stationary medical devices (home monitoring devices, connected imaging devices and scanning machines). Most patient interactions with the health care system involve the use of medical equipment and devices.

Like most other industries, the health care sector is increasingly realising the transformative nature of IoT technologies, as advances in computing and processing power, wireless technology and miniaturisation drive innovation in connected medical device development. Connectivity enhancement can be applied to most categories of medical devices. The rise in the numbers of connected medical devices, together with advances in the systems and software that support the capture and transmission of medical grade data, connectivity technologies and services, have created the Internet of Medical Things (IoMT).

The IoMT brings together the digital and physical worlds to improve the speed and accuracy of diagnosis and treatments, and monitor and modify patient behaviour and health status in real time. It also improves health care organisations' operational productivity and effectiveness by streamlining clinical processes, information and work flows.

Connectivity between sensors and devices aids real-time patient care, even from remote locations, while improving communication within and between medical facilities. The large volume of data generated creates opportunities for new models of care and supports the delivery of 4P medicine – medicine that is predictive, preventive, personalised and participatory.

The IoMT brings together people (patients, caregivers and clinicians), data (patient or performance data), processes (care delivery and patient support) and enablers (connected medical devices and mobile applications) to deliver improved patient outcomes efficiently.

While the IoMT has the potential to help alleviate some of the cost, access and care coordination challenges facing health care, the generation of data points through millions of connected medical devices will have little impact unless data can be turned into actionable insight.

More specifically, connected medical devices are a key enabler across the six predictions in our report *The future awakens: Life sciences and health care predictions 2022.* The extent to which the predictions are realised is heavily dependent on the continued innovation and adoption of connected medical devices at scale.

MarketsandMarkets valued the IoMT market at $41.2 billion in 2017 and expects it to rise to $158.1 billion in 2022. The connected medical devices segment (helping to diagnose, monitor and treat patients) of the IoMT is expected to rise from $14.9 billion in 2017 to $52.2 billion by 2022.

The rise of the IoMT comes at a time when health care is becoming increasingly expensive, with global health care spending expected to grow 4.2 per cent per year, from $7.1 trillion in 2015 to $8.7 trillion by 2020, largely due to a growing and ageing population, with more people living longer but with multiple comorbidities. As a result, without radical transformation, health care in many countries risks becoming increasingly unaffordable.

The medtech industry has an important role to play in helping to reduce costs, improve the quality and efficiency of care and support the shift to value-based care (VBC). However, the industry also faces a number of systemic challenges and opportunities that need to be addressed for the full value of the IoMT to be realised. These include:

- **Developing an in-depth understanding of end users** – as more providers adopt VBC models, the speed of adoption and integration of connected medical devices will increase. Data and insights on patients and processes is key to VBC. Challenges include the extent to which an organisation's IT infrastructure is able to handle or process the connections and data, and whether clinicians and patients can be convinced of the safety and effectiveness of the devices. Medtech companies need

to develop a deep understanding of the end-user and create business models and scenarios that demonstrate how their new and existing devices not only improve patient outcomes but also create value for key health care stakeholders.

- **Developing new funding, business and operating models** – as health care organisations focus more on improving quality and reducing the costs of providing care, they require medtech companies to demonstrate greater evidence on the added value of both new and enhanced products. We commissioned a survey that found that medtech companies are having mixed results in demonstrating the value of their connected medical devices, although some are engaged in providing services rather than just products. Different types of innovation will require different business models, and progress will depend on both the innovators themselves working in new ways to take on risks and rewards, and the evolution of existing payment systems by both public and private payers.

- **Understanding interoperability requirements** – interoperability is arguably the biggest challenge for medtech, including complying with various national and international standards and protocols around the exchange and use of data. There are also technical challenges such as creating an integrated governance framework and obtaining consent for access to health care data. For interoperability to work effectively, the direction of travel should be towards open platforms, based on open data standards. This will enable payers, providers and technology vendors to come together to make data more available to each another.

- **Maintaining cybersecurity** – cybersecurity issues are pervasive across medtech, as the increasing numbers and capability of connected medical devices present additional risks for data security. The scale and cost of breaches is often significant and far reaching. Although four-fifths of our survey respondents considered they were reasonably well prepared to deal with the cybersecurity of their devices, other research suggests many stakeholders do not have a strong understanding of such risks, how to prevent them and what to do once a risk has been identified. Regulators acknowledge that cybersecurity threats cannot be completely eliminated, and stakeholders need to work together and adopt a more proactive approach to managing risks. Medtech companies need to adopt a 'security by design' approach and establish real-time monitoring, cyber threat modeling and analysis, threat mitigation and remediation.

- **Successfully navigating regulatory change** – managing the raft of regulatory change occurring, particularly in relation to the new European and US regulations is imperative for both developing connected medical devices and the success of the IoMT. Managing the impact of regulatory change requires medtech companies to take a proactive and well-planned approach. If an innovation model is to be sustained, companies need to build engagement with regulators into their innovation model and involve clinicians and patients in product design.

- **Attracting digital talent and building digital capability** – there is increasing concern among key stakeholders that a growing skills gap will delay the deployment of IoMT solutions and constrain market growth. If medtech companies are to remain competitive they need to develop a new, digital-first skill set, including employing data scientists and multidisciplinary talent from creative and scientific backgrounds. Accessing this talent will require more resourceful recruitment and retention strategies, including collaborations and partnerships with a diverse range of existing and emerging players, especially academia, data-first tech companies and innovative new start-ups.

- **Maintaining trust in a digital age** – global technology companies and other new entrants into the health care ecosystem are becoming more involved in the connected medical device industry, and traditional medical device companies are becoming more involved in data management and analytics. Consequently, as medtech companies develop strategies and services based on the generation and transmission of patient data, they need to ensure they demonstrate clearly to patients, the public and health care professionals that the data are being protected and used responsibly. Medtech companies need to develop key principles of data management and consent that give patients control over their own data, including the right not to share.

- **Improving the adoption of medical technology at scale** – a key challenge for medtech is ensuring that health care organisations, clinicians and patients understand the added-value of connected medical devices and use them at scale to drive better economics and patient outcomes. Difficulties include the lack of governance standards and sufficient, robust evidence that demonstrate that connected medical devices are more cost-effective, and how they can help drive the VBC agenda. This includes ensuring that the devices are intuitive and easy to use and, where necessary, providing training and support to staff to embed the skills needed to optimise the use of the technology.

Creating an effective IoMT at scale requires collaboration and partnership working between patients, providers, payers, pharma, academia and other medtech manufacturers. Our research identified multiple case studies that demonstrate medtech's important role in the IoMT and the conditions that lead to the adoption of connected products and services. The key enablers driving the IoMT and the transformation of health care include:

- **Collaboration between health care providers and medtech is key to the effective deployment of the IoMT** – integrating connected medical devices into established care pathways is challenging and requires significant cooperation across the IoMT ecosystem. Collaboration strategies such as partnerships and joint ventures help ensure the effective transmission, aggregation, analysis and management of data from connected devices. These collaborations allow all stakeholders to improve their understanding of patient needs and deliver more proactive cost-effective care. Our survey respondents ranked collaborations with health care providers as the most important for the development of their respective businesses models, followed by collaborations with health care payers and other medtech companies.

- **Connected medical devices benefit patients, providers and payers** – partnerships with health care providers allow medtech companies to understand the clinical context in which devices are used. Medical devices are almost always designed for a specific application. Adding connectivity to a device allows data to be generated on a patient's condition and the effectiveness of the health care providers operations. Being able to quantify, contextualise and communicate these interactions allows the medtech industry to provide solutions that deliver value to all health care stakeholders.

- **Joining the dots between connected medical devices and health care IT systems** – a number of large medtech companies have developed connected ecosystems that act as a common platform to share, aggregate, and view data to drive both clinical and operational value. Linking disparate sets of data that sit within health care organisations is central to achieving connectivity at scale.

- **Applying advanced analytics to the data generated from connected medical devices to provide critical insights and empower better decision-making** – mining, managing and analysing a vast array of data from medical grade wearables, connected imaging devices and monitoring devices is a key part of deriving value from the IoMT. The insights generated by linking connected medical device and health data sets can play a key role in aiding health systems to reduce costs and improve quality, identify populations at risk, connect with consumers and better understand performance.

- **Medtech services that demonstrate improvements in patient outcomes and reduce health care costs** – medtech companies are utilising the increasing sophistication of connected medical devices, improved interoperability across health care organisations and advances in analytics to develop service orientated solutions that provide the tenants of VBC. These services include managed catheterisation laboratories and transformations from a product manufacturer to a health care provider helping improve patient outcomes and reducing the costs of health care.

How will the IoMT evolve to impact care?
The health care and life sciences industries are in transition from reactive and largely episodic models of care that are proving increasingly costly and inefficient to operate, to care models that are proactive, digitally-enabled and deliver better value for patients. Medtech companies and the IoMT can capitalise on the possibilities presented by these changes to help to connect patients, providers and payers and enable them all to become more patient centric, productive and cost effective.

These disruptive technologies are changing ways of working across the whole IoMT ecosystem. Big data, AI, mobile applications, 3D printing, advanced sensors and other technologies will continue to create new opportunities for medtech companies. Voice technology is being adopted faster than any previous technology from chatbots to doctor visits, to home health care. At the same time, large technology companies are using their vast reach and expertise to create an interoperable electronic health record that can integrate data from a variety of sources and enable real-time access. Although robotics and automation will inevitably replace some jobs, they will also add new ones that blend employee skill sets and the development of transferable skills.

A growing number of medtech companies are capitalising on the above trends to develop service-orientated solutions that support VBC. Often these services align closely with the therapeutic expertise and specialised products of the organisation enabling medtech to maintain high quality patient outcomes while reducing costs compared to similar services run by traditional health care providers.

Other companies are utilising IoMT capabilities to aggregate data and offer consultative services and predictive analytics, including opening up health data to organisations that have typically found it difficult to gain access to data outside of their own organisation. These and other developments provide clear opportunities for medtech to transition from a provider of innovative products to an insightful partner in health care (see Figure below).
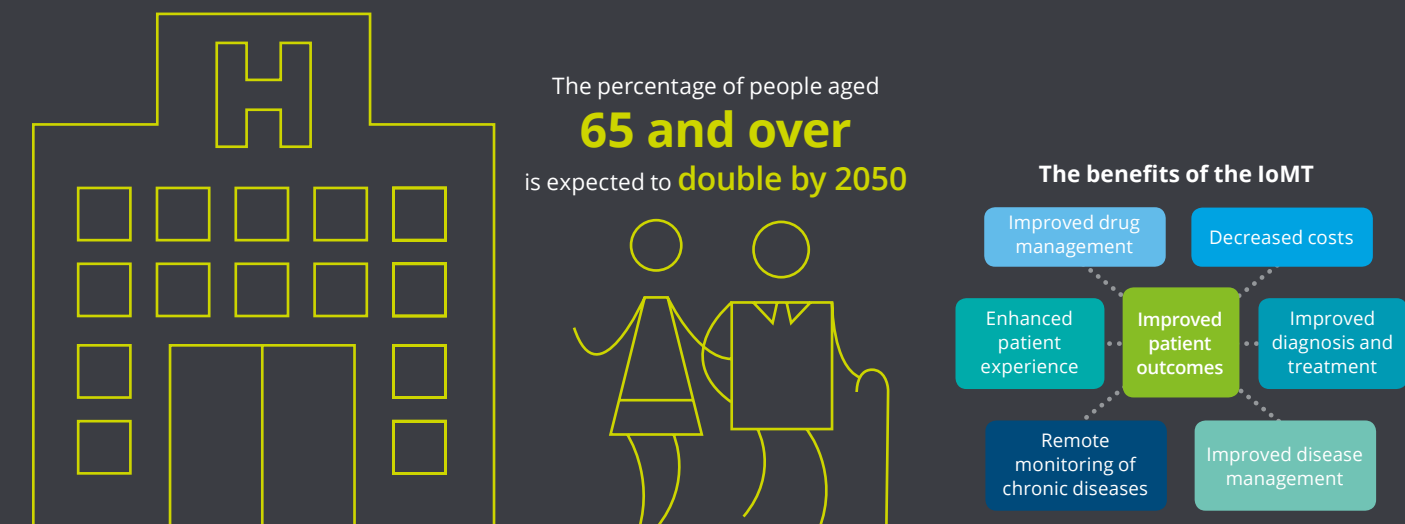
Connected medical devices are helping medtech companies move from innovative product suppliers to insightful partners in health care

Medtech as an innovative product supplier		
Clinical advantage	**Broader value creation**	**Operating leverage**
Can meaningful clinical advantage be demonstrated?	Can differential value be created for the system?	Can innovation be adopted at scale?

Key capabilities required

Deep understanding of care delivery models and how care is delivered across patient populations; and developing rules and capability around patient consent	Outcomes measurement and end-to-end evidence including partnerships for data creation, capture sharing and analytics to enable real-world evidence-based approaches to improve care delivery	Stakeholder engagement, collaboration and partnerships to understand the needs of patients, providers and payers in order to generate the next generation of innovation
Contracting and payment models that take in to account the value added from clinical innovation	Complementary services and solutions that enhance product offerings and support patients' and providers	Product innovation based on real-world evidence on patient outcomes and build engagement with regulators into innovation models

Company transition

Medtech as an insightful partner for patients and health care, rewarded for improving health care performance
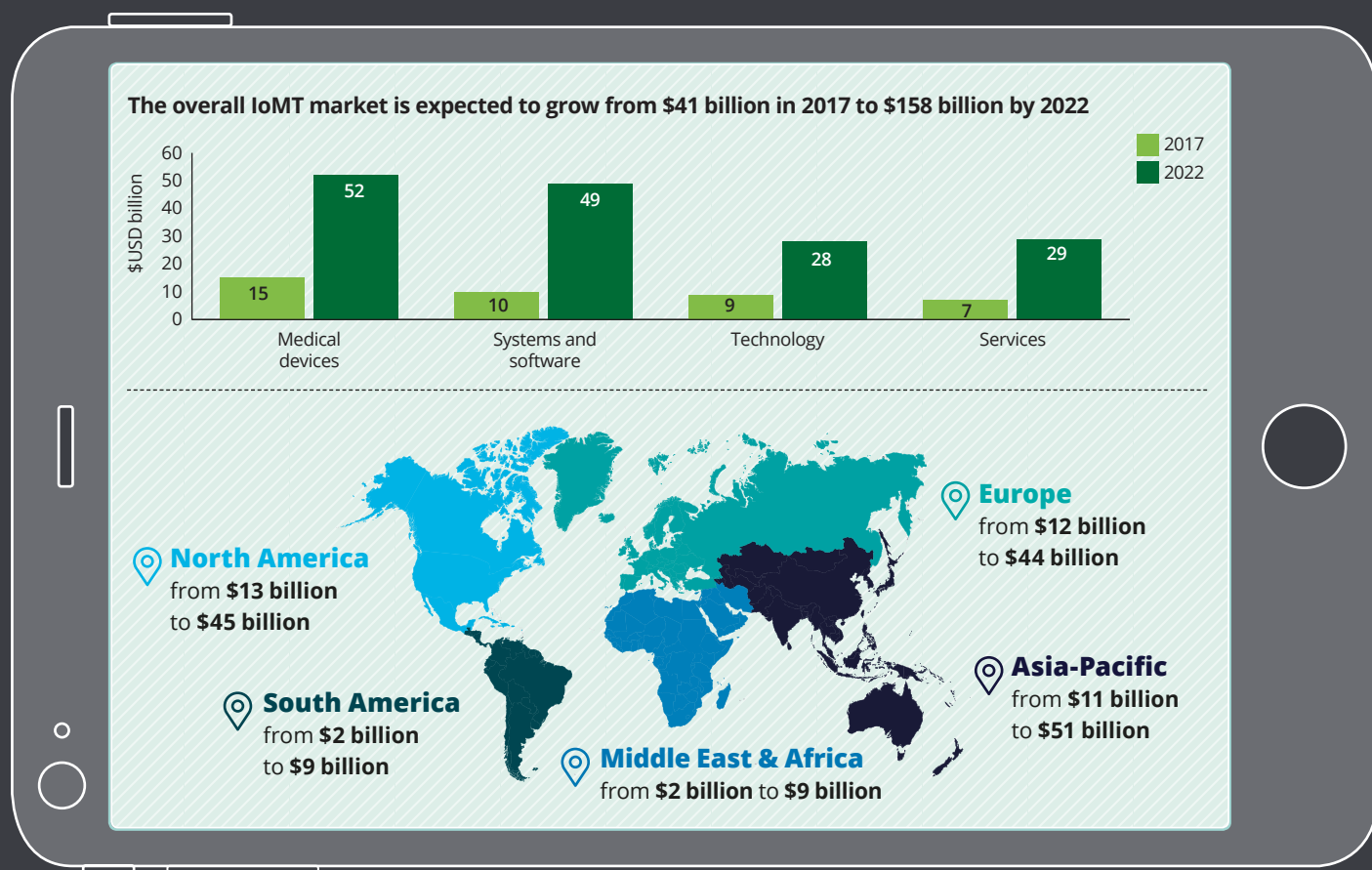
Health care is facing numerous challenges

Global healthcare spending is expected to grow from
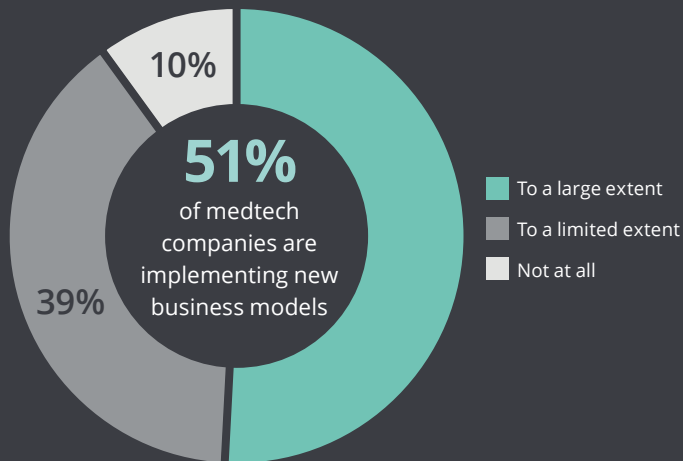**$7.1** trillion in 2015 to **$8.7** trillion by 2020

The percentage of people aged
65 and over
is expected to **double by 2050**

The benefits of the IoMT

Improved drug management

Decreased costs

Enhanced patient experience

Improved patient outcomes

Improved diagnosis and treatment

Remote monitoring of chronic diseases

Improved disease management

Significant IoMT market growth predicted

The overall IoMT market is expected to grow from $41 billion in 2017 to $158 billion by 2022

Legend:
2017
2022

$USD billion

Category	2017	2022
Medical devices	15	52
Systems and software	10	49
Technology	9	28
Services	7	29

North America
from **$13 billion**
to **$45 billion**

South America
from **$2 billion**
to **$9 billion**

Middle East & Africa
from **$2 billion to $9 billion**

Europe
from **$12 billion**
to **$44 billion**

**Asia-Pacific**
from **$11 billion**
to **$51 billion**

Is medtech ready for the IoMT?

...our survey of 237 respondents working in medtech companies developing connected medical devices revealed that:

51%
of medtech companies are implementing new business models

10%

39%

- To a large extent
- To a limited extent
- Not at all

71%
believe that health care providers and clinicians are not ready to utilise data generated from connected medical devices.

67%
believe that the regulatory framework will not catch up with what is possible today for another 5 years.
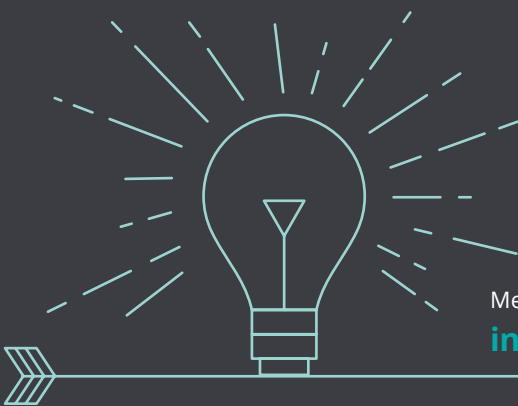
Medtech is transforming from an
innovative product supplier...

31%
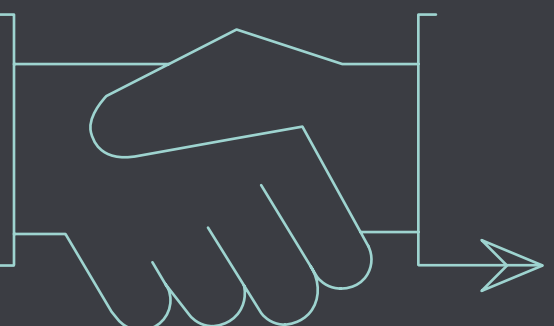are implementing new funding models for data as a service to a large extent

39%
are adopting a value-based approach to pricing to a large extent

43%
are using Real World Evidence to drive business decisions to a large extent

... to an insightful partner
for patients and health care, rewarded for improving health care performance

The above percentages are taken from our survey of 237 respondents from connected medical device companies
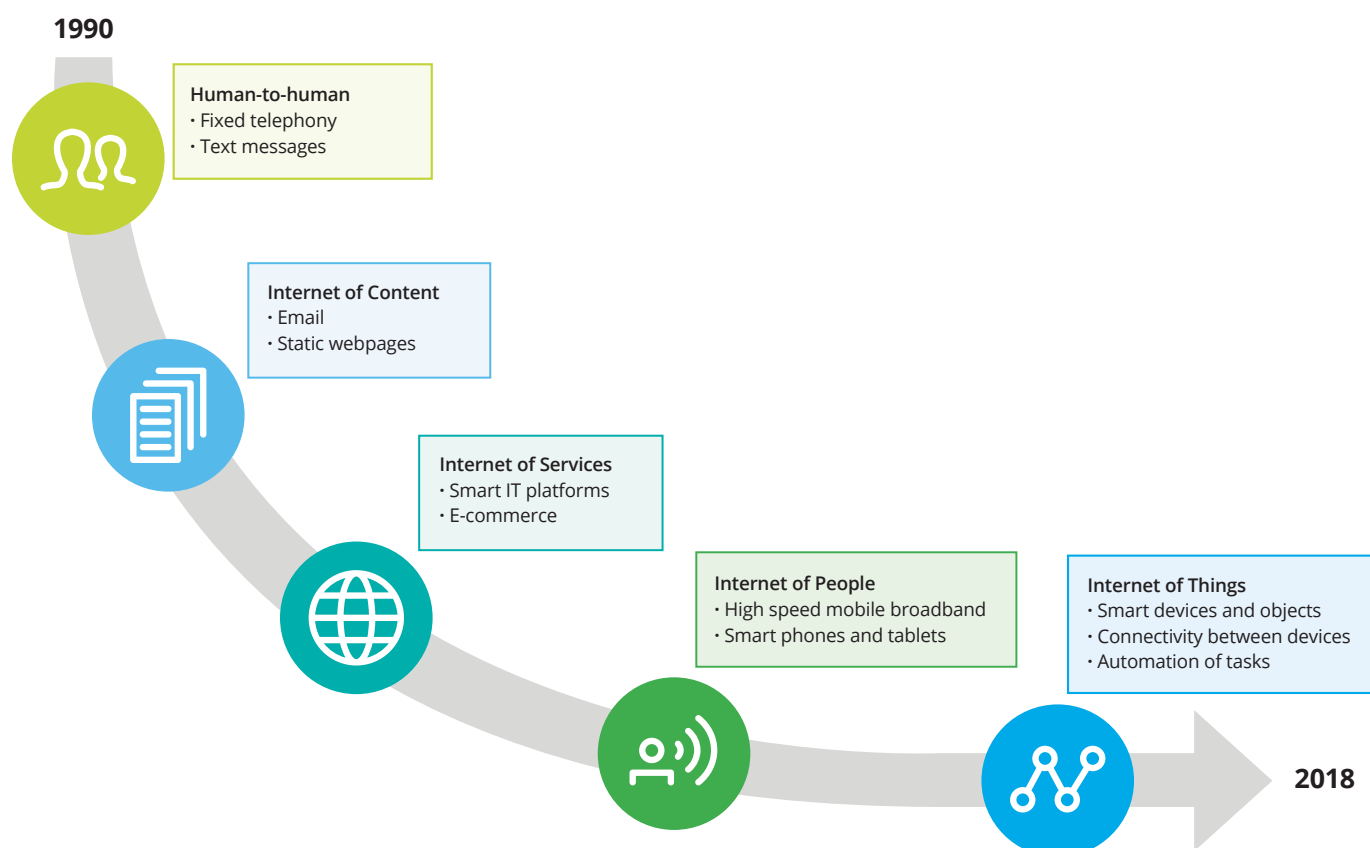
Part 1. Connectivity is transforming the medtech industry

A series of technological and cultural revolutions are allowing technology and people to be better connected to one another, leading to the development of a network of connected, smart devices and objects that can communicate with each other and automate key tasks. This is known as the Internet of Things (IoT).

These revolutions began with the invention of the internet and have shaped technology and society for the past 30 years (see Figure 1). IoT technologies are increasingly benefiting the health care sector, as advances in computing power, wireless technology and miniaturisation are driving innovation in connected medical device development.

The large volume of data created, along with the devices themselves, IT systems and software, connectivity technologies and services, are combining to create the Internet of Medical Things (IoMT).

Figure 1: Technological and cultural changes enabling the development of the Internet of Things

1990

Human-to-human
· Fixed telephony
· Text messages

Internet of Content
· Email
· Static webpages

Internet of Services
· Smart IT platforms
· E-commerce

Internet of People
· High speed mobile broadband
· Smart phones and tablets

Internet of Things
· Smart devices and objects
· Connectivity between devices
· Automation of tasks

2018

Source: Deloitte LLP, 2018

The development of connected medical devices

The medical technology (medtech) industry designs and manufactures a wide range of medical products that help to diagnose, monitor, and treat diseases and health conditions. There are more than 500,000 medical technologies currently available, which all share a common purpose – having a beneficial impact on people's health and quality of life.

Medical devices fall within 21 categories of medtech products, as determined by the Global Medical Devices Nomenclature (GMDN) Agency (see Appendix).[1] They represent a hugely varied product group, ranging from simple, disposable supplies such as plasters and syringes, through to surgical implements, monitoring devices and imaging machines. They also include medical laboratory diagnostic instruments and test kits, patient management software, and software that is used as a component in a medical device.

IoT technologies are increasingly benefiting the health care sector, as advances in computing power, wireless technology and miniaturisation drive innovation and the development of connected medical devices. Connectivity enhancement can apply across all 21 categories of medical devices.

The creation of the IoMT ecosystem

The rise of the IoMT is being fueled by an increase in the number of connected medical devices that are able to generate, collect, analyse or transmit health data or images and connect to health care provider networks, transmitting data to either a cloud repository or internal servers. Figure 2 shows the main stakeholders in the IoMT ecosystem.
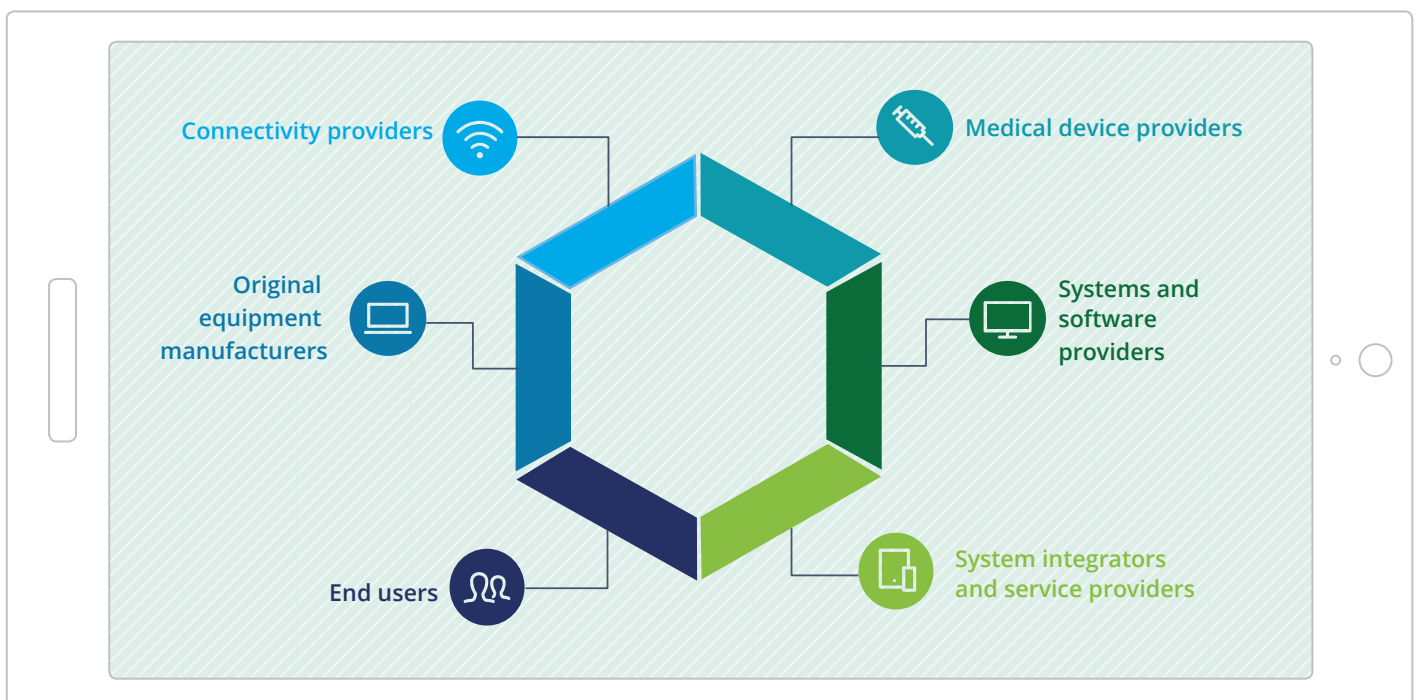
The medical technology (medtech) industry designs and manufactures a wide range of medical products that help to diagnose, monitor, and treat diseases and health conditions.

Figure 2: The IoMT ecosystem

Source: MarketsandMarkets, 2017

The IoMT bridges both the digital and physical worlds and can monitor and modify patient behaviour in real time to manage chronic conditions such as asthma, diabetes and high blood pressure. IoMT technology can also streamline various clinical processes and information flows and bring together people (patients, caregivers, and clinicians), data (patient or performance data), processes (care delivery and monitoring) and enablers (medical devices and mobile applications) to improve health care delivery.

Importantly, the IoMT generates intelligent and measurable information to help improve the speed and accuracy of diagnostics and target treatments more efficiently and effectively. It enables remote clinical monitoring, chronic disease and medication management and preventive care, and it supports people who require assistance with daily living, like the elderly and disabled, to live independent lives for as long as possible. It also has the potential to lower costs, improve efficiency and deliver better patient outcomes (see Figure 3).

The methodology for this report

The methodology for this report includes a detailed literature review, market insights provided by research companies Yole Développement and MarketsandMarkets, an online survey conducted by Research2Guidance, structured interviews with senior executives from a number of large medtech companies and insights provided by Deloitte colleagues working across the medtech and health care industries.
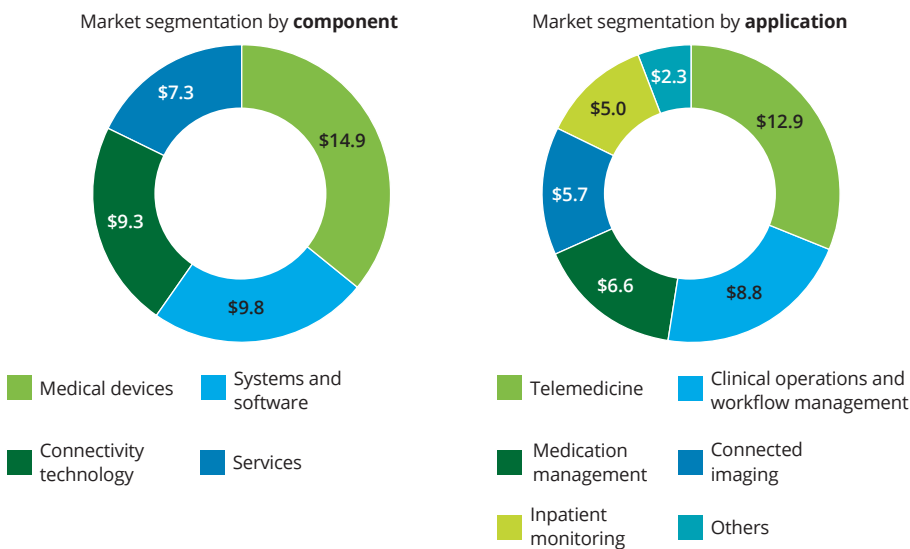
The growth of the IoMT market

The IoMT market, which can be viewed through either a component or an application lens (see Figure 4), is expected to grow at a compound annual growth rate (CAGR) of 30.8 per cent, from $41.2 billion in 2017 to $158.1 billion by 2022.[2] This growth is due to the rapid digitisation of health care systems to aid efficient patient care, the rise in the demand for mobile health care technologies and an increase in demand from an ageing population and people suffering from chronic diseases.

In 2017, North America accounted for the largest share of the IoMT market ($13.3 billion or 33 per cent of the total market) followed by Europe ($12.4 billion), Asia-Pacific ($11.0 billion), the Middle East and Africa ($2.4 billion) and South America ($2.1 billion). The IoMT market in Asia-Pacific is projected to grow at the highest rate, at a CAGR of 34.3 per cent during the forecast period, due largely to the level of unmet need and the increasing number of hospitals and surgical centres being built in this region.[3]

Figure 3: The seven main ways the IoMT impacts health care
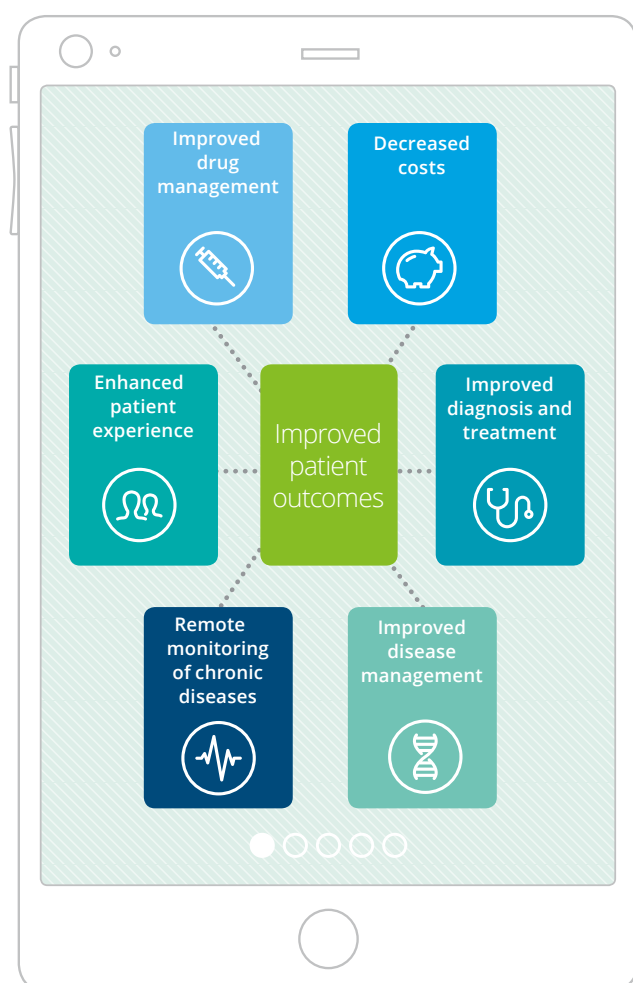
Source: Adapted from The Internet-of-Things: A revolutionary tool for the health care industry, Inside Magazine, Deloitte LLP, 2017

Figure 4: IoMT market segmentation by component and application, 2017 ($ billion)

Market segmentation by **component**

- Medical devices
- Systems and software
- Connectivity technology
- Services

Market segmentation by **application**

- Telemedicine
- Clinical operations and workflow management
- Medication management
- Connected imaging
- Inpatient monitoring
- Others

Source: MarketsandMarkets, 2017

The increasing numbers of connected medical devices and rising adoption of smartphones are expected to fuel the growth of the market still further.

The market for connected medical devices

The ability of the IoMT to help reduce the cost of care while improving its effectiveness is driven by the evolution of artificial intelligence (AI), particularly the rise of machine learning technologies. Increasing investment for health care IoMT solutions are driving market growth. The increasing numbers of connected medical devices and rising adoption of smartphones are expected to fuel the growth of the market still further. Potential constraints to this estimated growth include the extent to which health care organisations, clinicians and patients are willing to deploy IoMT solutions and a lack of governance standards.

Estimates of the size of the current and forecast market value for connected medical devices vary significantly depending on the criteria used. For the purposes of this report we use estimates from market research firm MarketsandMarkets. They categorise connected medical devices into three groups:

- **stationary medical devices** – include X-ray and mammography devices, CT and MRI scanners, ultrasound machines and nuclear imaging devices that measure physiological parameters. These relatively high capital cost, high-tech devices, which transmit images wirelessly to clinicians, are generally deployed by hospitals, clinics and diagnostics centres with the images incorporated into the patient's Electronic Health Record (EHR). In vitro diagnostic devices (IVD) are also included in this category. Stationary medical devices are critical to diagnosis and increasingly are integrated with other health care applications to overlay patient data and imaging to facilitate faster and more precise decision-making

- **implanted medical devices** – include hip replacements, pacemakers and defibrillators that monitor and treat cardiac conditions, nerve stimulators, bladder stimulators, diaphragm stimulators and a variety of biosensors to process different signals. Patients who require constant monitoring often receive implanted medical devices, which are intended to remain in the human body and are implanted following surgical or medical intervention, or are clinically inserted into a natural orifice

- **wearable external medical devices** – include insulin pumps for diabetes monitoring, skin patches, cardioverter-defibrillators and other devices, including smartwatches and activity trackers that produce data that are monitored by clinicians. Wearable external medical devices are used to monitor patients while in hospital and post-discharge, as well as on-going monitoring of patients with chronic conditions or frailty. Wearables used only for fitness tracking or self-monitoring are not included.

The market for these connected medical devices was $14.9 billion in 2017 and is expected to increase to $52.2 billion in 2022 (see Figure 5).[4]
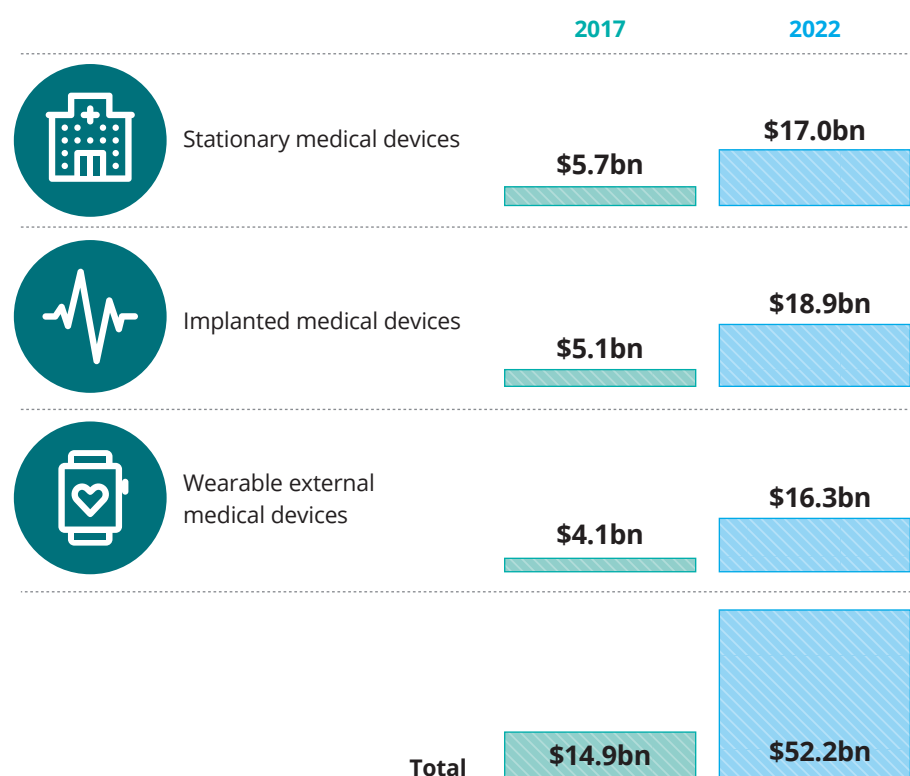
The remaining components of the IoMT ecosystem

The other three key components of the IoMT ecosystem are:

- **systems and software** – IoMT systems and software primarily focus on reducing the delivery time and cost of projects through device management and integration, information security, data collection and data analytics. Systems and software include remote device management, network bandwidth management, data analytics, applications security and network security solutions. The market for systems and software was $9.8 billion in 2017 and is expected to increase to $48.3 billion in 2022

- **connectivity technology** – connectivity technologies are the enablers of the IoMT ecosystem, connecting people and devices to the internet. Wireless technologies such as Wi-Fi, Bluetooth low energy (BLE), near field communication (NFC), Zigbee, cellular and satellite technologies are primarily used in health care. Factors that facilitate seamless wireless connections are interoperability between wireless standards, low energy consumption, and range extension. The market for connectivity technology was $9.3 billion in 2017 and is expected to increase to $28 billion in 2022

- **services** – IoMT services include system integration services, professional services and support and maintenance services. Service providers are providing personalised and optimised services that offer predictable and better business outcomes for health care organisations, which allow these organisations to manage the entire life cycle of the IoMT in health care solutions. The market for services was $7.3 billion in 2017 and is expected to increase to $29 billion in 2022.

Figure 5: The market for connected medical devices is predicted to grow from $14.9 billion in 2017 to $52.2 billion in 2022

	2017	2022
Stationary medical devices	$5.7bn	$17.0bn
Implanted medical devices	$5.1bn	$18.9bn
Wearable external medical devices	$4.1bn	$16.3bn
Total	$14.9bn	$52.2bn

Source: MarketsandMarkets, 2017

How medtech can help health care organisations tackle current health care challenges

Health care is increasingly expensive, with global health care spending expected to grow 4.2 per cent per year, from $7.1 trillion in 2015 to $8.7 trillion by 2020.[5] Among G7 countries, expenditure on health care as a percentage of gross domestic product (GDP) increased from 10.8 per cent in 2010 to 11.4 per cent in 2016.[6] Indeed, health care in many countries risks becoming unaffordable, as governments and other payers find their budgets increasingly constrained at a time when the challenges they face are growing significantly, driven by:

• unrelenting demand pressures from a growing and ageing population – 8.5 per cent of the global population (617 million people) are aged 65 and over, with the total expected to double by 2050 to 1.6 billion people[7]

• increasing public expectations for more personalised, equitable and convenient services

• advances in new treatments and technologies – prescription drug sales are expected to rise by 5.5 per cent a year (2016-2022) to $1.06 trillion by 2022,[8] while medtech sales are expected to increase by 5.1 per cent a year (2016-2022) to $522 billion by 2022[9]

• a mismatch between the demand for and supply of adequate numbers and types of staff – staff are the largest cost driver of health care, accounting for between 60 and 70 per cent of health care running costs.[10]

The medtech industry is well placed to help alleviate some of the cost, access and care coordination challenges facing health care. Medical devices can help staff to work more effectively and productively (e.g. using connectivity to track equipment patient and staff workflow), improve access to and speed of diagnosis (e.g. advanced point of care diagnostics), deliver more targeted precision treatments, improve medication adherence (e.g. apps, smart pills and pill boxes) and support virtual patient monitoring (e.g. sensors placed under the patient's mattress or within a chair and patches that continuously measure vital signs). IoMT solutions can help reduce health care costs by reducing hospital re-admissions, lowering medication non-adherence, and increasing wellness management using connected smart devices and wearables to collect and analyse medical data. Connected medical devices can also engage and empower patients and their carers to improve self-management. MarketsandMarkets expect that potential savings from deploying IoT in health care could be as much as $63 billion globally.[11] Case examples of some of the savings that can be generated are included throughout the report.

Drivers of connected medical device development

The medtech industry is characterised by a constant flow of innovation based on a high level of research and development (R&D) and close co-operation with users. Medtech companies constantly update their technology to improve their engagement and interactions with patients and health care providers, with products often upgraded or replaced every 18-24 months.[12] In 2017, 13,090 medtech patents were filed globally – the most of any category of products, and a 6.2 per cent increase from 2016. Across Europe, this trend was even more pronounced, as medtech patent filings increased by 7.1 per cent from 2016.[13]

Increasingly, companies are developing products that enter the market with the capability of internet connectivity. The same devices that companies have been producing for years are now able to connect to other networks and systems and generate data that provides a huge benefit for health care professionals in terms of delivering insight into outcomes, patient health and effectiveness of care delivery. The challenge for medtech is demonstrating to payers and providers the added cost-benefits of these enhanced or new connected products, and ensuring that clinicians and patients are convinced of the benefits and ease of use.

Wearable medical devices and home health monitoring devices are becoming more prevalent among patients of all ages. These devices allow vital data to be transmitted from a patient's home directly to hospital and other health care staff, resulting in real-time monitoring of a patient's health. Utilising these types of devices could result in considerable cost reductions and operational efficiency improvements. Similarly, advances in sensor technology are making the creation of data much easier. Early stage examples of sensors embedded in novel ways include adding them to pill bottles and hospital beds. Globally in 2016, the number of patients being monitored remotely grew by 44 per cent to 7.1 million and is projected to exceed 50 million by 2021.[14]

However, the generation of data points through millions of connected sensors will have little impact unless the data can be turned into insight and utilised effectively in the clinical workflow. Currently, the limiting factor is the ability to aggregate data. Companies are addressing this by working to increase interoperability and aid data aggregation, but its complexity means progress has often been slow.

Medtech companies who participated in our survey are increasing their focus on connected medical devices

In April 2018, we commissioned market research firm Research2Guidance to conduct a survey of medical device companies with connected medical devices. Of the 237 respondents, 73 per cent were from small companies (less than 250 employees); 15 per cent from medium-size companies (251 to 5,000 employees); and 12 per cent from large companies (six per cent had more than 50,000 employees). See our separate methodology paper for full details.

Survey respondents on average estimated that 48 per cent of their current portfolio of products are connected medical devices able to generate data today and expect the percentage to increase to 68 per cent in five years' time (see Figure 6).

Over half of respondents from small companies said all their products are connected, compared to around a quarter in medium-size companies and a third in large companies. This is likely because larger companies surveyed have significantly larger product portfolios with a number of well-established non-connected device offerings.

Across our survey respondents, the average percentage of their overall R&D budget allocated to the development of connected medical devices was estimated to be 34 per cent; all expected this percentage to grow, with the overall average in five years' time increasing to 42 per cent (see Figure 6). Smaller companies surveyed are currently allocating a significantly higher percentage of their R&D budget to the development of connected devices (43 per cent), compared with their medium – and large-sized counterparts (both ten per cent).

Again, this is likely due to the difference in product portfolios between the companies. For example, our interviews with large medtech companies highlighted that significant investments in emerging IoMT technologies are being made.[15]

"Being a large company, we need to gain flexibility and agility in order to compete with new entrants and mainly with automated tech. Therefore, we are pivoting our business models and operations, that today requires 'high touch'."

R&D Manager, Medtech company

Figure 6: Connected medical device manufacturers are anticipating an increase in the percentage of devices that are produced, as well as an increase in R&D budget

Estimated percentage of connected medical devices today and in five years' time

Today

52% Other   48% Connected

5 years

32% Other   68% Connected
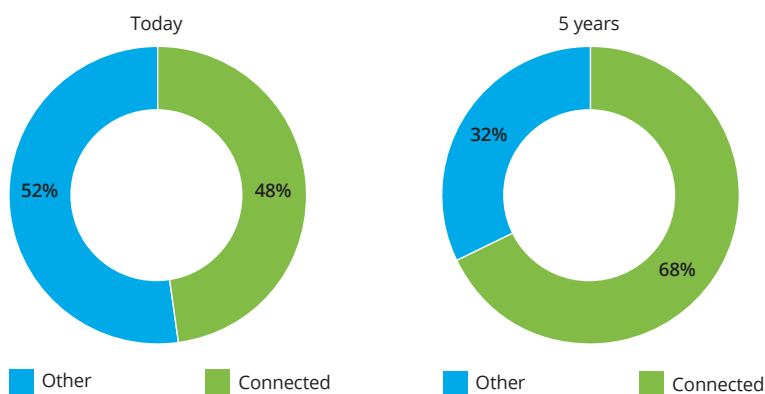
Estimated R&D budget allocation towards the development of connected medical technologies today and in five years' time
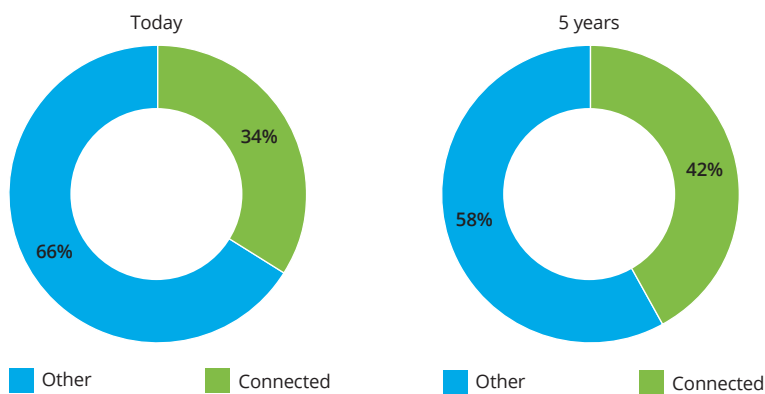
Today

66% Other   34% Connected

5 years

58% Other   42% Connected

The intention of medical device companies to invest increasing proportions of their R&D budget in connected devices, systems and software is supported by our literature review and from our structured interviews, with one global company now investing 60 per cent of its R&D budget into systems and software development.

Smaller companies surveyed are currently allocating a significantly higher percentage of their R&D budget to the development of connected devices.

Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.

Source: Deloitte research commissioned from Research2Guidance, 2018

Part 2. Challenges and opportunities for medtech

Cost, staffing and demographic challenges, combined with the exponential rate of technological change and advances in medical science are forcing a shift in the conventional model of health care provision towards value-based care.

The traditional fee-for-service health care model focuses on volume of care, where providers are compensated by the number of tests, visits or procedures performed. In a value-based care (VBC) model, hospitals and health care providers are compensated based on measures such as patient outcomes and satisfaction.

Today, a number of governments and other health care payers are expecting providers to adopt new VBC payment models that shift a higher level of responsibility and risk from payers to providers. Medtech companies have an important role to play in supporting this shift, including providing robust, reliable data and information to providers (and payers) on the downstream value that their devices, including connected products, provide. Indeed, the data and insights provided by connected medical devices can help providers improve cost, quality and productivity of care delivery, and support better patient engagement.

Participants in a Deloitte US survey of 20 Health system CEOs say that the transition to VBC is happening, but at a slower rate than initially anticipated. Many of the CEOs report that they are developing and expanding innovative delivery and payment models.[16] A successful value-based payments strategy requires payer/provider collaboration, sharing of patients' health data, and IT and analytical support. As more providers adopt VBC models, the rate of adoption and integration of connected medical devices will also increase. While the IoMT can provide these data and insights to help improve patient care and the overall cost-effectiveness of provider operations, challenges include the extent to which provider organisations' IT infrastructures are able to handle or process the connections and data, and whether clinicians and patients can be convinced of the safety and effectiveness of the devices. Medtech companies will need to address a number of systemic challenges if they are to optimise their role in the IoMT.

D. **Deloitte's view:** Medtech companies need to develop a deeper understanding of the end-user and their emerging needs, and create new business models and scenarios that demonstrate how their new and existing devices not only improve patient outcomes but also create value for key health care stakeholders.

"The industry must have more close relationships with the 'real' health care system and health care providers, namely doctors and nurses. Without the partnership of the medical world all smart devices will stay only 'nice-to-have devices' instead of really connected devices."
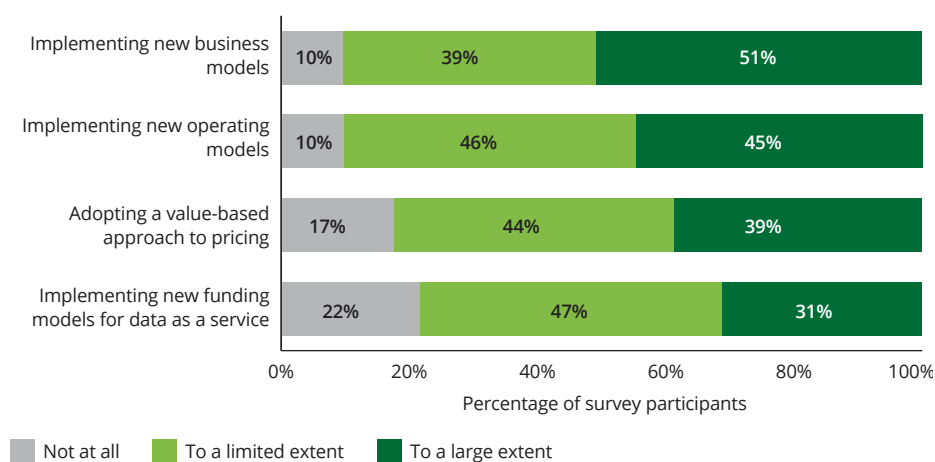
CxO, Medtech company

Developing new funding, business and operating models

Health care organisations looking to reduce their expenditure on services are taking a number of measures to lower the costs of equipment and devices, such as forming group purchasing organisations, consolidating purchasing to a small range of trusted products and changing the way medical devices are reimbursed. These factors are changing fundamentally the way in which medtech companies commercialise their products, leading companies to develop new funding and business models for their connected medical devices and software.

Our survey of connected medical device companies found mixed results in the success they are having in developing new business models. While 90 per cent of our surveyed companies said they were implementing new business models, 51 per cent were doing so 'to a large extent' versus 39 per cent 'to a limited extent'. Similarly, most respondents are implementing new operating models, although this was split evenly between 45 per cent 'to a large extent' and 45 per cent 'to a limited extent'. The majority of companies are also adopting a value-based approach to pricing, with a lower percentage implementing new funding models for data as a service (see Figure 7).

Figure 7: Medtech companies are implementing new business models and ways of working

Not at all   To a limited extent   To a large extent

Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.

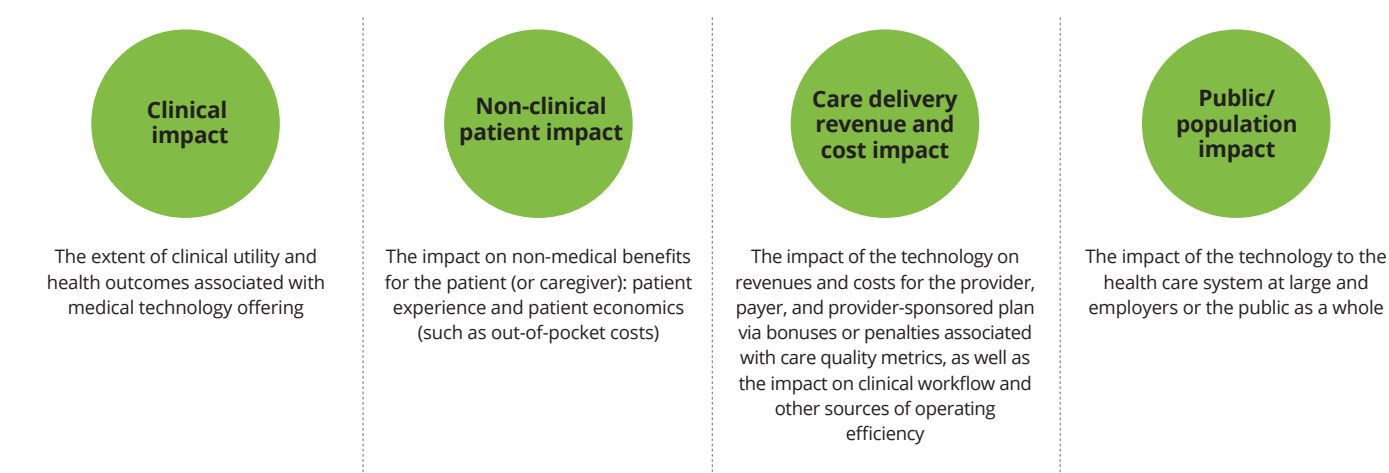Source: Deloitte research commissioned from Research2Guidance, 2018

A significant challenge for medtech is whether, and if so how quickly, these new business and operating models will be able to increase revenue and profitability. Furthermore, new entrants are disrupting the sector, which will require incumbents to take significant portfolio decisions (including divestitures of lower margin segments) and adopt new channels of care (e.g. telemedicine and remote monitoring).

In 2017, Deloitte Consulting LLP and AdvaMed, in collaboration with taskforces of member companies representing medical device and diagnostic companies, developed an approach to help stakeholders more effectively assess the value of medical technologies. At the heart of the recommendations are a set of core principles to guide the assessment process.

These start with comprehensively defining the categories where a medical technology can have impact, as considered from the perspective of the different stakeholders (ranging from the patient and their family and caregivers, through to individual clinicians, provider institutions, commercial payers, and government bodies).

These factors are changing fundamentally the way in which medtech companies commercialise their products, leading companies to develop new funding and business models for their connected medical devices and software.

Figure 8: A value framework for innovation in health care

Clinical impact

The extent of clinical utility and health outcomes associated with medical technology offering

Non-clinical patient impact

The impact on non-medical benefits for the patient (or caregiver): patient experience and patient economics (such as out-of-pocket costs)

Care delivery revenue and cost impact

The impact of the technology on revenues and costs for the provider, payer, and provider-sponsored plan via bonuses or penalties associated with care quality metrics, as well as the impact on clinical workflow and other sources of operating efficiency

Public/ population impact

The impact of the technology to the health care system at large and employers or the public as a whole

Source: Deloitte Consulting LLP and AdvaMed, 2017

Figure 8 describes the four main categories of value drivers which are a core consideration in deciding the appropriate business model to adopt.[17] We explore some specific examples of the new and emerging business models in Part 3.

There is also a large spectrum of innovation types, from engineering driven incremental innovations that mostly result in enhanced products aimed at identifying improvements to stay competitive – which are unlikely to attract additional payments – to concepts like human centred design that clearly create additional value for the health care system and which require new reimbursement models (see Case study 1).

Case study 1. Medtronic's outcomes-based reimbursement model with two large insurance companies

Medtronic reached agreements with two large American health insurers to employ an outcomes-based reimbursement model for patients opting in to use the Medtronic insulin pump systems. One such agreement utilised Medtronic's new insulin pump, the MiniMedTM 670G, a hybrid closed loop system that leverages a continuous glucose monitoring sensor to instruct the pump to deliver insulin to the patient automatically when required. The outcomes-based reimbursement model enables a risk sharing approach by both the payer and manufacturer that links reimbursement of these new devices to improved A1C (glycated haemoglobin) levels in the patient.[18,19]

D. **Deloitte's view:** While some new reimbursement models are already in use, most focus more on prevention and longer-term cost avoidance that traditional reimbursement mechanisms were not built to reward. It is likely to take several years for the health care system to evolve to be able to truly reward innovation. The different types of innovation will require different business models, and progress will depend on both the innovators themselves working in new ways to take on risks and rewards, and the evolution of existing payment systems by both public and private payers.
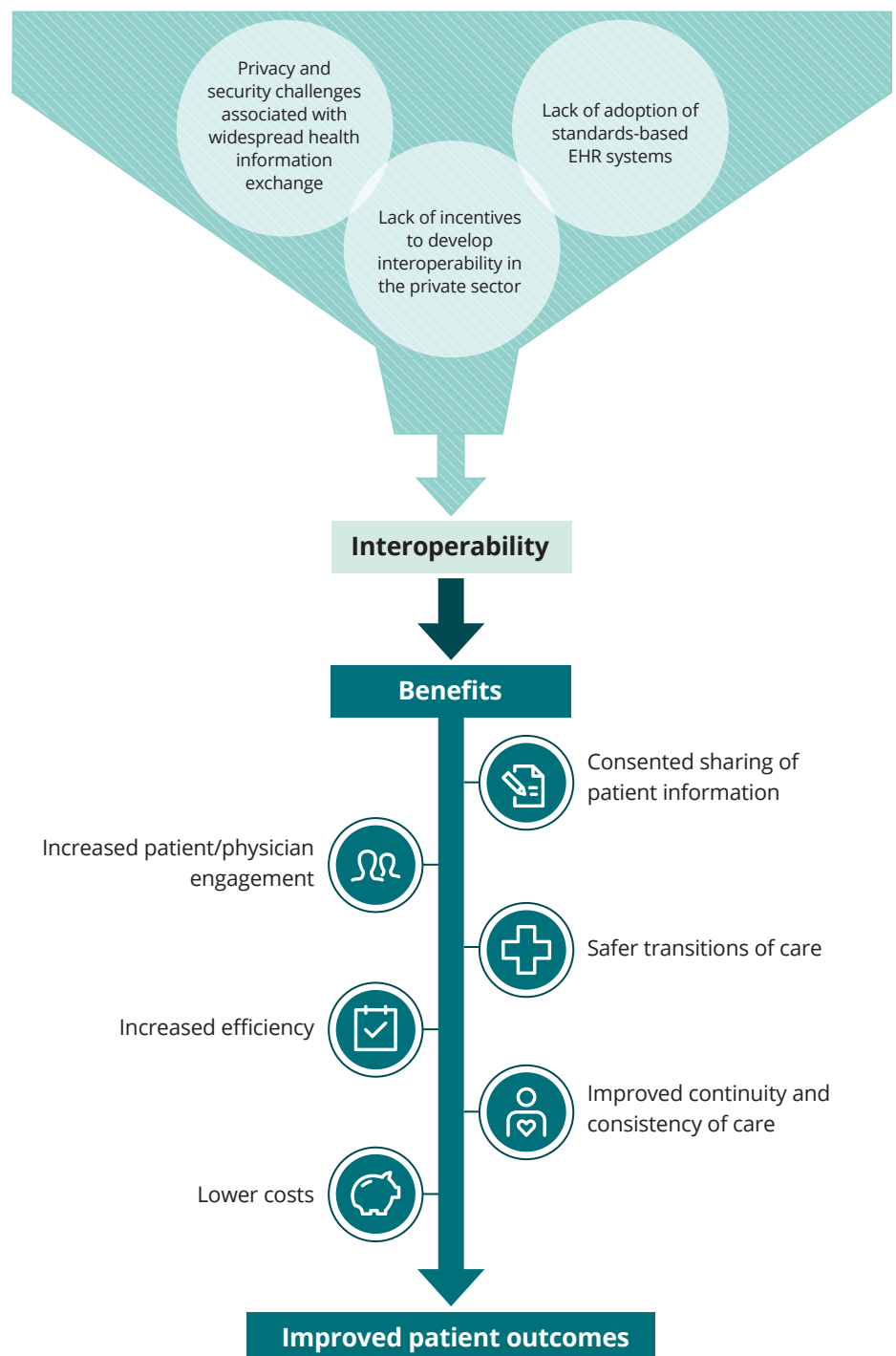
Addressing interoperability

Health systems and equipment increasingly connect over wired and wireless networks. Interoperability describes the extent to which systems and devices can exchange and interpret shared data. It also allows for the authorised use of data and the exchange of medical data to facilitate decision-supported patient centric care and reduce medical errors.

Interoperability in health care is extremely complex and relies on being able to establish connectivity and communication between devices and IT systems, and between data and workflows while enabling secure and transparent data exchange through consensus standards and protocols. However, there are serious barriers to achieving interoperability that medtech companies need to understand if they are to ensure the effective deployment of their connected devices and realise the benefits of interoperability (see Figure 9). A key question that needs to be resolved is who 'owns' the data and can drive direct or indirect commercial benefit from it?

There are serious barriers to achieving interoperability that medtech companies need to understand.

Figure 9: Barriers to and benefits of interoperability

Privacy and security challenges associated with widespread health information exchange

Lack of adoption of standards-based EHR systems

Lack of incentives to develop interoperability in the private sector

Interoperability

Benefits

Consented sharing of patient information

Increased patient/physician engagement

Safer transitions of care

Increased efficiency

Improved continuity and consistency of care

Lower costs

Improved patient outcomes

Source: Deloitte LLP, 2018

19

Hospitals often use hundreds of customisations to make EHRs user-friendly and have multiple connecting systems that increase the complexity of sharing information. Connected medical devices introduce even more data sources, challenging providers still further, especially in finding ways to store, share, and use patient-generated data from wearable health technology and smartphones. Indeed, many health systems still lack interfaces that can gather and interact with emerging technology. Payment and behavioral information is also likely to be a future application that will require more sophisticated layers of interoperability.
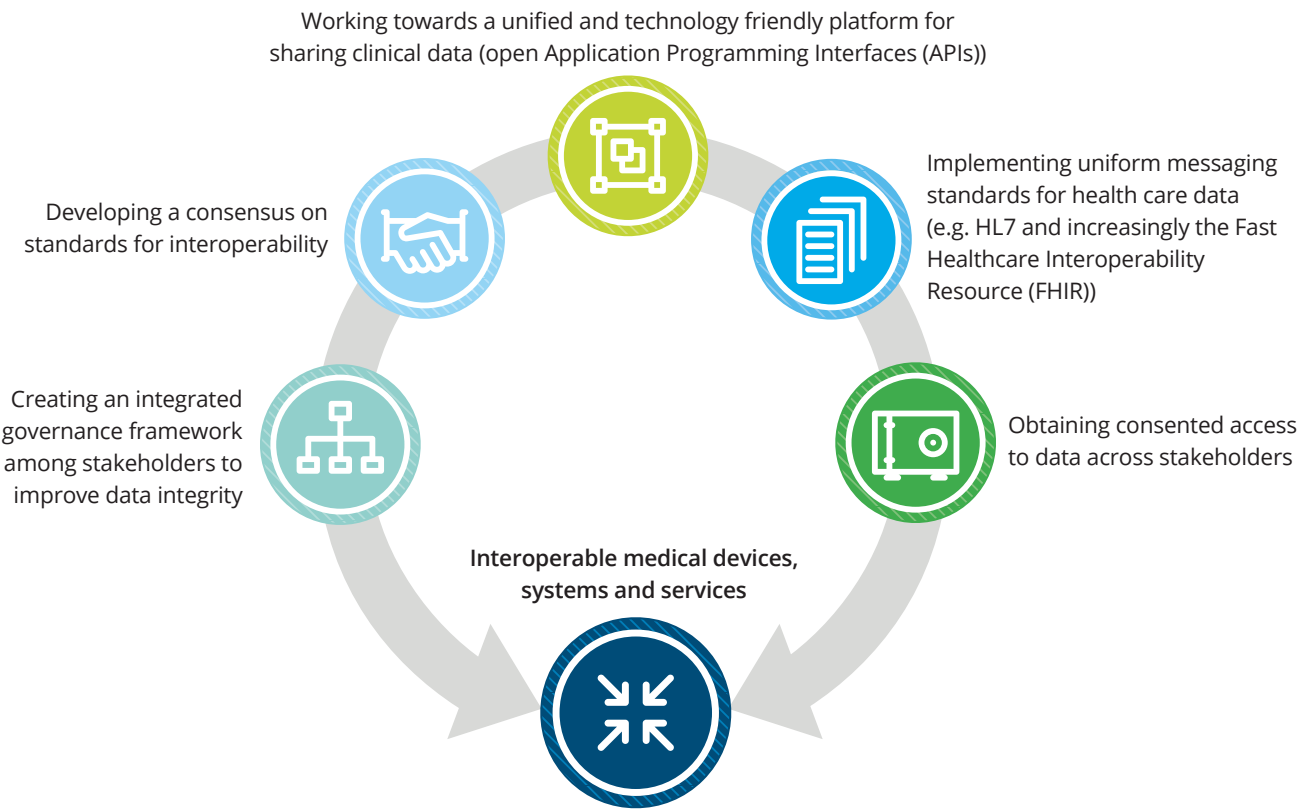
The increasing deployment of value-based care models means collaboration between payers and providers will be a necessity. Although new regulations are attempting to introduce new standards, these standards are not always implemented in the same way within and between organisations, impacting the chances of interoperability.

A number of our interviewees noted that the Health Insurance Portability and Accountability Act (HIPAA) that the US Congress passed in 1996 proved to be a barrier to the development of interoperability.

The Act made health care providers accountable for keeping protected health information (PHI) confidential, and infringements invite hefty fines and potential jail terms for those who fail to comply.[20]

There are also a number of technical and organisational challenges that need to be overcome if interoperability is to be implemented effectively (see Figure 10). However, recognising the importance of interoperability is crucial for all professionals working in the health care industry and for all medtech companies wishing to optimise the use of their connected devices.

Figure 10: Key actions life sciences and health care stakeholders should consider when tackling the interoperability challenge

Working towards a unified and technology friendly platform for sharing clinical data (open Application Programming Interfaces (APIs))

Implementing uniform messaging standards for health care data (e.g. HL7 and increasingly the Fast Healthcare Interoperability Resource (FHIR))

Developing a consensus on standards for interoperability

Obtaining consented access to data across stakeholders

Creating an integrated governance framework among stakeholders to improve data integrity

Interoperable medical devices, systems and services

Source: Deloitte LLP, 2018

Although interoperability is clearly a challenge, the results of our survey suggest that the majority of respondents from companies that have developed connected medical devices feel they are well prepared to face this challenge – 76 per cent of respondents believe they are 'reasonably well' or 'very well' prepared to develop interoperable connected medical devices (and software systems). Again, this high degree of confidence may be due to the fact that these companies are actively dealing with interoperability challenges.

Nevertheless, interoperability is a shared responsibility, and findings from our interviews with medtech leaders indicated that the challenge in developing interoperability is dependent on being able to collaborate with health care providers. Our survey results support this finding, with only 43 per cent of respondents indicating that they are collaborating with health care providers on connected medical devices 'to a large extent'.

The Office of the National Coordinator for Health Information Technology laid out a vision for achieving interoperable health IT that supports a "broad scale learning health system" by 2024.[21] It noted that while there has been some progress in establishing standards and services to support health information exchange and interoperability, electronic health information is rarely shared across organisational, vendor and geographic boundaries. Electronic health information is also not sufficiently standardised to allow seamless interoperability, due to inconsistently expressed vocabulary, structure, and format, thereby limiting the potential uses of the information to improve health and care. Learning lessons of previous and current health information exchange infrastructure to improve interoperability is a priority.

Widespread interoperability across varying systems can only be achieved through reliance upon standard technology interfaces that establish clear rules for communicating. Currently, some of these technology standards are 'open,' others are 'restricted' or 'closed,' meaning they don't achieve the highest possible level of interoperability. This creates different environments for stakeholders:

- with open standards, any vendor of communications equipment or services can implement all standards necessary to interoperate with other vendors. In turn, consumers of these products can choose the product that meets their needs and switch at will without fear of losing functionality or control of their data

- with closed standards, there are restrictions on which vendors can implement the standard, which in turn impact consumer choice and market competition. These restrictions can be a lack of access to a democratic standardisation process, onerous licensing terms, or proprietary technical 'hooks'.

APIs that allow disparate applications to connect will be an important tool for increasing health data exchange, preventing information blocking and fostering interoperability of health information. Moreover, well-managed API exchanges usually include authentication, authorisation, encryption and signatures to ensure secure connections. Furthermore, as cloud-based platforms advance the use and functionality of EHRs, they have the potential to solve the interoperability problem between different EHR systems. Not only do cloud software systems tend to work better with other cloud software, they are also more scalable than their server-based counterparts and can increase data accessibility while providing a stable and flexible environment for managing information securely.

D. **Deloitte's view:** Interoperability is arguably the biggest challenge to health care's ambition for a patient-centred, digitally-enabled, health care ecosystem. If the challenge is to be addressed, open platforms, based on open data standards is the direction of travel that needs to be followed to enable payers, providers, and technology vendors to finally come together to make data more available to one another.

"We don't support interoperability in the open source sense, but certainly in the connecting to make services more seamless."

CxO, Medtech company

Maintaining cybersecurity

The increasing interconnectivity of IoMT-enabled devices collecting and sharing patient data significantly increases the number of potential vulnerabilities within a system. As medical devices are connected to home networks, public Wi-Fi or cellular networks to transmit information back to the hospital's network, information becomes more prone to hacking and compromises the privacy of the individuals concerned.

Protecting patients from cyber threats represents a new and ever evolving challenge for both medtech and health care organisations alike. The increasing capability and usage of connected medical devices can also serve as additional points of failure for data security. Over the last ten years, there have been a number of incidents revealing the security vulnerabilities of connected medical devices.[22]

As more health care applications and platforms move to the cloud, data has more value than nearly any other commodity, and hospitals, doctor's offices, pharmacies and other health care facilities store an abundance of valuable data, making them prime targets. Health care-provider networks are constantly under attack by ransomware, hacks and other threats. Although new technologies and government initiatives to improve cybersecurity are on the rise, the value of patient data is increasing as well, and with it, the amount of cybercrime.

Recently, numerous large data breaches have occurred, with as many as 79 million people affected in one such health care breach.[23] Moreover, the cost of such data breaches are significant and often far-reaching. The Ponemon Institute estimated the cost per capita of a data breach in health care in 2017 as the highest compared to 17 other industries.[24]

The Ponemon research was based on a survey of both connected device makers and health care providers to determine if both groups are aligned regarding the need to address risks to medical devices. It found a lack of alignment about current risks and a serious disconnect between the perceptions of device manufacturers and providers about the state of medical device security which could prevent collaboration in achieving greater security. The research estimated that 67 per cent of device makers believe an attack on one or more medical devices they have built is likely, with 56 per cent of providers believing such an attack is likely. Despite the likelihood of an attack, only 17 per cent of device makers and 15 per cent of providers are taking significant steps to prevent attacks. Accountability for the security of medical devices manufactured or used is lacking. While 41 per cent of providers believe they are primarily responsible for the security of medical devices, almost one-third of both device makers and providers say no one person or function is primarily responsible.[25]

Fixing security flaws often requires software patches that are reactive to the threat rather than proactive. Once a flaw is identified, implementing changes across a large number of devices, IT systems and stakeholders is difficult to do and requires a concerted effort among all stakeholders to rectify the flaw, often making connected medical devices the weakest links within health care networks.[26] Moreover, research indicates that key stakeholders do not have a strong understanding of the cybersecurity risks within their organisation, how to prevent them and what to do once a risk has been identified.

Preparation is critical in staying connected and protected. However, even with a fully staffed IT department, most healthcare organisations need to identify a cloud-based IT-solutions partner or cloud service provider (CSP) that offers the most up-to-date infrastructure on which to support its network and establish cloud service agreements and service level agreements (SLAs).[27]

Interestingly, respondents to our survey of connected medical devices indicated that they consider their organisation 'reasonably well' or 'very well' prepared to deal with the challenges of maintaining device cybersecurity (see Figure 11). Moreover, our survey results also indicated that larger companies felt better prepared than smaller companies – possibly as larger companies have more resources to dedicate towards maintaining the cybersecurity of their products.

"In the increasingly connected world of devices, mobility, and cloud, the need for better intelligence has led to the increase in adoption of IoT health care software and services."

CEO, IoT and Cloud provider company

The increase in publicity about cyber-attacks and preparation for the EU General Data Protection Regulation (GDPR) may have increased the importance given to tackling this risk.

Figure 11: Preparedness of medtech companies towards maintaining the cybersecurity of connected medical devices
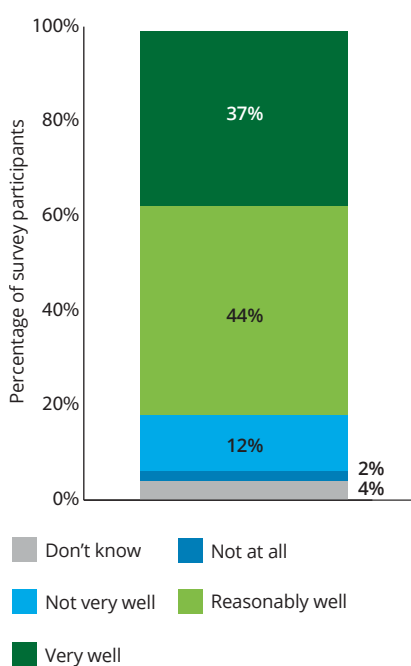
Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.
Source: Deloitte research commissioned from Research2Guidance, 2018

The FDA (US Food and Drug Administration) acknowledges that because cybersecurity threats cannot be completely eliminated, manufacturers, hospitals and facilities must work to manage them to balance protecting patient safety and promoting the development of innovative technologies and improved device performance.[28] Many countries are beginning to address this emerging risk with regulatory policies, such as the FDA's Pre and Postmarket Management of Cybersecurity Medical Devices,[29,30] which provide manufacturers with some clarity on how to handle ever evolving issues in cybersecurity. Additionally, industry groups such as the Association for the Advancement of Medical Instrumentation (AAMI) have released security risk management guidance for connected medical devices. Following several years of development, the European Commission (EC) produced new rules in 2017 to ensure the safety of medical devices in the future. The new regulations aim to increase security and regulatory certainty and take into account the latest developments in the sector including medical software, apps and cybersecurity practices.[31]

Looking to the future, both the FDA and the European Union Agency for Network and Information Security (ENISA) have provided guidance on the implementation and security considerations required for interoperable medical devices.[32,33]

D. **Deloitte's view:** Given the scale of potential security issues affecting connected medical devices, all stakeholders managing and utilising the data generated from connected medical devices need to take a more proactive and collaborative approach to identify and resolve security issues. Medical device manufacturers need to adopt a 'security by design' approach where a device is designed from the ground up to be secure instead of adding security features after it has been delivered and deployed. To mitigate cybersecurity risks, organisations will need to avoid disconnected governance and establish real-time monitoring, cyber threat modeling and analysis, threat mitigation and remediation. AI and machine learning can help medtech and health care organisations anticipate emerging cyber threats.

"[My] company has put increased resources into cybersecurity, in addition to the mitigations designed into the products even though we haven't had any issues thus far."

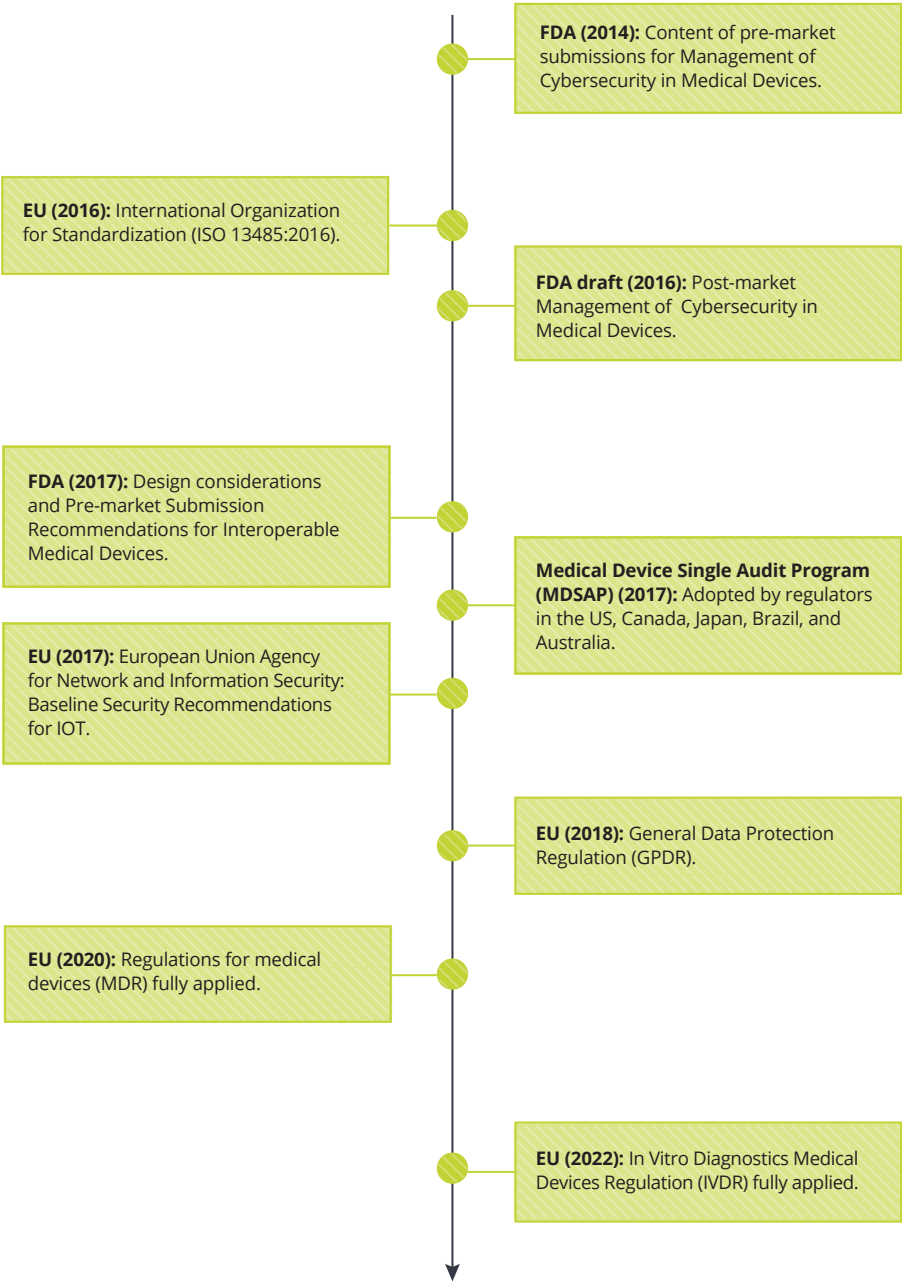**Regulatory/Quality/Compliance Manager, Medtech company**

Successfully navigating regulatory change

Over the past few decades the regulation of the safety of medical devices has remained relatively unchanged. For the majority of devices, the only formal evidence required was the CE marking. However, in Europe, the 2011 silicone breast implant scandal and product recall of the metal-on-metal hip implant highlighted serious weaknesses in the then regulatory system and strengthened the case for modernisation.[34]

Moreover, as medical devices become ever more sophisticated and innovative, regulations in most countries have failed to keep pace with scientific and technical developments. The increasing use of digital technologies has exacerbated this situation. As a result, concerns over the safety of medical devices and data security have led regulators to put in place, or plan to put in place, legislation and protocols that aid in the management and implementation of medical device safety, accountability, cybersecurity and interoperability (see Figure 12).[35] The industry expects obtaining CE marking will be more challenging following the new regulations.

For the majority of devices, the only formal evidence required was the CE marking.

Figure 12: Timeline of key regulatory changes impacting medical devices

FDA (2014): Content of pre-market submissions for Management of Cybersecurity in Medical Devices.

EU (2016): International Organization for Standardization (ISO 13485:2016).

FDA draft (2016): Post-market Management of Cybersecurity in Medical Devices.

FDA (2017): Design considerations and Pre-market Submission Recommendations for Interoperable Medical Devices.

Medical Device Single Audit Program (MDSAP) (2017): Adopted by regulators in the US, Canada, Japan, Brazil, and Australia.

EU (2017): European Union Agency for Network and Information Security: Baseline Security Recommendations for IOT.

EU (2018): General Data Protection Regulation (GPDR).

EU (2020): Regulations for medical devices (MDR) fully applied.

EU (2022): In Vitro Diagnostics Medical Devices Regulation (IVDR) fully applied.

Source: Deloitte LLP, 2018

Medtech companies are currently facing a triple hit on medical device regulatory compliance. New regulations from the European Union, Canada, and the United States are being implemented simultaneously, which will impact all companies wishing to do business in these geographies.[36] In particular, the regulatory landscape in Europe will change significantly over the next five years, as new EU regulations are fully enacted.

The EU Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation

In June 2016, new legislation was agreed by all EU member countries to adopt the Medical Devices Regulation (MDR). Similarly, in April 2017 the In Vitro Diagnostic Medical Devices Regulation (IVDR) was approved. The new rules apply in full after a transitional period – spring 2020 for MDR and spring 2022 for IVDR. The aim is to establish a modern and more robust EU legislative framework to ensure better protection of public health and patient safety and affect all companies wanting to do business in the EU (see Figure 13).[37,38]

However, industry representatives frequently raise concerns that regulators find themselves slow to react to trends that could significantly improve the operations of both medical technology and health care organisations. In our survey, 66 per cent of respondents either 'agree' or 'strongly agree' that the regulatory framework will not catch up with what is possible today for another five years – a finding echoed by most of our interviewees. However, proactive steps are being undertaken by regulators, particularly the FDA to catch up with trends within the industry, including recommendations for pre-market submission of interoperable medical devices, published in 2017.[39]

The General Data Protection Regulation

The General Data Protection Regulation (GDPR) is intended to strengthen and unify data protection for all individuals within the EU and from 25 May 2018 is automatically applicable across all member states. It also applies to any company that does business with, or has customers in, EU member states.

While GDPR is seen as a roadblock by some in the medtech industry, it also presents an opportunity to ensure that connected medical devices are more secure and private as a result. At present, many citizens in Europe have limited electronic access to data about their own health. The data is often untraceable and scattered in different places, which may impact adversely on diagnosis, treatment and follow-up. The enactment of the GDPR is intended to ensure that citizens will now have secure access to a comprehensive electronic record of their health data, have control of these data and are able to share their health data securely with authorised parties (for medical treatment, preventive services, research or for any other purpose they deem appropriate).

Figure 13: Key changes as a result of the EU MDR

Expansion of product scope for regulated medical devices and device reclassification according to risk, contact duration and invasiveness

Implementation of unique device identification for full compliance and traceability

More stringent clinical evidence and documentation of class III and implantable medical devices

More rigorous post-marketing surveillance

Increased transparency of a products clinical and safety data will be available to the public via EudaMed

Identification of person responsible for regulatory compliance

Systematic clinical evaluation of Class IIa and Class IIb medical devices
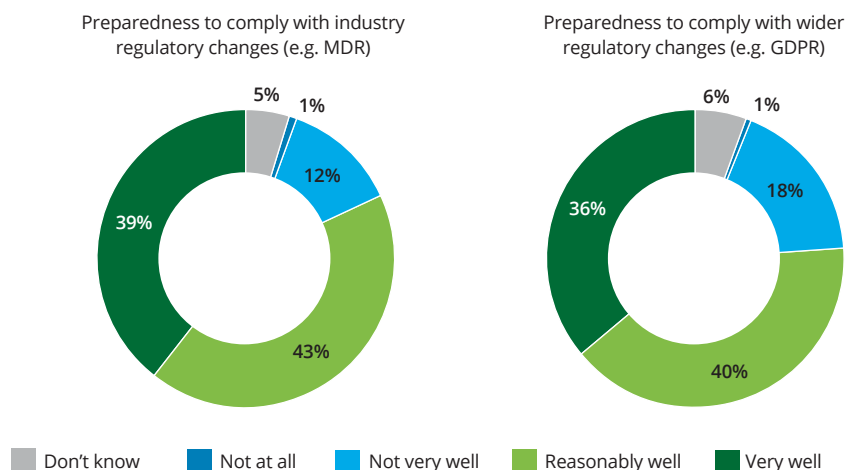
Source: Deloitte LLP, 2018

This should be irrespective of where the data is located and in line with data protection legislation. The regulation also aims to ensure that unauthorised access is prevented.

Industry opinion on regulatory change
Despite concern among industry professionals about new regulations, around four-fifths of our survey respondents indicated that their organisation is well prepared to deal with MDR and GDPR (see Figure 14). This is possibly due to the length of time regulators have allowed organisations to transition over to the new regulations.

While GDPR is seen as a roadblock by some in the medtech industry, it also presents an opportunity to ensure that connected medical devices are more secure and private as a result.

D. **Deloitte's view:** Recent and ongoing regulatory changes will impact every medtech company that currently sells or sponsors products in the European Union (EU). Managing the impact of regulatory change requires a proactive and well-planned approach. If medtech companies are to create a sustainable innovation model, they need to build engagement with regulators into their innovation models and involve clinicians and patients in product design. Medtech companies should consider establishing cross-functional steering committees to integrate R&D with commercial, manufacturing and market access. Meanwhile, the FDA's initiatives to develop a more collaborative approach to innovation may have lessons for other regulators to follow.

Figure 14: The preparedness of connected medical device manufacturers towards the implementation of industry specific and wider regulatory changes

Preparedness to comply with industry regulatory changes (e.g. MDR)

5% · 1% · 12% · 43% · 39%

Preparedness to comply with wider regulatory changes (e.g. GDPR)

6% · 1% · 18% · 40% · 36%

Don't know · Not at all · Not very well · Reasonably well · Very well

Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.

Source: Deloitte research commissioned from Research2Guidance, 2018

Attracting digital talent and building digital capability

There is a growing concern across the health ecosystem about the lack of skills to deploy IoMT solutions and the risk that this will constrain market growth. Medtech's workforce has traditionally been focused on electrical and mechanical engineering and product development supported by large traditional sales forces. Today it also requires a high level of skills in digital, advanced data analytics and machine learning, and a workforce that is educated and flexible. Data scientists with advanced degrees and training in maths, statistics and/or computer science and experience in data mining and data visualisation are much sought after skills. Regulatory changes and growing economic pressures across the IoMT ecosystem have also created a demand for new skills and capabilities to manage the path from R&D to market, to ensure that new devices gain commercial market access.

However, there is growing evidence of an emerging skills shortage affecting the medtech industry. Research undertaken as part of the development of the UK's Life Sciences Strategy in 2017 identified a growing skills gap as one of the greatest challenges for the UK's medtech industry.[40]

Although 79 per cent of our survey respondents believe that their company is 'very well' or 'reasonably well' prepared to build digital capability within their organisation, only 22 per cent of all respondents selected 'recruiting top digital talent' as one of their top three priorities for better utilising the data generated from connected medical devices. This may be because the companies in our survey are already producing connected medical devices and have invested in the requisite skills.

While mergers and acquisitions can help larger companies acquire the digital talent that will be needed, partnerships and collaborations with traditional and non-traditional players can also form part of an organisation's skills and talent strategy. Companies will also need to invest in developing an innovative, flexible digital culture in order to recruit and retain the digital talent needed to build the data-centred services that will drive value for patients, providers and their own organisations in the future.

Similarly, while the health care sector is expected to benefit immensely from IoMT technologies, the lack of skills to deploy IoMT solutions could also constrain market growth.[41] The addition of IoMT devices makes network management more difficult for health care IT teams as they deal with increased complexity. In our survey, 70 per cent of respondents agreed that health care providers and clinicians are not ready to utilise the data generated from connected medical devices.

D. **Deloitte's view:**
If medtech companies are to remain competitive, they need to develop a new, digital-first skill set including digitally savvy skills and multidisciplinary talent from creative and scientific backgrounds. Accessing this talent will require more resourceful recruitment and retention strategies, including collaborations and partnerships with a diverse range of existing and emerging players, especially academia, engineering companies, data-first tech companies and innovative new start-ups.

"Traditionally, medtech R&D is driven by mechanical and electrical engineers and related processes. IoMT related R&D focusing on software and sensors requires a different mindset and collaboration approaches with partners. This means a cultural shift for the R&D teams that needs to be managed actively."

Global Head of R&D, Medtech company

"I think we're well suited [to manage and utilise the large amount of data generated from connected medical devices]. [We] went outside the industry and recruited Silicon Valley executives [for] big data [analytics] to help our executive team a few years ago."

Executive VP – Quality and Regulatory Affairs, Medtech company

"The health care system is not fully ready for IoT, [and] has a lot of catching up to do. [It] does not have the technical capabilities, nor the professional technical manpower to handle and manage the technology. Technology is moving at a faster pace than the health care system and the regulatory system."

CxO, Medtech company

Maintaining trust in a digital age

A willingness for patients to be prepared to share data is critical to the long-term success of connected medical devices. For this to happen, patients need to have trust in how their data will be used.

While 80 per cent of respondents from our survey believe that their company is either 'reasonably well' or 'very well' prepared to obtain patient trust and willingness to share data, this contrasts with the findings from many patient surveys. However, the interactions medtech companies have with patients move beyond apps and web portals, as many connected devices collect and send data on a patient's well-being autonomously. Research has shown that vulnerabilities in connected medical devices are commonplace, and medtech companies and health care organisations are not as proactive as they need to be in tackling these challenges.[42]

As large technology companies become more involved in developing connected medical devices, and traditional medical device companies become more involved in data management and analytics, underlying trust issues that often occur between consumers and companies may emerge. In 2018, high-profile breaches involving large technology companies have brought concerns regarding the use and management of personal data to the forefront of public debate. A report by the Wellcome Trust notes that consumers distrust organisations that look to profit from health data.[43] Therefore, it is imperative that medtech learns lessons from other industries and manages privacy and security risks proactively as its business and operating models evolve.

> **D.** **Deloitte's view:**
> Medtech companies need to earn the trust of providers and patients by developing strong privacy and security arrangements (e.g. data encryption and authentication mechanisms), adopting key principles of data minimisation, data protection by design, and data protection by default, and giving patients control over their own data, including the right not to share, as well as enabling the patient to see who is using data and for what purposes. Embedded blockchain-like technology can provide a real-time mechanism to track how data collected by connected devices is processed, when it is used and for what purposes.

"There is always something you don't know around managing and using data. Exposure to more use cases will definitely help us."

CxO, Medtech company

"Patients will become more aware of [their] rights, [which] will impact how organisations create governance around ownership of data. It will depend on the age profile of patients – the younger generation might be happy for data to flow, [whereas the] older generation might not."

**Global IOT Partner Manager, Technology Company**

Improving the adoption of medical technology at scale

The main barrier to adoption of connected medical technologies involves acceptance by health care systems as a whole, as well as by individual health care professionals. Health care systems are struggling to recruit and retain the technical capabilities to deal with new technologies, with the pace of change in developing new technologies outpacing that of health care systems and regulations. Confidence in connected technologies is another barrier to the full scale adoption of connected medical technologies, with staff reluctance to engage with technology due, in part, to the scale, pace and proliferation of technology development and a lack of education and training in deploying them in a clinical setting.

The 2016 edition of Philips' annual *Future Health Index* lists the top ten perceived barriers to connected technology adoption from health care professionals (see Figure 15).[44] The report notes that the investments required to encourage the adoption of connected technology are a concern across all countries, and are shared by the patient and health care professional populations.

Half of health care professionals and patients believe connected care technology would increase the cost of health care overall, and there were worries about the resources needed for associated needs, such as training and data security.

Figure 15: Top ten perceived barriers to adoption of connected technology*
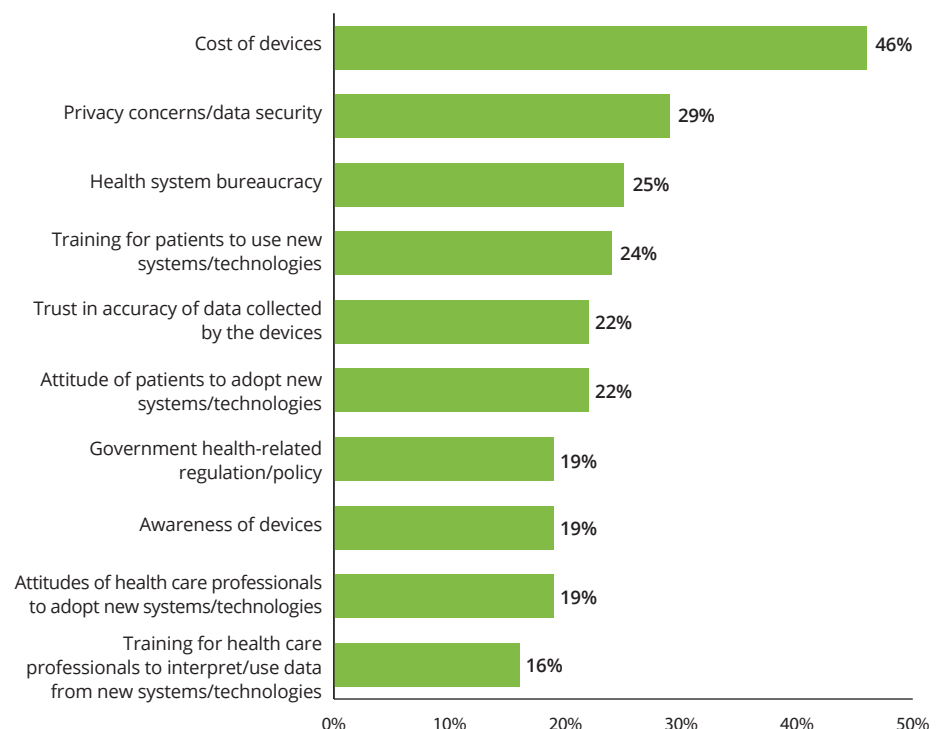
Source: Philips Future Health Index, 2016
*Respondents were asked to select their top three perceived barriers to adoption.

In England, Academic Health Science Networks (AHSNs) were established in 2013 to help the UK government's efforts to develop and spread adoption of innovation across the NHS. AHSNs are a network of 15 different regional organisations with the goal of improving health and generating economic growth. The role of AHSNs is to connect the NHS to academia, local authorities, the third sector and industry, in order to identify and drive the adoption and spread of health innovations across large populations (see Case study 2).

Each AHSN works across a distinct geography serving a different population in each region while sharing the same priorities, including promoting economic growth, diffusing innovation, improving patient safety, improving quality and reducing variation and putting research into practice.[45]

D. **Deloitte's view:** Medtech companies need to be able to provide robust and reliable evidence to health care organisations on how technological advancements and the data generated by connected devices improve the efficiency and cost-effectiveness of care delivery. This includes ensuring that the devices are more intuitive and easy to use, and, where necessary, providing training and support to staff to embed the skills necessary to optimise the use of the technology and realise the cost-benefits of adoption.

Case study 2. AHSN's promotion of the adoption of new technologies (GDm-health)

The AHSN network has promoted the adoption of GDm-health™ – a smartphone app that allows the remote monitoring, management and communication between pregnant women with gestational diabetes and health care providers. Gestational diabetes mellitus (GDm) affects roughly ten per cent of pregnant women, with an estimated 100,000 women across England impacted annually. Careful monitoring of blood glucose (BG) levels is essential for the successful management of the patients' condition.[46] The system is comprised of the GDm-health app, which is used with a blood glucose meter by the patient to send real-time patient-annotated BG results via Bluetooth or NFC (near field communication) to a clinical web-dashboard for the care team to see.[47] The web-dashboard enables health care professionals to prioritise care to women most in need and to manage patients in real time through text messages and to communicate with other staff involved in their care. The app makes it possible for women to receive feedback from their care team on their glucose levels and guidance to alter their diet or medication accordingly.

The Oxford Academic Health Science Network (Oxford AHSN) played a key role in establishing the proof of concept, as well as helping to find an industry partner to further test, develop and commercialise the GDm-health system. By March 2017, almost 2,000 women had taken part in the regional pilot, with the results showing a reduction in unnecessary clinic visits by 25 per cent, as well as better glucose control. The system is now being rolled out to other regions and is part of a five-year strategic research agreement between Drayson Health, the University of Oxford and Oxford University Hospitals NHS Foundation Trust starting in July 2017.

Part 3. Connected medical devices are transforming care

Creating the IoMT at scale requires close collaboration with patients, providers, payers, pharma and other medtech manufacturers. Our research identified multiple ways in which medtech is working towards building the IoMT, deriving value from it and transforming health care.

**Collaboration between health care providers and medtech is a core component of the IoMT**

Integrating connected medical devices into established care pathways is challenging and requires significant cooperation from multiple stakeholders to work successfully. Cross-industry collaborations are key in bridging gaps in expertise and creating solutions that deliver clinical, operational and financial value. Most medtech companies in the IoMT market are adopting collaboration strategies such as partnerships and joint ventures to increase their market presence and share risk. These collaborations can be used to support a number of aspects of the IoMT ecosystem, including the transmission, aggregation, analytics and management of data from connected medical devices. Health care providers, and in particular their EHRs, provide the central repository for data from multiple devices. For collaborations to be effective, health care providers need to grant medtech companies access to these data, under agreed and approved circumstances, including, where relevant, patient consent on how this data can be used.

Our survey respondents ranked collaborations with health care providers (68 per cent) as the most important for the development of their respective businesses, followed by collaboration with health care payers (45 per cent), and other medtech companies (42 per cent). A total of 87 per cent of respondents either agreed or strongly agreed that realising the benefits of connected medical devices and

delivering value and efficiency can only be delivered through collaboration with health care providers (see Figure 16). In practice, connected medical device companies indicated slightly greater success in collaborating with patients than they have

with health care providers (see Figure 17), highlighting that both medtech and health care providers need more constructive dialogue when developing and integrating connected devices into clinical practice.
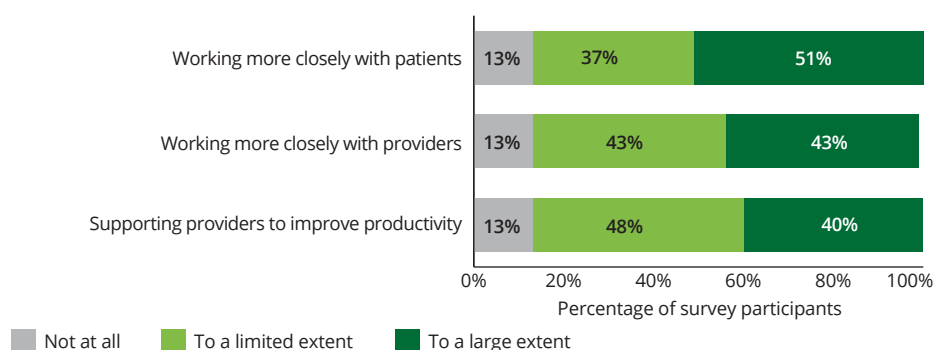
**Figure 16: Collaborations with health care providers**
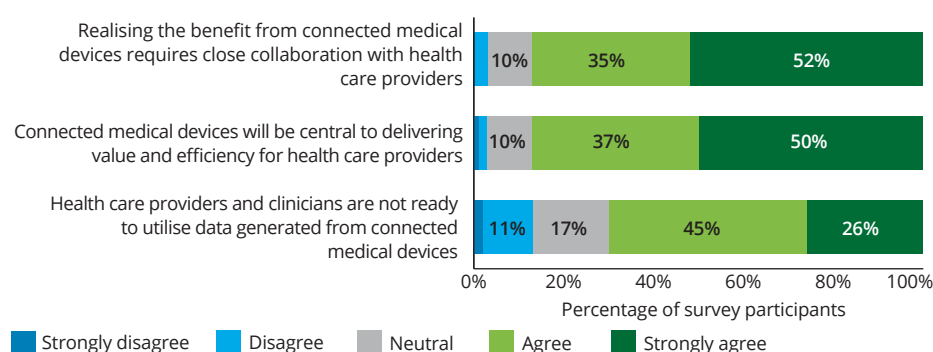
Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.

Source: Deloitte research commissioned from Research2Guidance, 2018

Figure 17: The extent to which medtech organisations are collaborating with patients and health care providers in response to connected medical devices

Note. The figures from our research survey relate to medtech companies with connected medical devices and are not representative of the medtech industry as a whole. Due to rounding the figures may not total 100 per cent.

Source: Deloitte research commissioned from Research2Guidance, 2018

A better understanding of provider needs will allow medtech and other key stakeholders to develop the industry intersections required to support a connected medical device ecosystem, from the collaborations needed to support interoperability to the technologies required for advanced analytics. Figure 18 highlights the multiple and often complex intersections between the relevant stakeholders in the connected medical device ecosystem. Although a number of organisations are leading the way in utilising collaboration, there is a need to develop a clear understanding of the points at which they occur, their governance, accountability and influence on how the IoMT operates. Optimising these collaborations will enable medtech to be pivotal in driving developments in VBC.

A better understanding of provider needs will allow medtech and other key stakeholders to develop the industry intersections required to support a connected medical device ecosystem.

Figure 18: Connected medical device collaborations can occur at multiple intersections and across industries
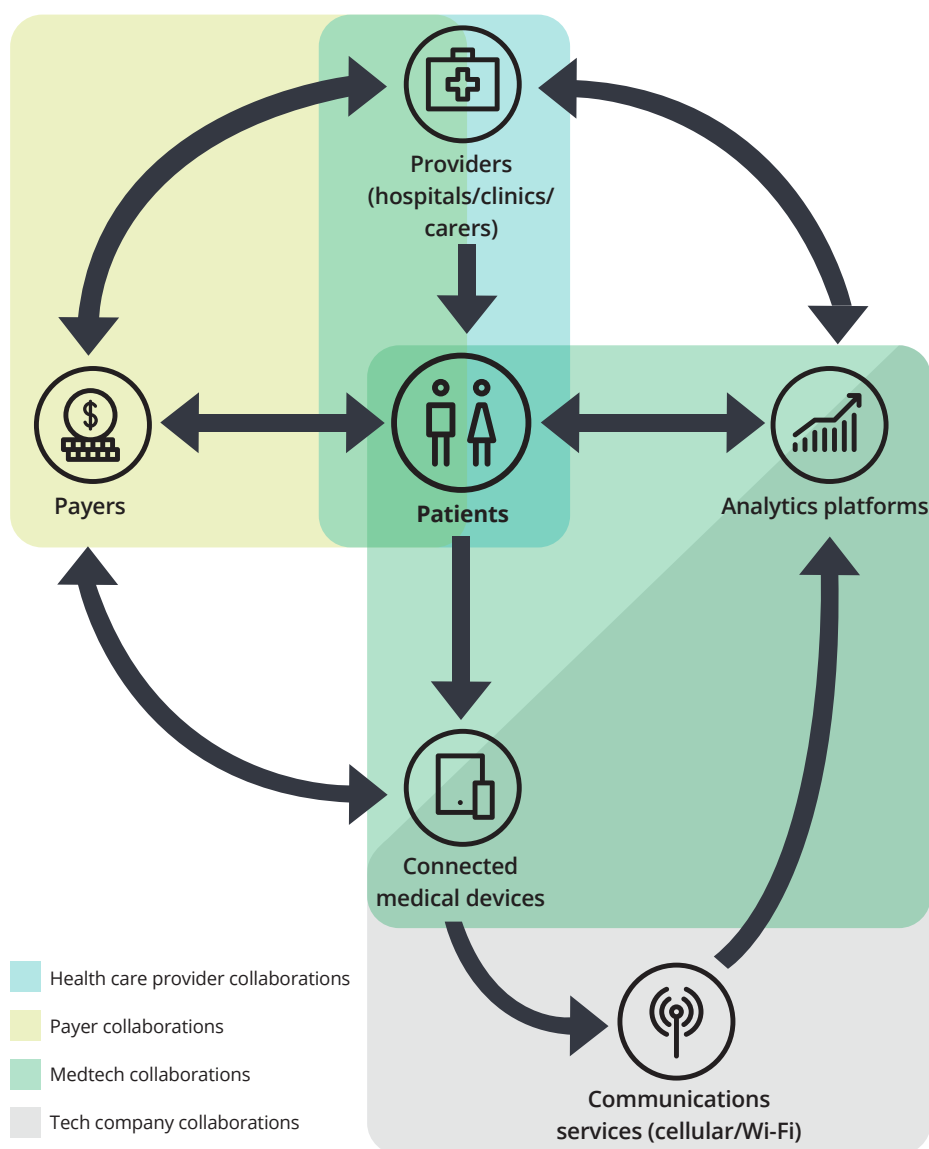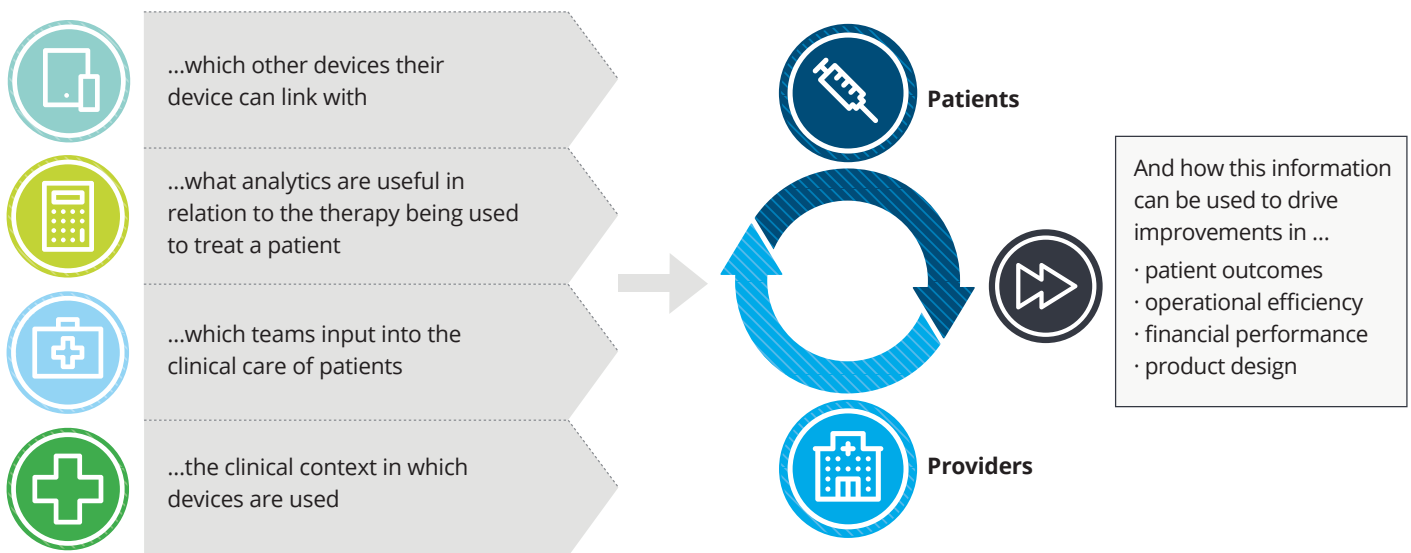

Note. Arrows indicate points at which data from connected devices can be transferred
Source: Deloitte LLP, 2018

Digitally connected medical devices are benefiting both patients and hospital providers

Medical devices are almost always designed for a specific application. Adding connectivity to a device allows data to be generated related to a patient's wellbeing and a device's operations, which can then be used to improve performance and outcomes (see Figure 19).

Figure 19: Collaboration can benefit both patients and providers

...which other devices their device can link with

...what analytics are useful in relation to the therapy being used to treat a patient

...which teams input into the clinical care of patients

...the clinical context in which devices are used

Patients

Providers

And how this information can be used to drive improvements in ...
· patient outcomes
· operational efficiency
· financial performance
· product design

Source: Deloitte LLP, 2018

A number of medtech companies are implementing solutions that wrap their connected device offerings around patient monitoring and services that allow providers to understand key health metrics of their patient population. Some of these connected solutions are linked to the therapies developed by the company, such as implantable cardiovascular devices (see Case study 3).

Case study 3. Medtronic CareLink

The Medtronic CareLink network is an internet-based remote monitoring system compatible with 99.9 per cent of Medtronic devices. The Medtronic CareLink Network service allows Medtronic implantable cardiac devices to be remotely monitored through a network that is accessible to a clinician at all times. Data is collected from a person's implanted cardiac device and stored on the Medtronic CareLink Clinician website. This website provides secure internet access to data received from implantable pacemakers, implantable cardioverter defibrillators, cardiac resynchronisation therapy with pacing devices, cardiac resynchronisation therapy with defibrillator devices, and implantable loop recorders. Clinicians can also receive CareAlert notifications, which are generated in response to clinical events, to identify potential device problems before they become more serious. The CareLink network service may reduce the need for the person to attend face-to-face follow-up appointments with their clinician.[48] Evidence from the operation of CareLink for patients with heart failure suggests that it decreases the time from the detection of a clinical event to a clinical decision, and it decreases the number of emergency visits and overall health care use in people with heart failure compared to standard face-to-face follow-up.[49]

Other connected solutions are delivering better patient outcomes and aiding health care providers to improve operational and financial performance (see Case study 4). These connected medical devices are proving increasingly crucial to the health care providers that have adopted them.

Other connected solutions are delivering better patient outcomes and aiding health care providers to improve operational and financial performance.

Case study 4. UK NHS utilising Bruin Biometrics' connected medical technology to improve patient outcomes and workforce productivity

Pressure ulcers (PU), are an area of localised damage to the skin and underlying tissue and are a prevalent medical problem that can result in pain, disfigurement, infection and death.[50] The prevalence of PUs in nursing homes across Europe ranges from 18 to 23 per cent and can be up to 57 per cent in some critical care units. However, with early detection, around 80 per cent of PUs are preventable. Bruin Biometrics' hand-held skin tissue assessment device – the SEM scanner™ – detects early, pressure-induced tissue damage, including PUs. The device detects changes in the sub-epidermal moisture (SEM), which has been found to indicate tissue damage three to ten days prior to visual skin damage or PU formation. The device has been used successfully in 13 participating NHS hospitals. Analysis of the outcomes for over 1,200 patients indicated that:

• over 50 per cent of hospitals achieved no new bedsores during the evaluation

• hospitals observed reductions in bed sores of up to 90 per cent

• nursing managers reported improved productivity and the release of nursing time, as well as significant cost savings related to reduced length of patient stay and treatment costs

• one hospital estimated that it could save £600,000 and 1,420 nursing hours annually if the technology was rolled out across the hospital.[51]

Joining the dots between connected medical devices and health care IT systems will enable the transformation of health care operations

As discussed in Part 2, achieving connectivity at scale requires interoperability – devices, systems and organisations communicating through a common language, with the ability to link disparate sets of data that sit within health care organisations. A total of 88 per cent of our survey respondents agreed that optimising the value from connected medical devices requires data sets to be linked to one another. However, there is no consensus on what the best method is to achieve large scale interoperability, with a range of solutions emerging.

Connected ecosystems are often designed to support the companies' own devices, or they do not integrate well into existing systems used by health care providers, leading to pockets of interoperability within a health care organisation that is unable to share information with other medical specialties within the same organisation. A number of large medtech companies, however, have developed connected ecosystems that act as a common platform to share and view data (see Case study 5).

Medtech companies are increasingly turning to collaboration to achieve interoperability that can work across an organisation and incorporate devices made by third parties. Some collaborations look to incorporate third party devices into their own digital ecosystem, integrating data from across a wide range of devices into their own solution, or they look to harmonise systems and data sharing among an organisation's own systems (see Case study 6).

Case study 5. Philips HealthSuite connects devices and services around a common platform

Phillips HealthSuite is an open, secure platform of services, capabilities and tools purpose-built for healthcare. It allows medical devices to share data in a secure, unified and open platform that collects, compiles and analyses clinical and operational data from a wide range of devices and sources. This data can then be accessed by clinicians, patients and carers remotely through mobile and desktop applications that can provide real-time patient data. The technology delivers precise, predictive, and personalised insights and can be used to enable telemedicine, remote monitoring, genomics analytics and precision diagnostics, and help drive behaviour change, and improve the operations of health care providers and help consumers with personalised services that help them improve their health and wellbeing. Currently, it is estimated that the Philips HealthSuite stores over 15 petabytes of data gathered from hundreds of millions imaging studies, medical records and patient inputs. Philips recently announced HealthSuite Insights, an industry-first service that delivers healthcare-specific tools and technologies to address the full process of building, maintaining, deploying and scaling AI solutions. Through HealthSuite's open platform, Philips has collaborated with research institutions to develop new solutions for patients living with chronic long-term illnesses. In one such example, Phillips worked with a University Medical Center to develop an integrated solution that uses a wearable sensor that can be placed on the chest of a COPD (chronic obstructive pulmonary disease) patient once they have been discharged from hospital. The sensor collects data on metrics such as physical and respiratory activity and heart rate, and it allows both individuals and clinicians to track the health of the patient.[52]

Case study 6. Qualcomm Life connecting the dots for health care and medtech companies

Qualcomm Life specialises in providing connectivity solutions to health care and life sciences organisations. Its product, Capsule, is capable of collecting and analysing data from hundreds of types of medical devices and integrating it into patient EHRs. Over 2200 hospitals have implemented its solutions to automate the collection and transfer of vital signs to the hospital's EHR system, a task usually done manually by nurses which can save up to 30% of nursing time. A study was made in one hospital in France, and by avoiding manual collection and transcribing data into the EHR system, the unit was able to save more than 164 hours annually, allowing nurses more time to care for patients, while also increasing the data collection from patients by 54 per cent.[53] Qualcomm Life has also collaborated with Philips to enhance medical device connectivity through its 2net Platform for its Healthsuite Platform.[54]

Applying advanced analytics to the data generated from connected medical devices to provide critical insights and empower better decision-making

Patient data provides insights into a health condition and the success of treatment, as well as insights on the efficiency of services delivered by health care providers. Mining, managing and analysing a vast array of data from medical grade wearables, imaging and monitoring devices play a key part in realising the value in the IoMT. The increasing connectivity between devices and data has led medtech companies to develop advanced analytical capabilities that are able to uncover hidden patterns and trends in information. This in turn is generating actionable insights and enabling self-learning systems to sense, predict, infer and conceive alternatives that may not otherwise be obvious. Analysis of these large data sets can also aid in improving the productivity of medtechs' R&D and Commercial operations.

The insights derived from linking connected medical devices and health data sets have a key role in aiding health systems to reduce costs, improve quality, identify populations at risk, connect with consumers and better understand performance.[55] These capabilities are essential components for the successful implementation of VBC. Some of these advanced analytical capabilities are derived from collaborations with large technology companies that provide analytics platforms able to run large data analytics across a variety of connected devices and other data sources (see Case study 7).

Case study 7. Dexcom and Verily collaborate for advanced analytics in health care

Dexcom – a developer of continuous glucose monitoring (CGM) systems, entered into a collaboration with Verily Life Sciences (formerly Google Life Sciences) in August 2015 to develop miniature CGM systems to help people with type II diabetes manage their condition. The partnership aims to create the next generation of CGM products and will incorporate Verily's miniaturised electronics platform and Dexcom's sensor technology. Ultimately, the partnership is focused on minimising the cost and size of CGM body-worn components and providing connectivity to enable more people to control their diabetes with timely, actionable information. Verily is developing miniature sensor electronics on an adhesive patch to make continuous monitoring less burdensome. The design of the patch allows continuous subcutaneous monitoring of the interstitial fluid, which may be less disruptive for those needing to measure their blood glucose levels. The patch has wireless connectivity to allow secure data sharing and continuous tracking of glucose levels. Dexcom's G6 CGM was given FDA approval in March 2018, which eliminates the need to calibrate the device with blood drawn from the finger. Instead, the sensors sit under the skin and read the interstitial fluid and send information to a smartphone or smartwatch. This new generation of devices may also offer up a wealth of information that can be taken advantage of through big data analytics.[56]

A total of 64 per cent of our survey respondents indicated that developing a stronger analytical capability to manage and interpret data was one of their organisation's top three priorities. Forty-seven per cent also highlighted that linking data with other patient data sets (such as genomics and electronic medical records) was a top three priority. Consequently, medtech companies are forging strategic partnerships with each other to collect, analyse and interpret data to provide insights to health care providers (see Case study 8).

The transformation of medtech business models

While the medtech industry clearly understands the value of utilising the data generated from their connected medical devices to improve both clinical and operational performance, only 54 per cent of our survey respondents agreed that they were either 'reasonably well' or 'well' prepared to monetise this data. Moreover, most companies in the industry are still at an early stage in the process of understanding its role beyond supplying products to health care providers and patients.

Case study 8. GE and Roche Diagnostics working together to provide clinical insights in oncology

GE Healthcare and Roche Diagnostics entered into a strategic, long-term partnership in January 2018 to develop and co-market digital clinical decision support solutions.[57] The initial focus of the collaboration is on products that accelerate and improve personalised treatment options for cancer and critical care patients. The two companies aim to develop dashboards that bring together data generated by the companies' capabilities in-vitro and in-vivo diagnostics to aid decision-making among oncology and critical care teams. The dashboards will utilise GE Healthcare's imaging and monitoring data, and Roche's biomarker, tissue pathology and genomics data as well as data from third party in-vivo and in-vitro solutions (company and product agnostic). The industry-first platform will use advanced analytics to provide workflow solutions and apps that support clinical decision-making. For example, oncology teams employing numerous specialists will have a comprehensive data dashboard available for review and collaborate and align on treatment decisions for cancer patients at each disease stage. Additionally, within the critical care setting, the integration of data from a patient's hospital monitoring equipment with biomarker, tissue pathology, genomic and sequencing data will allow physicians to identify, and even predict severe complications before they arise.[58]

A number of medtech companies are already utilising the increasing sophistication of connected medical devices, interoperability across health care organisations and the implementation of advanced analytics to develop service-orientated solutions that support VBC. Often these implementations align closely with the therapeutic expertise of the organisation and the products they produce. Fifty-one per cent of our survey respondents agreed that their company will be a data business and not a product business in the future. Some medtech companies are using their knowledge of a specific therapeutic area and data from the IoMT to develop managed services for high volume and high cost services such as catheterisation laboratories (cath labs) – see Case study 9.[59]

Some companies are utilising their IoMT ecosystems to aggregate data and offer consultative services and predictive analytics. Such collaborations are opening up health data to organisations that have typically found it difficult to gain access to data outside of their own organisation, such as smaller medtech companies.[63] These large and growing aggregated data sets are beginning to empower decision-making based on use of real-world evidence (RWE). Indeed, 88 per cent of survey respondents indicated that they are using RWE to drive business decisions.

Case study 9. Medtronic Integrated Health Solutions' Cath Labs managed services

In 2013, Medtronic formed Integrated Health Solutions (IHS) – a business focused on developing long-term partnerships with hospitals, health systems, physicians and payers to develop tailored services and solutions to improve clinical, operational and financial outcomes.[60] The services include the development, management, modernisation and optimisation of cath labs, with the objective of helping hospital cardiology departments to: improve patient outcomes, enhance operational performance, contain and manage costs. Medtronic's Cath Labs managed services (CLMS) is vendor independent and manages all aspects of a cath lab (regardless of the products used within them).[61] Currently, Medtronic IHS has 170 ongoing long-term partnerships in 24 countries across Europe (such as the UK, Italy and the Netherlands) and the Middle East, delivering value to health care organisations and supporting the delivery of high quality care more cost effectively. For example – the Maastricht University Medical Centre in the Netherlands Medtronic IHS realised:

• $2.5 million in savings in one year

• a 90 per cent reduction in patient admission time

• a 33 per cent reduction in the length of stay for cardiac resynchronisation therapy patients

• a 37 per cent reduction of cancelled procedures through better planning and scheduling

• a 43 per cent reduction in staff overtime.[62]

IHS Managed Services offer also covers other care settings beyond the CathLab, such as Operating rooms and ICUs.

Other medtech companies have transformed their underlying business models to deliver high quality patient outcomes while reducing costs of similar services run by traditional health care providers (see Case study 10).

Case study 10. From manufacturer to service provider – the transformation of Fresenius

Fresenius Medical Care has transformed itself from a supplier and manufacturer of renal products to a company that now operates one of the largest dialysis services in the world, providing both the equipment and delivery of the service. The organisation has served 322,253 patients, delivered 48 million treatments per year, and has 114,831 employees in Q1 2018.[64] Globally, Fresenius Medical Care accounted for 10 per cent of the total patients treated and 35 per cent of the total dialysis products in the market in 2017, while also operating the largest number of dialysis clinics (3,790 in Q1 2018).[65]

In the US, Fresenius Medical care has used its extensive network of equipment, clinics and specialist staff to create 24 out of the 37 End Stage Renal Disease (ESRD) Seamless Care Organisations (ESCOs). ESCOs are designed to allow dialysis clinics, nephrologists and health care providers to communicate and work together to improve and individualise the care patients with ESRD receive.[66] Results running from October 2015 through to December 2016 indicate improvements in patient outcomes and reduction in costs. These include:

• a nine per cent decrease in hospitalisation rates for these patients

• more than $43 million in gross savings

• an average 5.4 per cent reduction in expenditures per patient.[67]

"We strongly believe that the health care ecosystem is inevitably evolving to a model that closes the value chain in health care delivery. This requires payers to shift from a legacy transaction-oriented, claim adjudication business model to a new, analytics-based, shared risk provider compensation model."

CxO – Medtech company

Part 4. The future for medtech and the IoMT

Cost-effective and purposefully-designed, technology-enabled health care solutions can improve the well-being of millions of people and radically change the way services are delivered to patients.

Digitisation is helping to improve the continuity of care, promote improved health and prevent disease. It is driving the reform of health systems and their transition to new models of patient-centred care, enabling the shift from hospital-centred systems to more community-based and integrated care organisations. Digital tools have the potential to enable better use of health data in research and innovation to support personalised health care, better health interventions and health and wellness services.

These drivers of patient centricity and digitisation are not only important for the medtech industry but are also crucial for the future of the pharma industry, as is highlighted in our 2017 report, *Pharma and the connected patient.*[68]

A future where data is secure, aggregated and easily analysed will be a key enabler for the digital transformation of health care and the health and well-being of people on an individual, national, and global scale. Connected medical devices and the IoMT are pivotal to these shifts to new models (VBC, RWE and population health management (PHM)).

Medtech will enable digital health
The health care and life sciences industries are moving away from traditional reactive and largely episodic models of care that are proving increasingly costly and inefficient to operate, to care models that are proactive, digitally-enabled and deliver better care and value for patients. VBC, RWE and PHM are pivotal to the future operation of health care providers and payers. Medtech companies and the IoMT can capitalise on the possibilities presented by these changes, to help to connect patients, providers and payers to enable them to become more patient centric, productive and cost effective (see Figure 20).

Figure 20: The interconnected IoMT health ecosystem
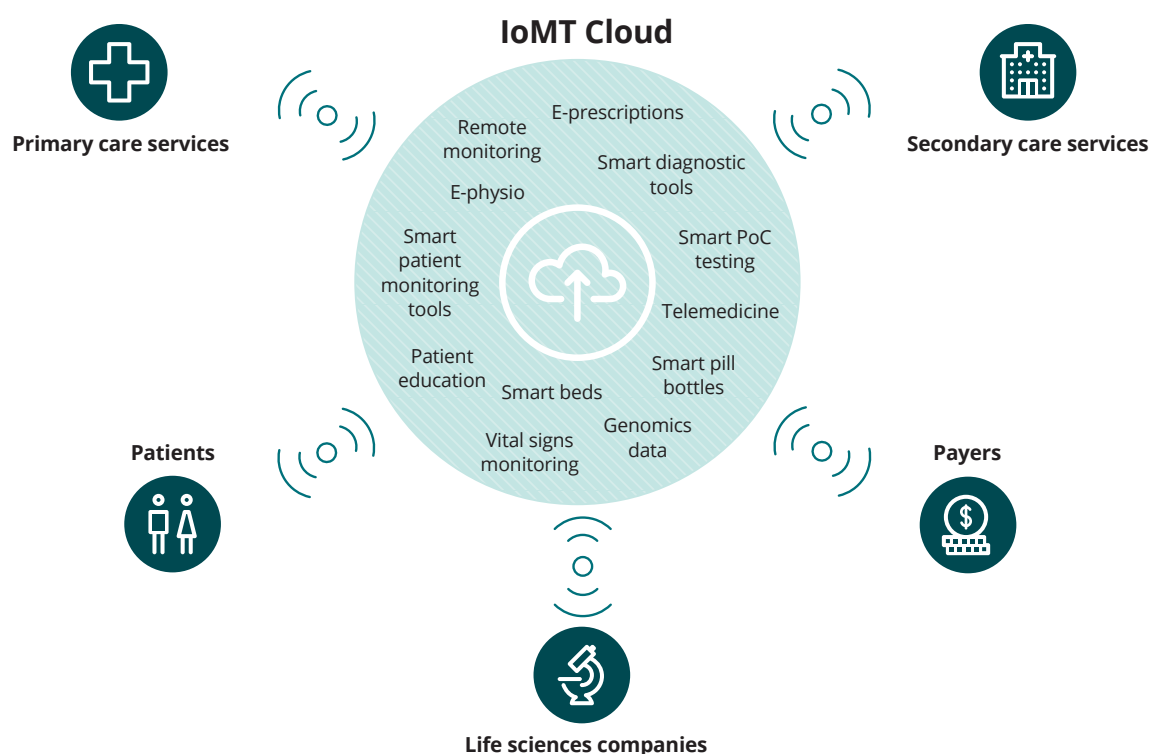
Source: Deloitte LLP, 2018

More specifically, as we move closer towards the predictions made in our November 2017 report, *The future awakens: Life sciences and health care predictions 2022* (see Figure 21), the current boundaries between the IoMT and consumer IoT will start to blur, giving rise to new opportunities for medtech companies.[69]

Figure 21: Six predictions for 2022 – both evolutionary and revolutionary

1

The quantified self is alive and well: The genome generation is more informed and engaged in managing their own health

2

The culture in health care is transformed by digital technologies: Smart health care is delivering more cost-effective patient-centred care

3

The life sciences industry is industrialised: Advanced cognitive technologies have improved the productivity, speed and compliance of core processes

4

Data is the new health care currency: Artificial intelligence and real-world evidence are unlocking value in health data

5

The future of medicine is here and now: Exponential advances in life-extending and precision therapies are improving outcomes

6

New entrants are disrupting health care: The boundaries between stakeholders have become increasingly blurred

Source: Deloitte LLP, 2018

Medtech technologies are a key enabler across all six predictions with numerous examples in each 'Evidence in 2017' section. The use cases include:

- consumers using health and fitness technologies to make informed decisions about their lifestyle choices, treatments and the care they receive and biometric data sharing between doctors and patients

- the rise of the smart hospital, virtual rehabilitation in orthopaedics and Mercy Virtual Care Center monitoring patients across 40 ICUs and providing telehealth services to people in their own home across seven US states

- DeepMind Health establishing strict rules to improve the safety and security of health data and AI enabled diagnostic technology and tech giants moving into health care

- the increasing numbers of connected smart phone devices cleared for use by the FDA and point-of-care technology enabled services providing population-based health management and hospital-to-home enterprise telehealth services.[70]

These and other digital health solutions, and the increasing ease with which they can be accessed, will drive growth across the medtech industry. Customers will not only include health care providers, but also consumers and payers. Large consumer tech companies will continue to blur the boundaries between stakeholders, pushing both medtech and health care companies to change their traditional business models. Payers and consumers will tend to prefer companies that help them improve their lives and treatment outcomes in a cost-effective way.

Many of the case studies in this report illustrate how some companies are already utilising the ubiquity of digital technology, such as remote monitoring, to aid in better post-operative and longer-term care for patients. These examples are likely to proliferate as tech companies make effective use of their digital expertise to develop ecosystems that bring together a plethora of medical device data on which advanced analytics can be run. Further progress in these digital initiatives will continue to transform health care and blur the lines between industries (see Case study 11).

Disruptive technologies will revolutionise medtech and the delivery of health care

Technology itself will become a treatment, as evidenced by the new generation of mobile apps increasingly appearing in treatment guidelines – initiatives like point-of-care testing to improve the diagnosis of sepsis,[73] tests to differentiate between bacterial and viral infections to reduce over-prescribing of antibiotics[74] and the FDA's call for medtech to help find alternative treatments to the opioid crisis.[75]

Mobile digital technology will also enable telehealth communication that brings providers and patients together at substantially lower costs than traditional consultations. Innovation in sensor technologies will lead to clinical grade wearables able to increase the quality and value of the data they provide, and could spur further growth in the wearables market.
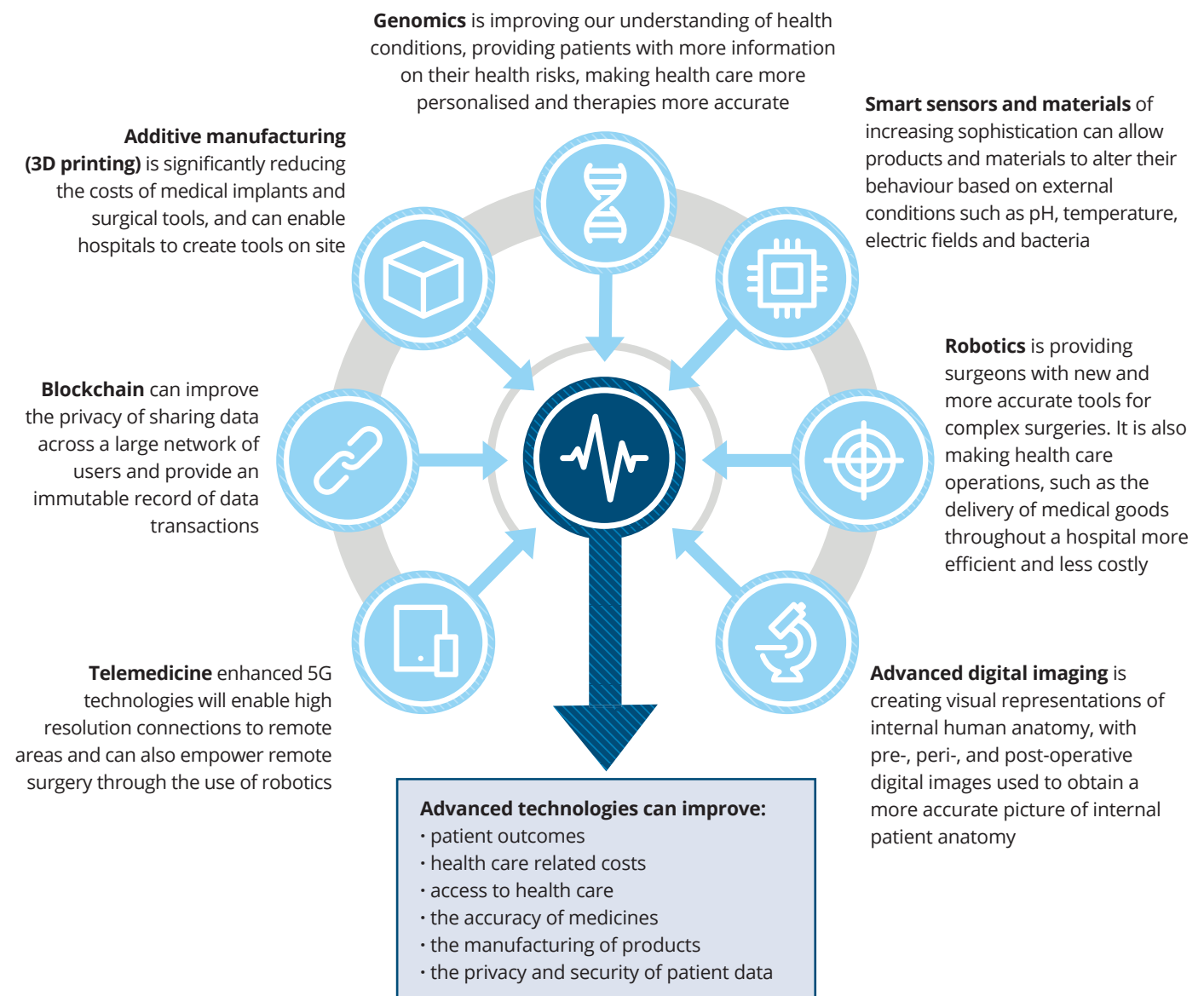
Big data, AI, mobile applications, 3D printing, robotics, advanced sensors, big data and the IoMT are leading to a fourth industrial revolution which will continue to create new opportunities for medtech companies (see Figure 22). These technologies can improve patient outcomes, the economics of health care, enable PHM, and drive beneficial changes during each stage of the patient journey.

Case study 11. Apple electronic health record

In early 2018, Apple Inc. updated its Health app, debuting a feature for U.S. customers to see their health records right on their iPhone®. The Apple® Health app allows patients to aggregate health records data from a variety of participating healthcare institutions, including information on allergies, conditions, immunisations, lab results, medications, procedures and vital signs. Apple Inc.'s health record feature is built on Fast Healthcare Interoperability Resources (FHIR) and incorporates the latest technologies in authentication, encryption and privacy. As of June 2018, more than 500 U.S hospitals and clinics are supporting health records on iPhone® for their patients.[71] hospitals and clinics are supporting health records on iPhone® for their patients. It was estimated that 728 million iPhones® were in use in 2017, and therefore the potential reach of Apple Inc.'s Health app is vast.[72]

Figure 22: Disruptive technologies can improve the pulse of health care

Genomics is improving our understanding of health conditions, providing patients with more information on their health risks, making health care more personalised and therapies more accurate

Additive manufacturing (3D printing) is significantly reducing the costs of medical implants and surgical tools, and can enable hospitals to create tools on site

Smart sensors and materials of increasing sophistication can allow products and materials to alter their behaviour based on external conditions such as pH, temperature, electric fields and bacteria

Blockchain can improve the privacy of sharing data across a large network of users and provide an immutable record of data transactions

Robotics is providing surgeons with new and more accurate tools for complex surgeries. It is also making health care operations, such as the delivery of medical goods throughout a hospital more efficient and less costly

Telemedicine enhanced 5G technologies will enable high resolution connections to remote areas and can also empower remote surgery through the use of robotics

Advanced digital imaging is creating visual representations of internal human anatomy, with pre-, peri-, and post-operative digital images used to obtain a more accurate picture of internal patient anatomy

Advanced technologies can improve:
· patient outcomes
· health care related costs
· access to health care
· the accuracy of medicines
· the manufacturing of products
· the privacy and security of patient data

Source: Deloitte LLP, 2018

Without a doubt, disruptive technologies are changing how we gather medical information and how we interact with medical professionals and caregivers. Robotics, AI, genomics and the wearable sensor industry will replace existing jobs, but they will also add new ones focused on blending employee skill sets and developing transferable skills.

AI will improve the efficiency and cost-effectiveness of diagnostics

Over the next two to three years, examples of AI use in everyday health care settings will become a reality, with radiology fueling much of this change, albeit the demand for real-time data analysis is much wider. AI will be integrated into the clinical workflow in existing tools like EHR and Picture Archiving Centres (PACs), empowering practitioners with just-in-time data. Images and data will be automatically routed to AI engines in order for clinically relevant information to be extracted in real time. Instead of wading through thousands of images or documents, the most important and relevant pieces of information will be identified by AI – whether it's textual information or image data pinpointing a nodule, tumor or simply something that changed in a scan. Advanced PACs that act as AI algorithm-routing engines will assist radiologists by sifting through massive amounts of data with great precision.[76]

Another example where AI is set to transform diagnostics is pathology, where AI can help laboratories to reduce unwarranted variations in performance. Pathologists will be much less likely to miss things because the computer algorithms will help them find them, radically changing how laboratories work. Advancements in AI could make pathology a fully-digital discipline.[77]

A 2016 Frost & Sullivan report suggested that AI has the potential to improve health outcomes by 30 to 40 per cent – not by replacing the decision-making of health care professionals, but by giving them new insights into vast amounts of data.[78]

The adoption of voice-enabled devices will improve clinician and patient engagement

Voice technology is being adopted faster than any previous technology. A 2018 Google survey found 53 per cent of people said it already 'feels natural' talking to a voice-activated device. One-in-six Americans now own a smart speaker, an increase of 128 per cent since January 2017 and, by 2020, 75 per cent of households are expected to have some kind of voice activated speaker, giving 258 million Americans direct access to voice assistants on a daily basis.[79] Voice-driven technology presents many opportunities for medtech companies to connect health care organisations with patients and caregivers like never before.

Several hospitals and health systems have embraced Amazon's app-like approach to the world of voice assistants, for example:

- Northwell Health created an Amazon Alexa skill that offers wait times and direction to nearby hospitals and urgent care locations[80]

- Boston Children's built KidsMD, a voice-enabled symptom checker that parents can use to get answers to medication dosing questions or questions about symptoms their child is experiencing[81]

- Libertana Home Health Care has been using Alexa voice assistants to support health care at home, to check in on patients and remind them to take medication or about upcoming appointments.[82]

Voice technology is rapidly evolving. AI will continue to expand the ways voice technology can be used to improve the patient experience, from chatbots, to doctor visits, to home health care. By 2020, its predicted that 50 per cent of all searches will be voice activated, which means that health care will need to optimise their websites and make sure their digital content is voice-search friendly to take advantage of longer phrase, spoken queries. Moreover, medtech and health care organisations will need to develop an understanding of the landscape of voice technology and how they can integrate this into meaningful voice strategies.[83]

The expanding role of medtech in improving the management of clinical trials

The IoMT is also aiding clinical trials, allowing information to be shared between patients, providers and regulators involved in the trial. A number of technology companies have entered this arena working with pharma to develop cutting edge biotechnology to provide solutions that allow trial investigators to design digitally-enabled trials and gather data from a patient remotely (see Case study 12).

Overcoming disparity in the quality of data is one of the key barriers to medtech adoption

A key challenge for medtech and health care organisations alike is the disparity in quality of data held on patient EHRs.[84] To overcome this challenge and provide a more cohesive data profile around patients, large technology companies are using their vast reach and expertise to create a continuous EHR that can integrate data from a variety of sources and enable real-time access as well as using AI technologies to aid in the analysis of large longitudinal datasets (see Case study 13).

Medtech's bright future as the key enabler in the transformation of health care

Continuing to solve the challenges identified in this report and supporting innovation will put the medtech industry at the forefront of digitisation and the delivery of high quality and affordable health care as the global population continues to age. Moreover, embracing disruptive technologies such as AI, robotics, blockchain and genomics will further enhance patients' access to medicines, improve diagnosis, care and treatment. Linking the rapidly advancing IoMT and the wider IoT with disruptive technologies will position medtech companies as key enablers of 4P medicine (medicine that is predictive, preventive, personalised and participatory), VBC, RWE and PHM. Going forward, there are some significant implications for all stakeholders in the IoMT ecosystem that need to be tackled forthwith (see Figure 23).

Case study 12. Otsuka Pharmaceuticals and Proteus Digital Health partner for digital medicines

In a partnership with Otsuka Pharmaceutical, Proteus Digital Health developed the world's first Digital Medicine, a drug/device product that combines Otsuka's ABILIFY® (aripiprazole) for serious mental illness with Proteus's ingestible sensor in a single tablet to record ingestion digitally and, with patient consent, share information with their health care professionals and caregivers. Proteus Discover comprises a small wearable sensor patch, ingestible sensors, a mobile app and a provider portal for medication effectiveness to help physicians improve treatment results. The company has also entered into partnerships with leaders from other industries such as Oracle and Novartis. These strategies have helped the company enhance customer experience and satisfaction.[85]

Case study 13. IBM Watson collaborations with medtech companies

IBM Watson Health has been collaborating with Medtronic since 2015 to develop a cognitive app that aids in the detection of important patterns and trends for diabetes patients. The collaboration led to development of the app 'Sugar.IQ', which uses real-time CGM data available from Guardian Connect CGM system. It uses IBM Watson's cognitive computing power to identify hidden patterns in diabetes data. The app is used to uncover behaviours influencing glucose levels and send relevant insights to users. It also allows users to inquire about how specific foods impact their glucose levels, and the mobile app is able to track food to deliver meal-related insights to help users better control their condition.[86]

Sweden-based Elekta announced a collaboration with IBM Watson in early 2018 in which Watson for Oncology will be paired with Elekta's digital cancer care solutions as a clinical decision support tool.[87] Elekta provides radiation therapy, radiosurgery, related equipment and clinical management for the treatment of cancer and brain conditions. The collaboration positions Elekta as the first radiation therapy company to offer capabilities that combine conventional health information systems with AI and cognitive cloud computing. Watson for Oncology is able to summarise key medical attributes of patients as well as provide information to oncologists to help them deliver effective treatment options. Watson for Oncology also provides a large collection of medical literature and insights about different treatment options for physicians to consider.

Figure 23: Actions for IoMT stakeholders that will benefit patients

Actions for medtech	Actions for providers	Actions for payers
• examine the level of connectivity of the devices in your portfolio and develop a business intelligence strategy including determining what data would be useful to collect	• understand what data assets are available and whether they are accessible and interoperable	• explore what data types and sources can shed new light on patient outcomes and the value of treatments and interactions
• pursue data integration as a strategic function that aligns to business objectives	• recruit the right skills to analyse data and build actionable reports	• develop a range of evidence-based value-based payment contracts to match to providers
• ensure products are built on open standards that are widely accepted by the industry (for example FHIR) and can accept or utilise APIs	• have clear systems and processes for obtaining patients consent to the use of their data	
• be generous in sharing data, including bartering data sharing for broader access to other health data sets	• adopt industry endorsed standards (such as FHIR) to improve interoperability	
• build interoperability into all connected medtech products based on understanding the IT systems of customers and the medtech company	• adopt a clear business intelligence strategy and define how the IT systems can receive and integrate data from multiple sources and how it can be shared	
• hire people who understand the new and emerging technologies and can think about business models differently	• prioritise P4 medicine and an integrated PHM approach to care delivery and determine which connected medical devices will best support these initiatives	
• develop a deep understanding, not just of providers and payers, but immerse the business in understanding how the patient will use and experience devices and any restrictions patients may place on the use of their data	• assess the relevance of VBC business models and determine which would best meet your circumstances and what technology would generate the outcomes data required to meet the expectations of consumer–driven health care	
• focus on recruiting, up-skilling and retaining a workforce that is digitally skilled		
• collaborate early with regulators on innovation		

Source: Deloitte LLP, 2018

Appendix: Nomenclature and medical device classifications used in the report

The Global Medical Device Nomenclature (GMDN)

The GMDN is a list of generic names used to identify all medical device products that are used for diagnosis, prevention, monitoring, treatment or alleviation of disease or injury. The GMDN provides health authorities/regulators, health care providers, conformity assessment bodies and others with a single generic naming system that can be used to exchange medical device information and support patient safety. The GMDN is used for:

- data exchange between manufacturers, regulators and health care authorities

- exchange of post-market vigilance information

- supporting inventory control in hospitals

- purchasing and supply chain management.

The GMDN is recommended by the International Medical Device Regulators Forum (IMDRF), is used by over 70 national medical device regulators to support their activity and is managed by the GMDN Agency. Table 1 lists the 21 categories of medical devices and provides examples of devices in each category.[88]

Table 1: Classification of medical technologies as determined by the GMDN

Code	Classification	Example
01	Anaesthesia and respiratory devices	Oxygen mask, gas delivery unit, anaesthesia breathing circuit
02	Body fluid and tissue management devices	Haemodialysis devices and heart-lung machines
03	Body tissue manipulation devices	Liposuction devices
04	Cardiovascular devices	Cardiac stents and pacemakers
05	Complementary therapy devices	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
06	Dental devices	Dentistry tools, alloys, resins, floss, brushes
07	Disability-assistive products	Wheelchairs, walking frames, hearing aids
08	Ear/Nose/Throat (ENT) devices	ENT microscopes and workstations
09	Endoscopic devices	Gastroscopes, laryngoscopes
10	Gastro-urological devices	Specialised urology catheters
11	General hospital devices	Hospital beds
12	Healthcare facility products and adaptions	Gas delivery systems
13	In vitro diagnostic medical devices (IVDs)	Pregnancy test, genetic test, glucose strip
14	Laboratory instruments and equipment	Most IVD which are not reagents
15	Neurological devices	Implantable neurostimulators and CSF drainage catheters
16	Obstetrical/Gynaecological devices	Delivery forceps and vaginal speculums
17	Ophthalmic devices	Spectacles, contact lenses, intraocular lenses
18	Orthopaedic devices	Hip or knee joint replacement devices
19	Physical therapy devices	Heat therapy products
20	Plastic surgery and cosmetic devices	Breast implants
21	Radiological devices	CT scanners

Definition of connected medical devices

A connected medical device is one which is able to generate, collect, analyse or transmit data or images, and can connect to health care provider networks and transmit data to either a cloud repository or internal servers in order to prevent, diagnose or treat diseases. For the purposes of this report medical devices should have received or be in the process of receiving regulatory approval (e.g. FDA, CE). Devices for wellbeing and fitness are not included. All of the device classifications above have the potential to be connected medical devices due the increased capability and use of hardware such as embedded sensors and software, powered by IoT technology, with connectivity provided by faster cellular network (3G and 4G), WiFi, Bluetooth Low Energy (BLE), Zigbee, Near Field Communication (NFC) and Satellites.

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