The background features a complex digital interface with a glowing blue and white human silhouette. The interface includes various data panels, charts, and navigation elements. At the top, there are tabs for 'SYSTEM-PREF.', 'CLOUD', 'SEARCH', and 'NETWORK'. A 'SECtion' panel shows 'DECODE-CODE: MORSE-202-21-32-09-114-00-00-10'. A 'PULSE' panel displays '36' and '75'. A 'SUMMARY: ZONE-A' panel is visible. A hand is interacting with a tablet displaying a 'PROFILE' section with a silhouette and numbers '46' and '73'. Other panels show 'MISSIONDAY: 0001', 'LINK-SPOT', 'MISCAN', 'FLOW: 100%', 'DETAILS: AREA-CODE: K', 'ROTATION-BALANCE-SPEED', and 'RESOURCE-GATHERER-SUPPORT'.

Pulse of the Industry: medical technology report 2023

Accelerating medtech's digital opportunity

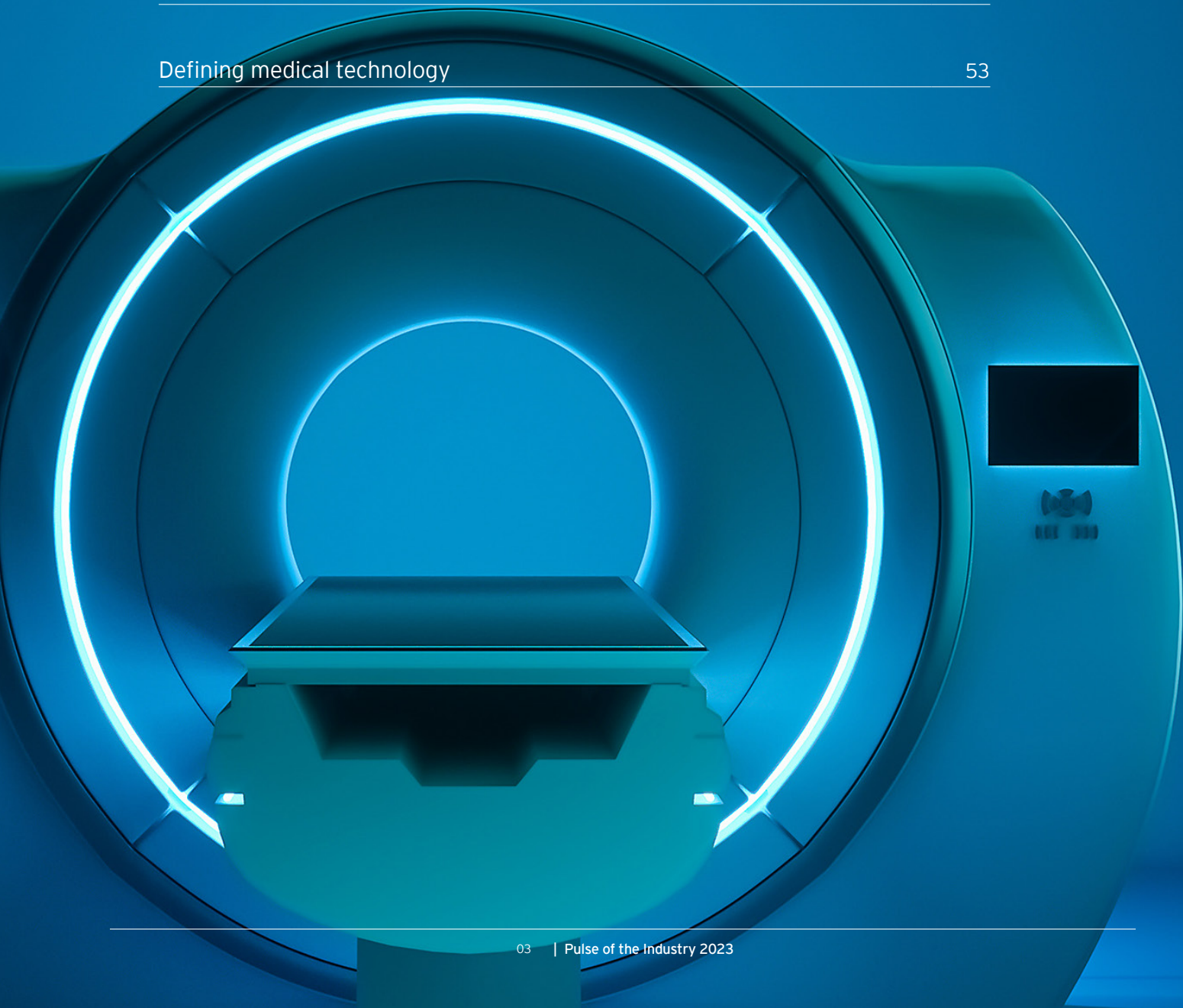
The EY logo consists of the letters 'EY' in a bold, white, sans-serif font. A yellow diagonal bar is positioned above the 'Y'.

Building a better
working world

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The year in review: accelerating medtech's digital opportunity

The 17th annual edition of our Pulse of the Industry medical technology report finds the industry in a state of flux. In recent years, the medical technology (medtech) industry has performed very strongly, driven by the COVID-19 pandemic and the associated need for new non-imaging diagnostics and research-related equipment.

In last year's report, we celebrated the industry's surge of public company revenue to more than a half trillion US dollars, as well as a third consecutive year of double-digit R&D growth. However, we also noted early indications of more challenging conditions ahead, signaled by a muted M&A market and decreasing public market valuations for companies in the sector, as well as a 30% decline in overall industry financing. This financing slump included the disappearance of special-purpose acquisition company (SPAC) deals; a sharp decline in initial public offerings (IPOs), which were down 99% in total value; and venture capital (VC), which saw a 21% drop in funding.

One year later, the headwinds that were becoming evident have further intensified. Geopolitical upheaval, slow commercial and supply chain disruption recovery, a shifting regulatory environment, and stubborn global inflation all have contributed to the uncertainty affecting the industry. Adding to these factors, questions are emerging around how the rise of GLP-1 (glucagon-like peptide1) therapies might impact aspects of the sector over the longer term. However, the aging global population and the associated rise in the number of underserved chronic disease patients provide strong fundamentals for long-term growth. Moreover, the acceleration of digitalization across the industry with new advances in the power of data analytics (most notably demonstrated by the rise of artificial intelligence (AI), including the breakthrough generative AI models in 2023) opens new possibilities for the industry's future.

The convergence of these technological advances with a heightened demand for personalized, flexible approaches to care forms the basis for a new vision of health care for the future, which we have termed the intelligent health ecosystem (IHE), a concept that we'll explore further in this report. But ultimately, amid the shifting forces affecting the industry and the challenges and opportunities they offer, medtech has undergone a year of reset, with its performance largely returning to pre-pandemic norms. This reset leaves medtech with key strategic questions to answer.

1. How can medtech restore its growth trajectory?

Total revenue for medtech reached US\$573 billion in 2022, as growth fell from a post-pandemic high of 16% in 2021 to just 3.5% in 2022, the lowest level since 2015. This slowing trend continued into the first half of 2023, with commercial leader (public pure-play medtechs with at least US\$500 million in annual revenue) revenues decline of 1.1% growth compared to the previous year. This continuation of 2022's pattern suggests that the industry's strong performance in 2021 could be an outlier – a onetime post-COVID-19 correction rather than a return to the trajectory of the period from 2000 to 2007, when medtech averaged 15% annual revenue growth rather than the 5% average seen from 2008 to 2020.

Figure 1

Macro challenges for the global economy

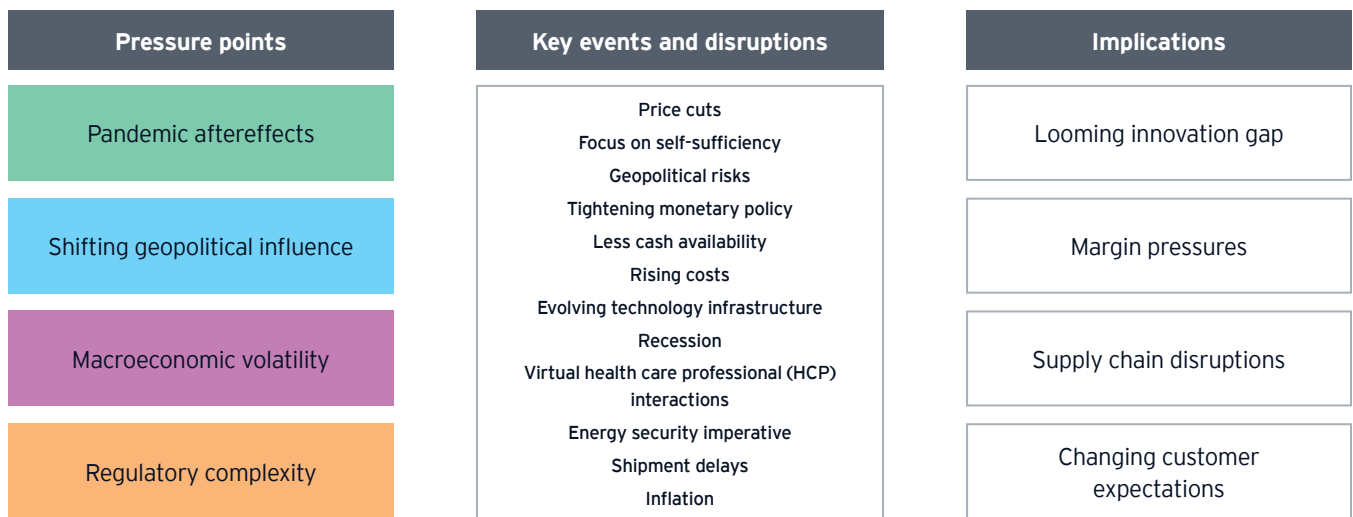
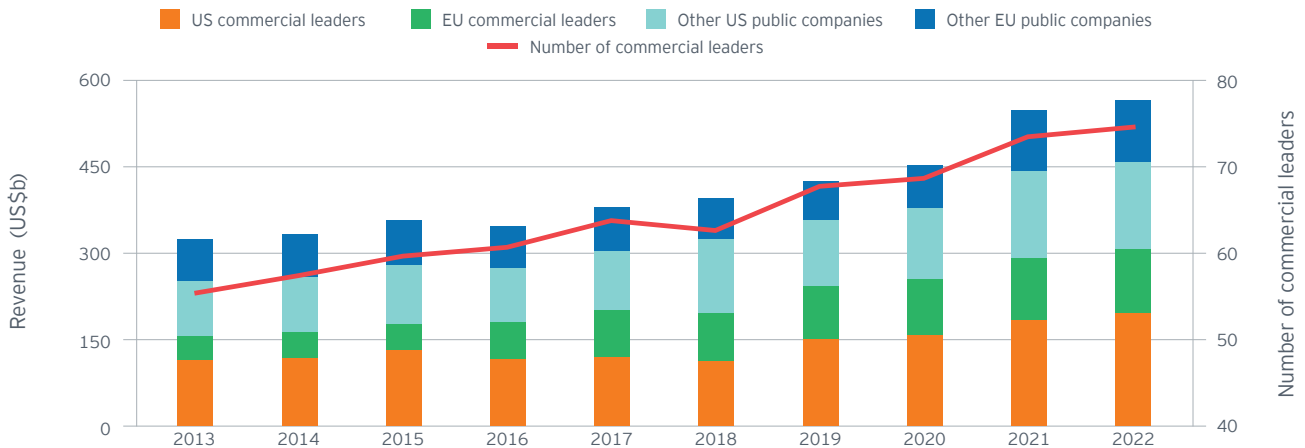


Figure 2

US and European medtech public company revenues, 2013-22



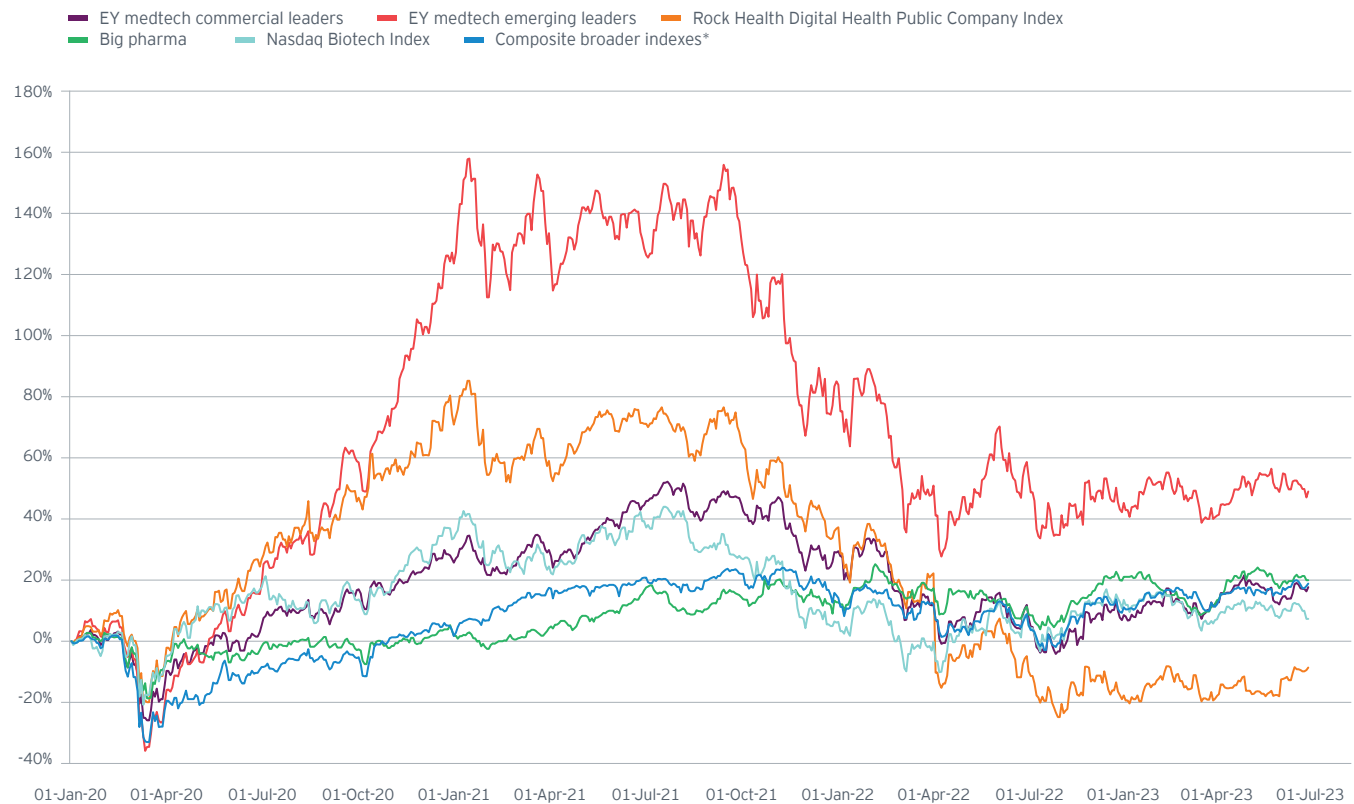
Source: EY analysis and Capital IQ. Commercial leaders are companies with revenues at or above US\$500 million. Other companies include figures for conglomerates.

2. What can the industry do to increase its attractiveness to investors, particularly in a period of continued uncertainty?

Medtech's public valuations have fallen in parallel with the sector's top-line growth. Stock prices for medtech, as with broader indexes, peaked toward the end of 2021. But by midyear 2022, roughly half of the stock price gains the industry made during the pandemic had been wiped out. As of the end of July 2023, growth had flatlined and medtech valuations were just 22% higher than they were in January 2020, in line with the broader indexes. In parallel with this reset, medtech trading multiples also fell back from a pandemic-era peak of 16.3x in September 2021 to 7.3x by the end of H1 2023 (for context, the 10-year average trading multiple for the industry was 8.4x). And according to one recent report, medtech is trading at the lowest sentiment levels seen since the financial crisis in 2008 and 2009.¹

Figure 3

US and European medtech market capitalization relative to leading indexes, 2020-H1 2023



Source: EY analysis and Capital IQ.

Chart includes companies that were active on 30 December 2022.

*Composite broader indexes refers to the daily average of leading US and European indexes: Russell 3000, Dow Jones Industrial Average, NYSE, S&P 500, CAC-40, DAX and FTSE 100.

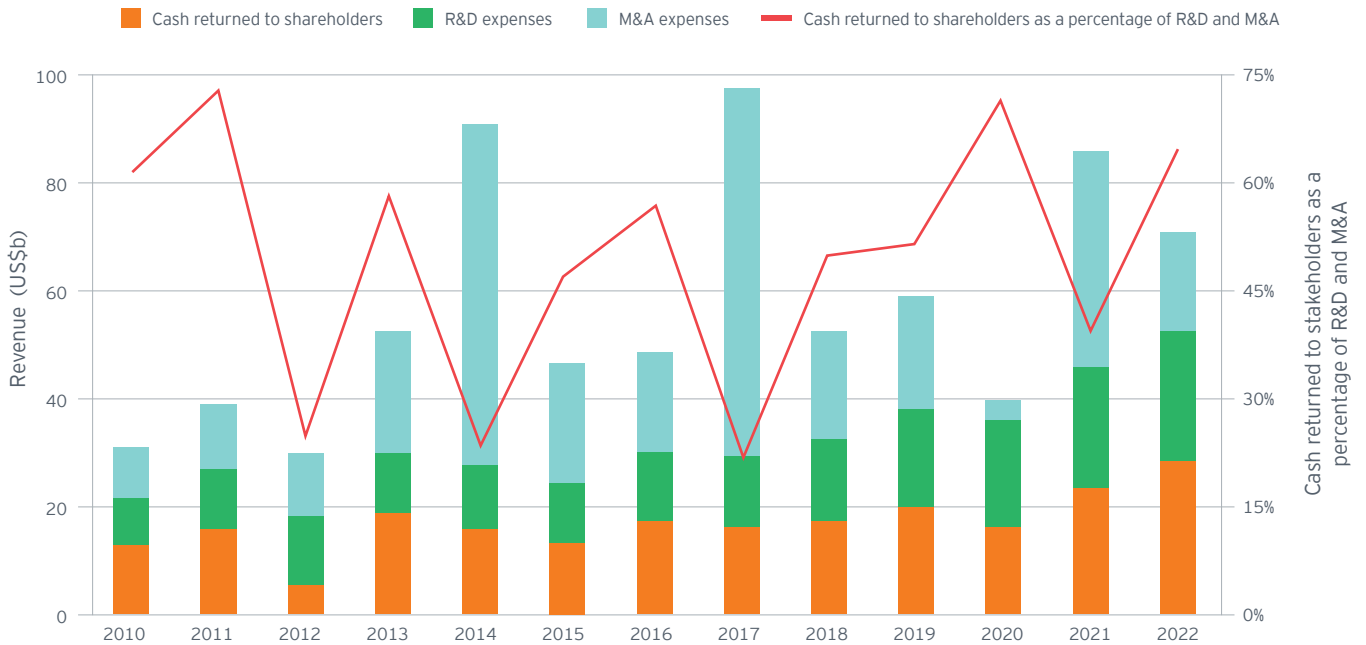
1. "JPMorgan says time to buy MedTech based on past," *MSN website*, <https://www.msn.com/en-us/money/markets/jpmorgan-says-time-to-buy-medtech-based-on-past/ar-AA1fWQGC>, 29 August 2023.

3. How can medtech effectively invest in activities that will drive strategic growth?

In 2022, medtechs rewarded their investors with substantial cash returns to shareholders in the form of dividends and buybacks. The US\$27.8 billion returned to shareholders represents the highest level of returns since we began publishing *Pulse of the Industry*. At the same time, medtech's investment in growth-oriented activities looked less secure in 2022. Though the industry's R&D investment reached a record US\$24.7 billion, this represented a dip in the three-year uptick in the industry's R&D spending growth, which reached an all-time high in 2021 but reverted to historical norms in 2022. M&A expenditure, on the other hand, fell 44%, a steep decline in investment in inorganic growth.

Figure 4

US and European medtech commercial leaders spending trend, 2010-22



Source: Capital IQ, company financial statement data and EY analysis.

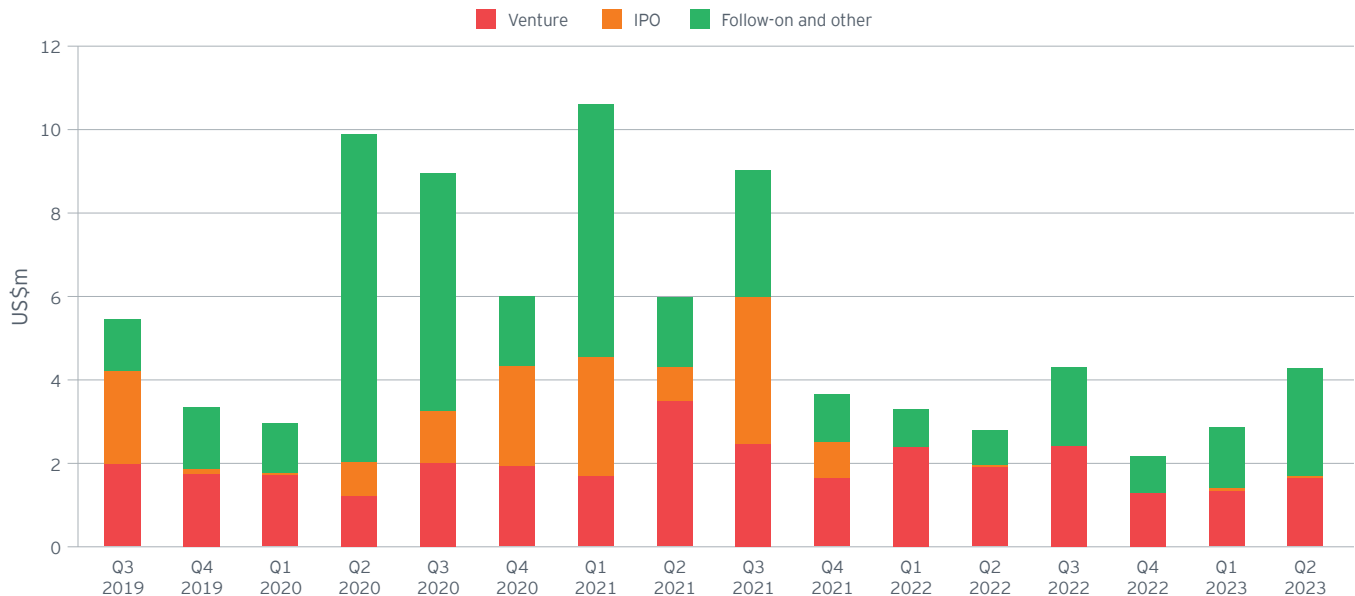
4. How can medtech enable healthy ongoing investment in the broader innovation ecosystem?

From the onset of the pandemic up through the third quarter of 2023, medtech was the beneficiary of an investment spree driven by COVID-19 across the entire health care ecosystem. As the crisis eased and relative normalcy returned, investment in medtech displayed its traditional cyclical pattern, with generalist investors retreating from the sector while rising inflation and other macroeconomic factors hindered growth for many companies. This shift was reflected in a marked tightening in industry financing in 2022.

Though total medtech financing rose 9% to US\$32.8 billion last year, this activity largely derived from a 71% jump in industry debt, which rose to US\$19 billion, and unlike in previous years, the largest debt offerings did not fund acquisitions, but rather went to repay and refinance existing debt, working capital, stock buybacks and other capital expenditures. Equity financing fell 27% to US\$13.8 billion, its deepest point in seven years. This drop reflects a 21% fall in venture financing to its lowest levels since the period from 2015 to 2016, with only 106 venture rounds of US\$5 million or higher executed in the 12 months preceding June 2023. In addition, the industry witnessed a near-total disappearance of the IPO market. This fundraising hit will impact the industry's broader ecosystem of smaller medtechs, which drive innovation but are reliant on financing from the industry's leaders or from external investors to support their R&D activities.

Figure 5

Equity capital raised in the US and Europe by period, Q3 2019-Q2 2023

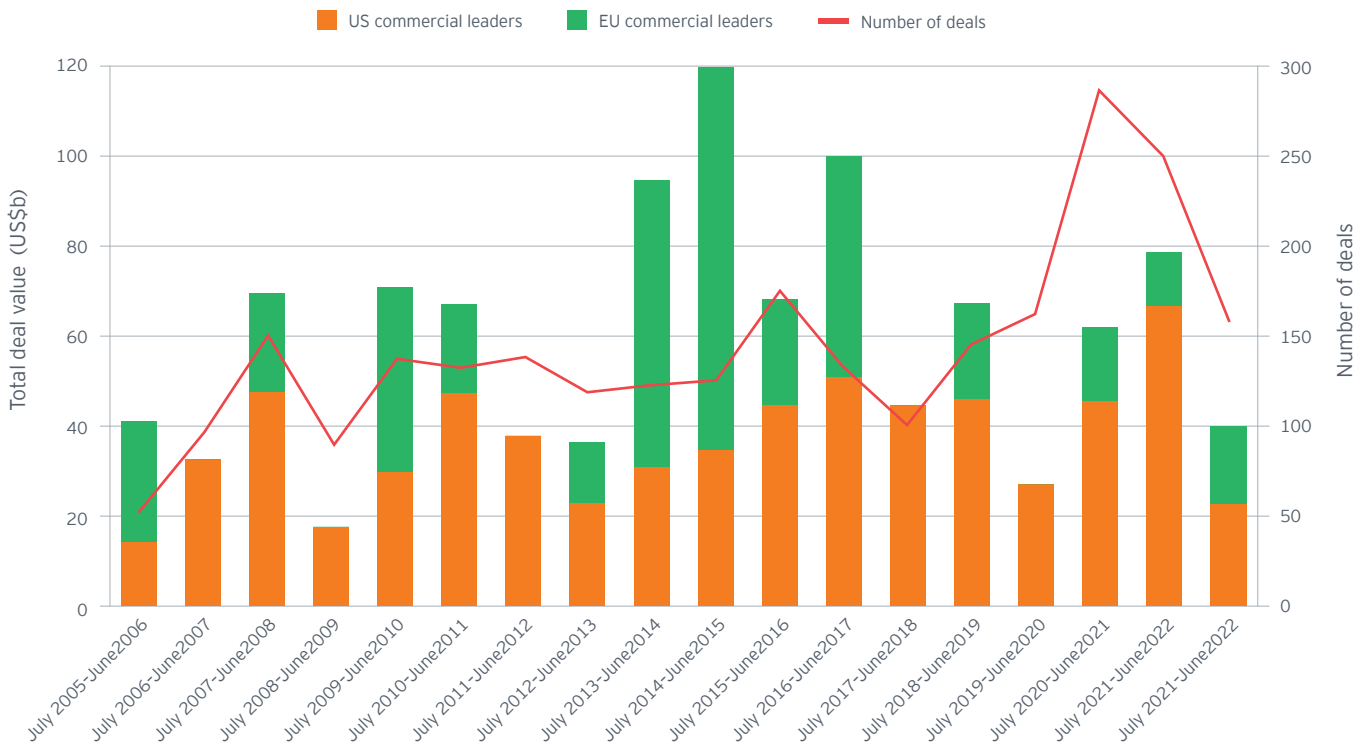


Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ. Private investments in public equity (PIPEs) included in "follow-on and other."

As financing levels dip, these companies will feel pressure to make an exit via acquisition. However, as noted, M&A in the sector also fell in 2022, with the negative trend continuing into 2023. In the 12-month period ending 30 June 2023, deal values were down 44%, and only the US\$16.6 billion Johnson & Johnson acquisition of Abiomed kept values from hitting a 10-year low.²

Figure 6

M&A in the US and Europe by year, H2 2005-H1 2023



Source: EY analysis, Capital IQ and Thomson ONE. Chart includes deals with value disclosed (medtech deal where either acquirer or target is located in the US or Europe).

As the medtech industry seeks to answer the aforementioned questions, it should consider its approach in light of the broader changes that are affecting health care and the life sciences sector, bringing the possibility of transformative innovation for the industry in the near future. Rapidly evolving technologies, increasingly sophisticated consumer demand for more personalized and convenient health care, pressure to change payment models due to aging populations, and a rise in chronic disease incidence are all long-term trends that have unavoidable and significant implications for the industry and will ultimately lead health leaders to rethink how care should be delivered in the future. Our vision for the future direction of life

2. "Johnson & Johnson Completes Acquisition of Abiomed," *Johnson & Johnson website*, <https://www.jnj.com/johnson-johnson-completes-acquisition-of-abiomed>, 22 December 2022.

sciences is the technology-driven reinvention of the sector, which we call the intelligent health ecosystem (IHE). The IHE is a blueprint for a smart, connected, personalized, patient-centered health care model for the future. Within this new model, health care will be:

- Built on ecosystem-wide collaboration and frictionless data sharing between parties
- Delivered by a seamless integration of virtual and digital care channels
- Enabled by the convergence of new technologies and data, and capable of delivering value for all stakeholders

Figure 7

The intelligent health ecosystem of tomorrow

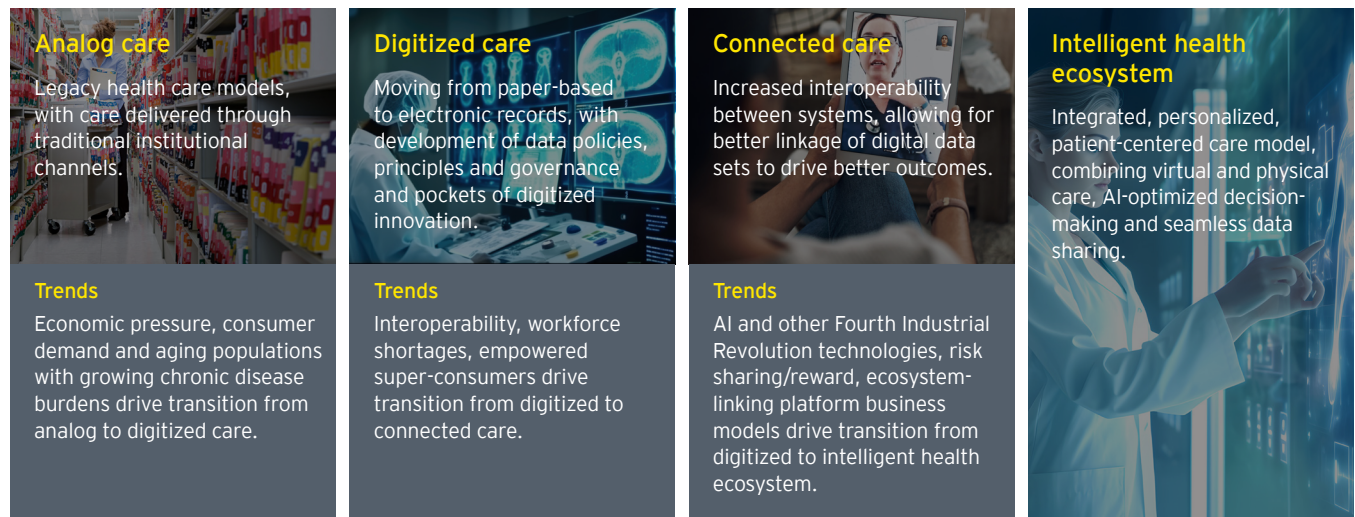
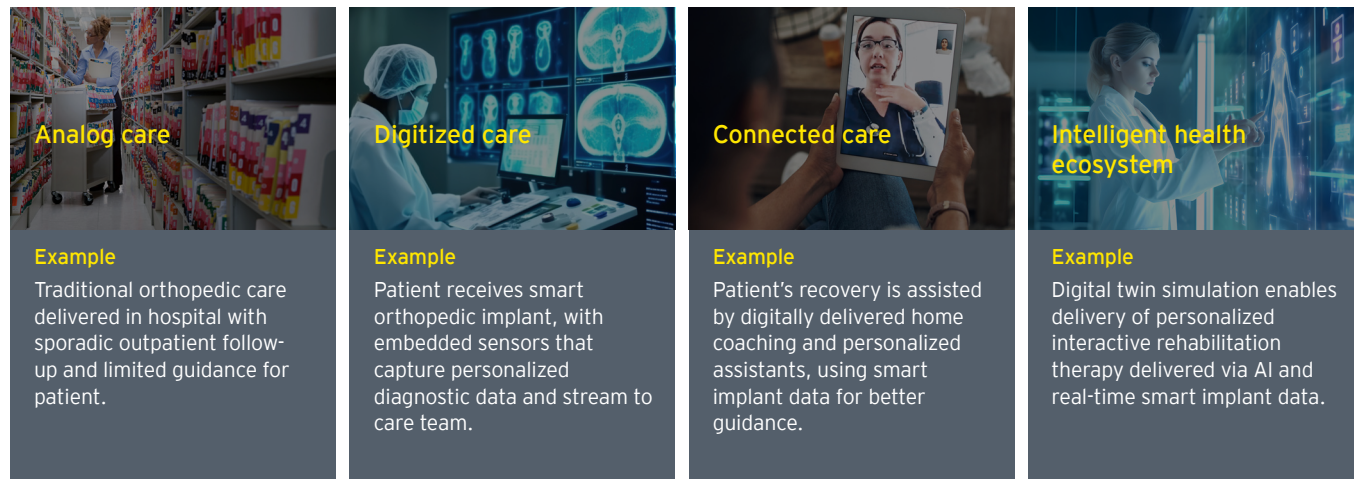


Figure 8

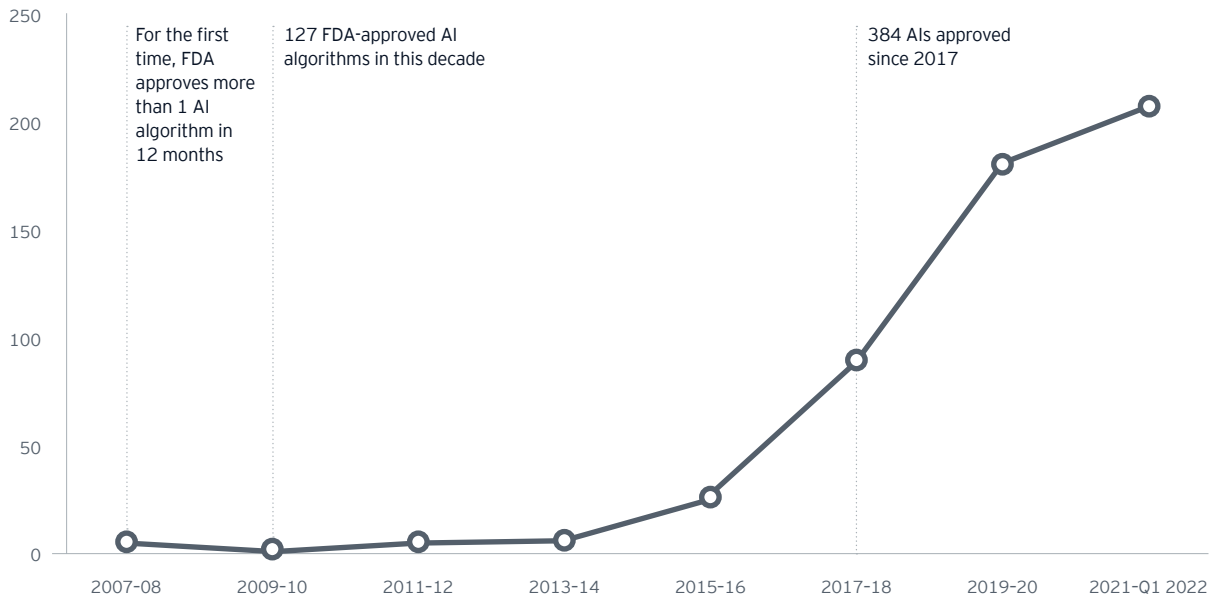
Smart devices will become just one component in care delivery within an intelligent health ecosystem: orthopedic devices example



The rise of these new technologies in the medtech industry is widely reported, with big data, artificial intelligence (AI), cloud computing, sensors, virtual and extended reality systems, and fifth-generation broadband all recognized as future drivers for the industry. Amid a generally slow year for the industry, the pace of innovation for these cutting-edge technologies continued to accelerate. One example of this growth was in the applications of AI in the sector, with at least 91 new algorithms gaining FDA approval in the first 10 months of 2022, making an immediate impact in the diagnostics and imaging diagnostics markets. And while venture financing dropped during this period, some new innovations were attracting capital, including Alphabet's Verily Life Sciences, which raised an additional US\$1 billion in September 2022 to support its efforts in real-world evidence generation and health care data platforms.³ In addition, the cardiac diagnostic developer HeartFlow attracted US\$215 million for AI-powered software that maps the coronary arteries and any potential blockages through a 3D CT scan.

Figure 9

FDA approvals for AI algorithms, 2007-October 2022



July 2022
 Viz.ai wins approval for algorithm to automatically detect subdural hemorrhage.

July 2022
 Verily receives approval for Zio Watch and ZEUS System, an end-to-end solution for identifying and monitoring atrial fibrillation.

June 2022
 EarliTec Diagnostics wins FDA approval for an AI system to help diagnose autism spectrum disorders in children aged 16-30 months.

Source: FDA.
 Database last updated on 5 October 2022

3. "Alphabet's Verily raises \$1 bln in funding round," *Reuters website*, <https://www.reuters.com/technology/alphabets-verily-raises-1-bln-funding-round-2022-09-09/>, 9 September 2022.

Innovations like these – a few examples among many across the medtech ecosystem – bring the prospect of new breakthroughs and new approaches to care in the sector, driven by advances in data and technology. Medtechs need to continue to embrace these innovations, seeing them not as potential bolt-ons to existing offerings, but instead as keys to unlock a bolder strategic vision. Within the IHE, these rising technologies will ultimately converge, forming a smart infrastructure for care delivery anytime and anywhere, beyond legacy institutional care channels. As medtechs seek to adapt to this changing operating environment, they must evaluate and redesign their business models on an ongoing basis, as explained in a recent EY article, “Redesigning operating models to drive life sciences excellence.”

In this report, we explore the drivers that are pushing the industry away from its current norms toward a qualitatively different future approach, evaluating the challenges and opportunities the sector will face as it attempts to bridge the gap from the present to the IHE. In particular, we will take a deep dive into the following opportunities and challenges:

- ▶ The rise of digitalization across the value chain and the opportunities it unlocks for medtechs
- ▶ The emergence of powerful new technological modalities, focusing on generative AI (GenAI) and its implications for the industry (including the potential administrative and other operational efficiencies the technology could help deliver)
- ▶ The opportunities to use digital technologies and data to improve supply chains and other business functions
- ▶ The changing nature of customer demands with a growing emphasis on ambulatory care and other care delivery outside the traditional institutional channels
- ▶ The complex geopolitical situation, particularly the challenges in China, one of medtech's key markets and a geography in which a fast-evolving operational landscape is driving the industry's push to rethink its operations and processes

As always, the report also includes several guest perspectives from medtech leaders on a host of top-of-mind subjects. First, we'll hear from GE HealthCare and Siemens Healthineers on how digitalization, including AI, is creating significant shifts in health care. And last, we spoke with Johnson & Johnson MedTech about the opportunities and challenges for medtechs in China.



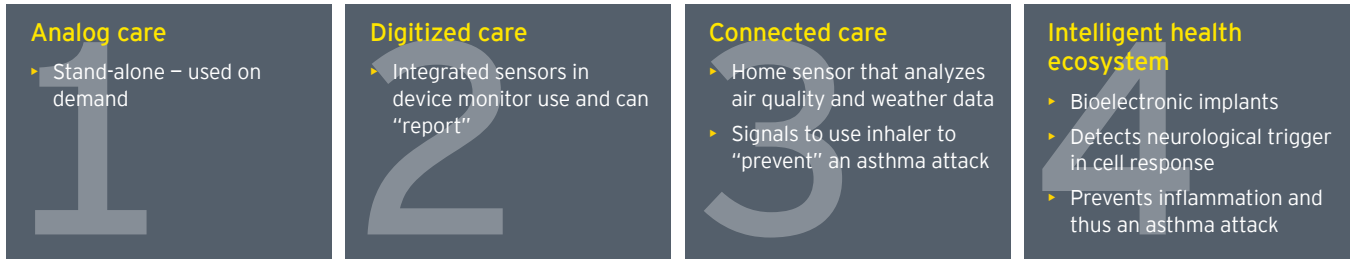
Digitalization in medtech: the unfinished revolution

The digitalization of the medical device industry has progressed over the past five decades, since the first use of computers at the beginning of the 1970s. As usage of digital technology has risen, from the personal computer revolution of the 1980s to the rise of smartphones, cloud computing and AI in the 21st century, medical devices have increasingly incorporated digital technology and algorithms as standard components, with large language models and AI playing an increasingly major role.

EY PERSPECTIVE

Figure 10

A potential intelligent health ecosystem of tomorrow will go beyond simply being digitalized and connected, becoming a truly smart system



However, the lack of digital standards and interoperability across health care systems has limited the potential impact of medtech’s accelerating digitalization. At present, we effectively have a legacy analog health care system with pockets of digitalization, particularly in areas such as imaging diagnostics, where the use of digital technologies and AI analytics is well established. In the therapeutic device field, medtechs are developing ever-smarter devices, such as closed-loop insulin management systems for diabetics, AI-assisted surgical robotic platforms and wearable biosensors. However, these devices are often siloed within a complex ecosystem in that they can capture and transmit data, but the broader systems (human and technological) needed to receive the data and convert it into valuable interventions are still often disconnected.

Consider digitally enhanced devices such as smart inhalers or smart implants. Smart inhalers capture user data and can stream it to physicians to monitor, among other things, the status of a patient’s respiratory condition and the effectiveness with which they use their inhaler. Yet, studying and using this data requires additional time and attention from already overstretched clinicians.

Similar limitations may affect smart implants. The first smart knee implant reached the market in 2021, and, as with smart inhalers, it can capture patient data and share it with clinicians. Yet, clinicians will need to be persuaded of the potential value of this data to improve clinical outcomes.

The challenge that health care faces is not a shortage of data: Today, billions of gigabytes of health data are generated each year, with medical devices contributing to the expanding mass of data around each individual patient. As such, the health industry needs to build a broader ecosystem that can connect, combine and use this data to deliver better personalized care. This approach

is the promise of the intelligent health ecosystem (IHE), our vision for the future of care delivery with a better and more personalized, tech-enabled and data-driven health experience. In the context of the IHE, smart devices would not work in isolation but instead would become part of a seamless network, enabling comprehensive, real-time detection, prediction and intervention.

For instance, in this future state, a smart inhaler would become an integrated component in an IHE that would also bring together sensors that track both environmental and personal data to monitor respiratory risk to the patient and trigger timely action. Ultimately, in a closed loop system, this action may be delivered without need for manual intervention from the patient, with implanted bioelectronic sensors that detect signals of inflammation and disarming neurological triggers.

Similarly, a smart implant would become just one facet of an IHE-delivered solution in which sensors in the implant offer continuous diagnostic monitoring to be fed to care teams in a way that can be easily embedded in workflows. These outputs can be used to provide personalized coaching to the patient. Ultimately, the patient data can be used to create a digital twin, offering better all-around management to the patient.

Creating the IHE will require better alignment and collaboration between stakeholders to jointly realize the potential value of this more connected, powerful and far-reaching ecosystem and to address technical challenges such as the need for systemwide cybersecurity measures to enable interoperability and secure data sharing. Still, the opportunities of collaborating on this vision are immense; in the environment of the IHE, the digitalization of medtech can finally unfold its true potential to deliver personalized care outcomes and experiences.



How AI can transform medtech and deliver precision health care



Elisabeth Staudinger

Member of the Managing Board, Siemens Healthineers



Every person has the right to health care, and where one lives shouldn't determine how well or how long they live. Digitalization brings timely care much closer to people who live in remote areas where medical professionals are few and far between.

Ernst & Young LLP (EY US): How is digitalization changing the face of medical technology and health care?

Elisabeth Staudinger (ES): Rising costs, a shortage of medical professionals and an increase in non-communicable diseases are among today's greatest health challenges in a world where more than half the population still lacks access to quality health care. Digitalization has the power to help us overcome these challenges and make health care more accessible, affordable and precise.

Every person has the right to health care, and where one lives shouldn't determine how well or how long they live. Digitalization brings timely care much closer to people who live in remote areas where medical professionals are few and far between.

Artificial intelligence (AI) and machine learning (ML) in particular will transform health care. AI is already being used to support remote patient monitoring, simplify imaging, and help medical staff make better decisions around diagnosis and treatment. In addition, technology can expand the capacity of individual clinicians to treat more patients. For example, one radiologist can operate three or four different MRI scanners at once, and one clinician who focuses on ischemic strokes can concurrently treat multiple patients in different locations.

Scaling medicine in this manner, and linking patients and health care professionals in new ways, can bring quality care to more patients at a lower cost. Siemens Healthineers has a strong legacy in this field. We have been implementing digitalization and AI for over 20 years, and these are major focus areas for us.

EY US: In what ways does Siemens Healthineers use digital technology to improve diagnosis and treatment?

ES: It starts with seemingly simple things like helping to position a patient correctly for an imaging scan. An MRI normally takes about 20 minutes and is noisy and uncomfortable for the patient. With AI-based algorithms, this time can be cut to about five minutes without compromising diagnostic quality. Something that simple can hugely improve both the patient's experience and the operational workflow.

Siemens Healthineers has deep experience in interpreting imaging data and applying AI to improve diagnostic speed and quality. We have a whole suite of applications that can save radiologists time and reduce error. If, for example, radiologists are looking for lung nodules on a chest X-ray, then AI can read those images quickly and accurately. This AI-augmented precision applies to treatment as well as diagnosis. In cancer treatment, for instance, more than half of patients will receive radiation therapy to destroy malignant tissue. The goal is to target the linear accelerator precisely to conserve healthy tissue. But this approach requires medical physicists to perform complex manual tasks to determine exactly where the tumor is, and there are not enough of these specialists to manage the number of cancer patients we have today. Moreover, when the patient comes in for treatment, other factors may compromise accuracy – they may have gained or lost weight, for example. Digital and AI tools can help medical physicists by outlining the tumor tissue and providing measurements, delineations and 3D modeling to help focus the high-energy beam correctly.



EY US: What are the opportunities and challenges around the data you collect?

ES: Over time, we have built a pool of around 1.5 billion images, which we annotate and feed to Sherlock, our supercomputer based in Princeton, New Jersey, to train algorithms to interpret imagery. Of course, there are many relevant data sources besides imaging that we analyze, from heart-rate information to blood tests and genetic information. At Siemens Healthineers, we are fascinated by the possibilities of digital twinning, integrating all the data sources around a patient to model a digital representation of the individual. This technology would assist us in simulating precision medicine by defining the best treatment, predicting risk factors, and delivering health coaching to monitor and support a patient who is going through therapy. This digital-twin concept is a vision that drives our work. It is challenging, but we can move toward making it a reality if we keep the ultimate goal in mind: a fairer, more efficient, better-performing health care system for everyone, everywhere.

Protecting patient data in health care is extremely important. Some hospitals favor on-premises solutions where the data is kept within the boundaries of the organization. Others use cloud-based solutions where elaborate mechanisms can be implemented for data protection. Cybersecurity is of the utmost importance to Siemens Healthineers, and we continually strive to improve our security and data privacy.

EY US: Which companies do you work with as you develop your offerings?

ES: We have a very strong in-house footprint with big software teams in the United States, Asia and Europe. When we use images to feed our supercomputer’s algorithms, we need to process and annotate those images. However, we also have a network of collaborators spanning the globe in that we work very closely with clinicians and hospitals who know their patients’ needs best, defining requirements and testing algorithms for effectiveness.

Many other companies work on AI in imaging, and we will also team up with those companies as needed. One challenge for smaller AI players is their limited distribution mechanisms. They may be able to build an interesting use case for an algorithm, but it needs to fit seamlessly into the workflow to provide practical support to busy clinicians. So these smaller companies need bigger partners, and if a company has a good solution – perhaps in an area we have yet to focus on in-house – we can be that bigger partner. We can integrate their solution into our platforms and make their algorithms available. It is this close collaboration that enables us to bring our solutions to more and more patients and achieve our goal of improving the accessibility, affordability, quality and precision of health care for everyone, everywhere.



Medtech's critical role in keeping people healthier at home longer

Health care is already evolving away from its traditional roots in brick-and-mortar sites to a model of hybrid care delivered continuously with digital tools.





EY PERSPECTIVE



COVID-19 and the regulatory response aimed at helping manage the pandemic drove a surge in telehealth access and hospital-at-home programs, with the US Centers for Medicare & Medicaid Services (CMS) permitting hospitals to apply for waivers for home treatment of acutely ill patients (over 280 hospitals in 37 US states had joined the program by the end of May 2023).⁴ The US government's omnibus bill of January 2023 extended the waiver flexibility to the end of 2024, but as the pandemic crisis is behind us, we should not look for a return to the less flexible legacy models of care delivery. On the contrary, as the intelligent health ecosystem begins to emerge, this transition to flexible care will accelerate, and medtechs will need to adapt to the change in care channels.

A growing base of evidence supports this shift toward hybrid care models that integrate in-person, home-based and virtual care, allowing patients and providers to seamlessly flex between these modes of care. The shift will require a rethinking of workplace roles, redesigned payment incentives and the growth of concepts such as digital command centers where clinicians can monitor key biometric data, care coordination and hospital at home.

Data suggests that if these challenges can be met, the transition to hybrid care will reduce costs and improve outcomes while freeing up both hospital beds and staff – a key need as health systems attempt to serve an aging, increasingly chronically ill population with a reduced pool of health workers. Remote care can help close these

gaps, with one pilot scheme in Western Australia, for example, indicating that inpatient telehealth delivered via virtual ward rounds in the absence of available general practitioners enabled 87% of patients to be monitored without need for transfer.⁵ In Alberta, Canada, virtual care has expanded access to a dispersed population with limited direct access. And in the US, a trial at Mass General Brigham suggested that home-delivered care could cut the cost of an episode of care by 38%.⁶ We explore other recent experiences with hybrid care models schemes and the evidence of effectiveness they have generated in a recent Ernst & Young LLP article, "How virtual and in-person care merge for a healthier, sustainable future."

For medtechs, the challenge is to learn how to adapt their operations to help these evolving care models gain scale. They also need to approach design with the consumer and clinician in mind. One study from the Netherlands noted that up to 32% of care could be shifted to the home but that this would require an investment in medical devices that can deliver remote monitoring and care.⁷ Many leading medtechs are already investing significantly in remote care, a market projected to grow with a 20% compound annual growth rate from 2022 to 2030.⁸ In addition to developing these technologies, medtechs must seek to partner with a wider range of stakeholders, including health organizations, retailers, governments and community organizations, to help new hybrid care models achieve scale.

4. "Minute Insight: Inbound Health Now Offers Post-Surgical Hospital Care At Patients' Homes," *Medtech Insight website*, <https://medtech.pharmaintelligence.informa.com/MT147960/Minute-Insight-Inbound-Health-Now-Offers-Post-Surgical-Hospital-Care-At-Patients-Homes>, 31 May 2023.

5. "Snapshot: WACHS Command Centre," *Government of Western Australia website*, https://wacountry.health.wa.gov.au/~media/WACHS/Documents/Services/Command-Centre/Command_Centre_snapshot_v2.pdf, 28 August 2023.

6. "Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial," *National Institutes of Health website*, <https://pubmed.ncbi.nlm.nih.gov/31842232/>, 17 December 2019.

7. "Budget impact analysis of providing hospital inpatient care at home virtually, starting with two specific surgical patient groups," *BMJ Open website*, <https://bmjopen.bmj.com/content/12/8/e051833>, 1 August 2022.

8. "Remote Patient Monitoring Market size worth \$ 166.52 Billion, Globally, by 2030 at 20% CAGR: Verified Market Research®," *PR Newswire website*, <https://www.prnewswire.co.uk/news-releases/remote-patient-monitoring-market-size-worth-166-52-billion-globally-by-2030-at-20-cagr-verified-market-research-301872847.html>, 10 July 2023.



EY PERSPECTIVE

But teaming in this way means proving to the ecosystem that medtechs are an essential partner in improving care outcomes and the experience of both clinicians and consumers. By improving data fluidity in the ecosystem, medtechs can play an indispensable role in enabling value-based care models. Personalized care can only happen if informed by a full range of data that reflects the realities of how people live. Being a full partner in the health ecosystem can help medtechs better design their products for both the consumer and the clinician.

Medtechs will also need to work closely with the ambulatory surgical centers (ASCs) that have grown rapidly in recent years, enabling many procedures (especially in the orthopedics field) to move toward outpatient settings. The Ambulatory Surgery Center Association claims that operations delivered in this manner are up to 45% less expensive than hospital admissions due to the lower overhead costs.⁹



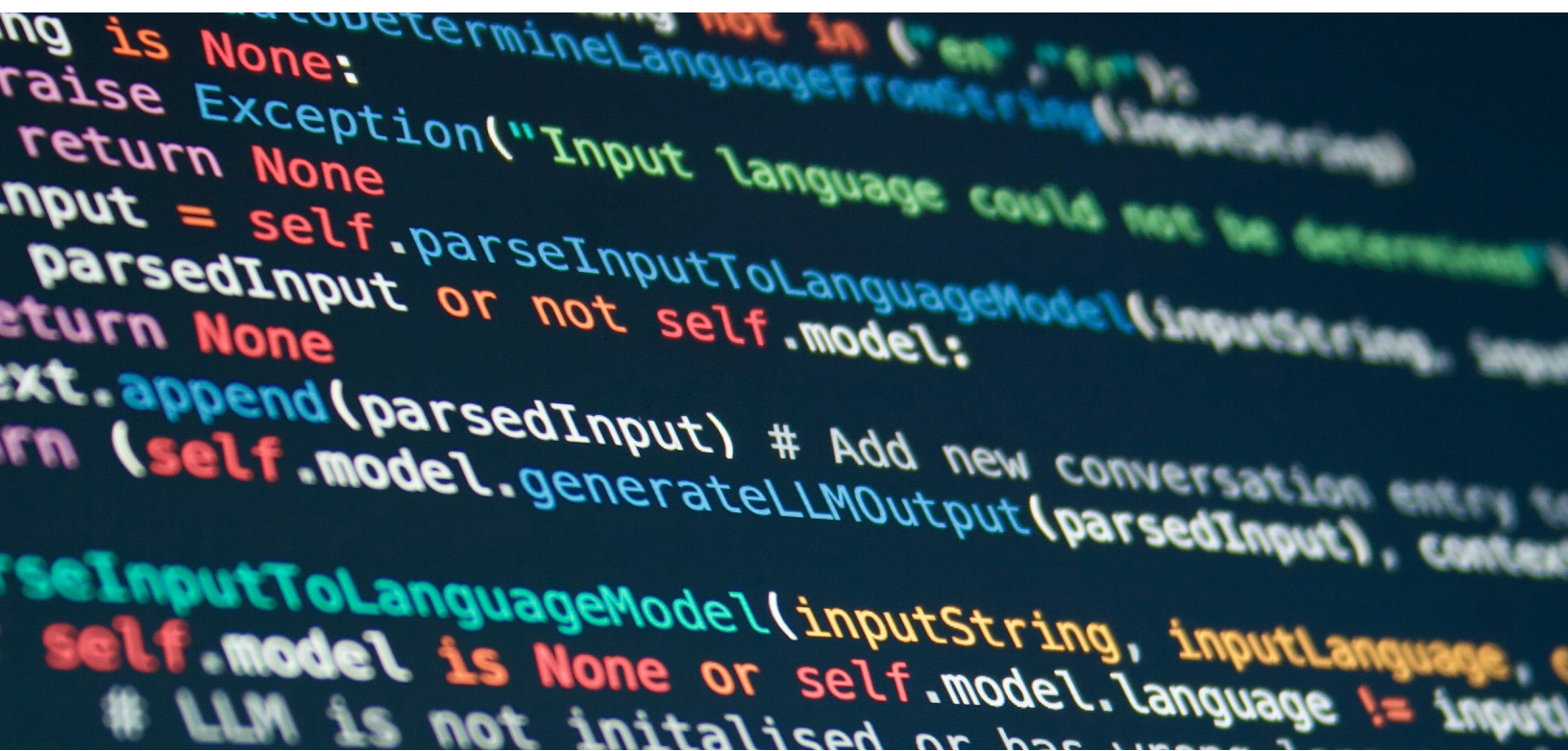
In addition, medtechs should seek to bring their innovations directly to patients. Direct-to-consumer (DTC) devices are a growing market, with the FDA permitting, for example, over-the-counter sale of hearing aids in 2022. This market opening will potentially admit a range of new entrants from big tech players to retailers, while widening customer choice and driving down costs. But as medtechs move closer to patients, human-centered designed is critical to consumer adoption, as is making sure the technology is available, actually installed and used correctly in the home. Expanded broadband access is also critical for engaging rural and disadvantaged communities.

Another major area of DTC focus is the home diagnostics market, which gained significant traction during the pandemic. Large medtechs, including Abbott, Becton Dickinson, Labcorp and Siemens Healthineers, are all active in the in-home diagnostics space, with offerings ranging from COVID-19, flu and RSV diagnostics to cancer, fertility and diabetes testing. Moreover, Quest Diagnostics has stated that DTC testing will become a US\$2 billion breakout business by 2025,¹⁰ helping medtechs move closer to patients and away from the constrictions of traditional care delivery models.

With the greater depth of individualized patient knowledge generated through remote monitoring apps, wearables and other sensors that are driving the rise of hybrid care models, the opportunities to improve care rise exponentially. A far more proactive, data-driven, user-friendly and personalized care management model, stratified according to consumer preferences and lifestyle and health options, now has the chance to emerge. Serving patients from primary care through to post-surgery, this improved care model will aim to keep the patient healthier at home for longer, avoiding the need for patients to move to higher-cost emergency departments while also delaying disease progression. Ultimately, this journey will lead to the intelligent health ecosystem: a future in which health technology becomes omnipresent and ambient, wrapping the patient in a moving cloud of care that constantly analyzes and refines itself to deliver better outcomes and a better health experience.

9. "The ASC Cost Differential," *Ambulatory Surgery Center Association website*, <https://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/paymentdisparitiesbetweenascsandhopsds>, August 2016.

10. "Quest eyes \$2B DTC testing potential to capitalize on 'breakout' consumer growth," *MedTech Dive website*, <https://www.medtechdive.com/news/quest-eyes-2b-dtc-testing-potential-to-capitalize-on-breakout-consumer-g/596609/>, 12 March 2021.



Building on breakthroughs: generative AI's opportunities and lessons for medtech

The breakout success of generative AI in 2023 is a signal of how dramatically new disruptive technologies can gain importance and how rapidly companies may need to adapt. Capable of creating text, images, and other media based on analysis of high volumes of training data, generative AI came to prominence this year with the mainstream impact of various large language models (LLMs). Medtechs, like companies in every sector, have found themselves grappling with the implications and opportunities of these new technologies.



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Across the health care space, one of the immediate applications of generative AI is its ability to automate aspects of content creation. For health care providers, this primarily represents an opportunity to generate clinical documentation around clinician-patient interactions without the direct input of the clinician. Combining an LLM with conversational and ambient AI would allow clinicians and patients to converse as usual while the clinical notes are generated. The same acceleration of content generation has implications across the operational workflow of the entire health ecosystem. The rigorous regulatory frameworks present in the sector represent a significant demand in terms of paperwork and bureaucracy, including across tax, legal and other critical functions. These administrative processes have traditionally required major commitments of time and human input, but optimized generative AI models that can expedite this operational burden will free up time and energies for reinvestment into more value-additive activities.

These regulatory and operational applications will be identified and implemented within medtech companies, as with other health and life science players, since the potential risks are low once quality assurance has been established. Assuming the source of the data is finite and the GenAI tool follows a trusted governance model, the possible benefits of this approach are extensive, particularly at a time when companies in the sector are wrestling with staffing shortfalls and other workforce challenges such as physician burnout in the wake of the extraordinary demands imposed by the pandemic crisis. Another major area of adoption for generative AI in medtech will surely come in commercial operations. For example, the technology's ability to tailor the technical language for physician or a patient will help streamline medical communications. There are also efficiencies to be created by using AI learning models to fit patients for orthopedics, for example.





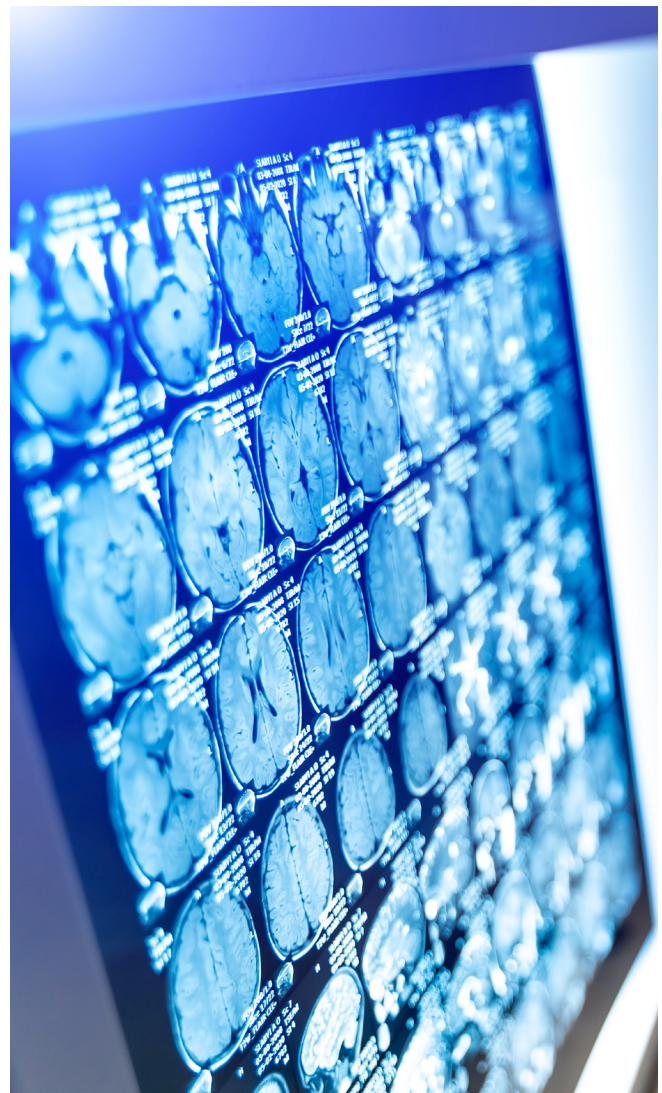
EY PERSPECTIVE

In addition to operational optimization, generative AI will also be useful in the hospital setting. These frontline applications in health care delivery could include, for example, using LLMs to generate clinical reports, treatment plans, and guidance or advice to patients. Potentially, generative AI in this context could also expand the current role of digital triage, which today is usually carried out by simple algorithms. But when built around human conversational interactions with a generative AI tool that can produce complex and sophisticated responses to patient inputs, these algorithms could provide significant diagnostic and analytical functionality. Through this application, generative AI platforms could take on a more demanding, value-additive role themselves, yet because the associated risks are higher, companies will need to develop policies and procedures related to governance, risk and legal.

The same challenge will affect frontline medtech applications of the technology. For example, generative AI models can theoretically be used to develop novel medical device designs. Given specified inputs, a 3D generative AI model also could create a range of possible design prototypes, perhaps including personalization in accordance with the specific inputs the model receives. Designers could then refine or reiterate these models. In some respects, this approach to medical device design would represent the next generation of generative design, a technology for 3D modeling based on cloud computing with AI elements.

Above all, it will be critical for medtechs to understand generative AI in context: It will not be a stand-alone solution to business challenges but will rather form part of the suite of digital tools the industry can leverage. Within this portfolio of offerings will be significant convergence and crossover. Generative AI may contribute to the effectiveness of other digital offerings, writing and refining better software for medical devices and generating novel training data sets to improve radiology algorithms or other machine learning models and other applications.

The broader lesson of the generative AI excitement in 2023 is that as innovation accelerates, we can expect new tools and technologies to break into a market that already boasts a high level of maturity and potential use cases. To seize the opportunities these new technologies present and integrate them rapidly into their own evolving intelligent health ecosystem offerings, medtechs need to maintain an agile mindset and operational approach. Companies that do so will be well positioned to build long-term value.





How AI is going to revolutionize imaging



Parminder Bhatia
Chief AI Officer, GE HealthCare



While generative AI is a budding technology, GE HealthCare has been using artificial intelligence and machine learning (AI/ML) in its medical device products for more than a decade. The recent GE spinoff company has become a pioneer in emerging health technologies, leading the way for innovative forms of medical imaging that create efficiencies for both patients and providers. We recently sat down with a key hire for GE HealthCare, new Chief AI Officer Parminder Bhatia, to discuss how the technology has evolved and what lessons he brought from his former employer, Amazon.

GE HealthCare has more than 45 AI-enabled device authorizations from the FDA.

EY US: Tell us about GE HealthCare’s history with AI and how that has evolved over time.

Parminder Bhatia (PB): I’ve been following GE HealthCare for a long time, and my decision to join them recently was driven by their dedication to innovative advancement. GE HealthCare utilizes machine learning to help enhance diagnosis and streamline radiology workflows.

GE HealthCare has more than 45 AI-enabled device authorizations from the FDA. Our SonoCNS product, for example, cuts ultrasound fetal brain exam keystrokes by 80%. And our new Sonic DL offers MRI scans up to 12 times faster than traditional methods, allowing cardiac imaging in just one heartbeat. Additionally, AIR™ Recon DL, a deep-learning MRI technology, boosts quality, care efficiency and the radiologist’s workflow. Not only does it reduce scan time by nearly half through automation without compromising on image quality, but it has also served over an estimated 10 million patients since we introduced the technology in 2020, early in the pandemic. These innovations exemplify GE HealthCare’s decade-long commitment to progress. It’s a continuous process that keeps going.



EY US: Over the last several months, generative AI has become a hot topic. Has GE HealthCare started thinking about how it can use generative AI or large language models?

PB: Yes, definitely. GE HealthCare recognizes the transformative potential of generative AI and large foundational models and is taking active steps to harness their capabilities. My previous tenure at Amazon equipped me with valuable insights and experience, as I spearheaded the company's HealthAI initiative. This initiative saw the birth of trailblazing services like Comprehend Medical, which stands out as a premier health care-specific natural language processing (NLP) tool on the cloud. After that, I spent three years working on foundational models and generative AI technologies. So I joined GE HealthCare to bring these two competencies together.

Since my move to GE HealthCare, we've set our sights on a broader horizon. We're driven by a mission to revolutionize health care interfaces by integrating voice, text and the latest in AI visualizations. This approach isn't just about technological novelty; it's also about creating user-centric tools that aim to redefine how medical professionals interact with and leverage technology, improve their efficiencies and, ultimately, improve patient experience and outcome.

But our ambitions don't stop there. We're challenging the status quo by developing AI solutions that are not limited to specific anatomies or imaging techniques. We are also working toward models that can be applied across a range of diagnostics modalities, such as CT scans, MRIs and ultrasounds. This broad-spectrum approach was underscored by our recent achievement: a 510(k) clearance for an innovative automatic MRI slice placement for workflow efficiency model designed for MR brain scanning, AIRx™. Similarly, we aim to develop AI capabilities that address multiple anatomies at once, rather than just one. After achieving a 510(k) clearance for an auto-segmentation model that covers 40 organ parts in CT, our goal now is to create models that are versatile enough for CT, MRI and ultrasound data. Our heavy investment in this direction is anticipated to significantly boost growth in AI applications for workflow, optimization and decision support.

As we deepen our investments in AI, our key areas of focus include honing operational efficiency and pioneering advancements in service automation. We're acutely aware of the post-sales lifecycle of our products, and we're dedicated to offering unmatched support to our clients following device deployment. Through a fusion of automation and AI-driven tools, we aim to set new industry benchmarks in customer service and operational excellence.





EY US: Where do you see GE HealthCare taking its work with these emerging health technologies?

PB: At GE HealthCare, our D-3 precision strategy focuses on integrating smarter devices, a disease-specific approach and digital solutions to address workflow inefficiencies and enhance care quality. We aim to develop scalable technology that can tackle a wide range of diseases using digital prowess. Generative and foundational models are vital here, as they could allow us to quickly adapt to different diseases for screening, early detection, progression and even pinpointing noninvasive biomarkers with minimal training (zero-shot or few-shot setting). Envision a future where we can swiftly create digital tools following a new drug’s approval, optimizing the entire disease management workflow within weeks. That’s our direction.

EY US: What are your thoughts on the importance of AI explainability, and how is GE HealthCare building that into its products?

PB: AI explainability is a cornerstone of responsible AI, and at GE HealthCare, we prioritize making our AI models transparent and understandable. The surge in popularity of generative and foundational models, especially within health care, stems from their proficiency in multimodal settings. Imagine an AI system that can interpret an image and, in parallel, articulate its findings in clear, human-like language. This capability not only helps users understand the results; it also aids in refining the model itself. For example, generative AI can distill complex medical reports, presenting summaries tailored to different audiences: from patients to clinicians and radiologists. The same data can yield varied interpretations, making the information more accessible and relevant to the user, be it the radiologist, surgeon or patient.

However, explainability is merely one aspect of our commitment to responsible AI. Interoperability, defined as the ability to interpret and function across various platforms and settings, is vital, especially in addressing data privacy concerns. Bias minimization, another integral aspect, ensures our AI models are fair and unbiased. Last, we believe in rigorous, multisite validation. This thorough vetting, conducted over numerous locations, is essential before any of our technologies are deemed ready for real-world applications. At GE HealthCare, we have a legacy of medical device innovation whereby we always have had to show our work and explain how our products are built via our quality and regulatory frameworks. We are in an advantageous position to leverage that legacy to ensure supported and responsible AI.

How medtech can build resilient supply chains for the future

For medtech, supply chain has emerged as a priority operational concern, with companies increasingly recognizing the need to better deploy digital technologies and data-driven insights to increase their operational efficiency and resilience while improving working capital levels.





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The global pandemic shone a spotlight on supply chain risk exposures, causing high-demand volatility as demand surged for certain key product lines (e.g., ventilators, personal protective equipment, diagnostics) and plunged for other goods, with elective surgeries deferred or canceled. As the pandemic has eased, further operational challenges have emerged, including rising equipment and labor costs driven by soaring inflation and interest rates, port congestion and other shipping challenges; increased energy costs in the wake of geopolitical uncertainty in Eastern Europe; and multiple other disruptions.

Key issues for industry supply chains today include securing access to labor, raw materials (including alloys and metals) and key components such as semiconductor chips, which have witnessed a significant increase in lead times since 2020. Sterilization of equipment is another ongoing concern, with a spate of lawsuits and updates to the National Emission Standards for Hazardous Air Pollutants (NESHAP) pressuring companies to reduce use of ethylene oxide (a recognized human carcinogen that is increasingly linked to adverse health outcomes).

For medtechs, negotiating these and other emerging operational challenges will mean investing strategically in greater supply chain resilience, defined by these five criteria:

- ▶ **Reliability:** the degree to which a supply chain yields consistent performance and quality
- ▶ **Time to innovate:** the time it takes to bring a new product to market, factoring in the regulatory approvals for the manufacturing system
- ▶ **Agility:** the supply chain's reaction speed to changes in the market, in demand mix or in regulation
- ▶ **Risk exposure:** the degree to which a supply chain is exposed to existing or new risks
- ▶ **Efficiency:** the financial impact considering capital and operating expenditures as well as remnant cost

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There is no off-the-shelf model for companies to improve resilience across all these dimensions. We can expect to see greater traction for strategies such as building better supply chain visibility, enabled by digital upstream and downstream monitoring of dynamics within the supplier base and customer base. Technology platforms are already emerging to drive these strategies forward. Approaches such as this augmented supply chain visibility will go hand in hand with more proactive supply chain planning, better definition of manufacturing and distribution capacity, and improved supplier collaboration. Tighter integration of operations between medtechs and their key suppliers, including sharing information on forecasts and projected risk exposures, may become an increasingly critical part of how the supply chain system works.



Beyond enhanced collaboration, greater emphasis on manufacturing location is also set to play a key role in how medtechs plan their supply chain strategies. While supply chains in the life sciences, as in other industries, have become increasingly globalized in recent decades, we may now be witnessing a countertrend toward more localization, with governments placing greater strategic emphasis on self-reliance at a national or regional level. Some degree of unwinding is likely to take place in regard to medtech supply chains. The end state, however, is likely to be not full localization but rather the emergence of a variety of hybrid models, balanced across local, regional and global sites to enable greater resilience.

As they work with governments to establish priorities and parameters for future supply chain planning, medtechs will also need to weigh other factors in their efforts to identify preferred manufacturing sites. These factors will include:

- ▶ Negotiating and de-risking local complexities, such as regional conflicts and instability and data restrictions within certain markets
- ▶ Evaluating the financial stability within different geographies as global macroeconomic volatility continues
- ▶ Assessing sustainability, regulation and carbon footprint in different geographies
- ▶ Determining the relative availability of talent, with companies needing access to key skills and expertise in the regions where they intend to focus their manufacturing strategies
- ▶ Building an energy strategy that can secure supply, including assessing energy independence within certain countries

Medtechs will continue to develop their strategies for securing and improving supply chain operations in multiple directions. In every case, a key factor will be ensuring that companies build their approach and decision-making processes on a higher quality and quantity of data, as they seek the optimal approach to construct robust medtech supply chains for the future.

Tapping into new markets: how to enter China's medical device industry

With a population approaching 1.5 billion people, China and its vast market bring undeniable allure for just about every sector. For companies in the health care space, a confluence of factors is making the Chinese market a must.





EY PERSPECTIVE

China's aging population, increased affluence and greater access to health care due to rapid urbanization mean there are millions of potential new patients for companies across the health ecosystem. It is a market that is growing faster than other already mature health care markets, and for many of the big players in the medical device space, it is the number two market behind the US. The medical device market in China, worth US\$46 billion in 2022, is expected to grow by 8.6% to more than US\$70 billion by 2027.¹¹ But tapping into this growth is not easy, and selling in China requires a different savvy than entering some of the more established markets.

Commercialization plans that have worked for decades in markets such as the US and Europe are not suited to the regulatory environment that characterizes the Chinese health care market, prompting medical device manufacturers to explore new strategies for accessing the more than 1 billion consumers in the country and often requiring companies to be in China, for China.

Conquering the challenges

The first step to accessing the Chinese market is understanding the country's complex regulatory system and the leadership approach that is the driving force behind that regulation.

China's publicly announced economic plans over the last several years, including the Made in China 2025 plan, have put a strong emphasis on bolstering the country's internal know-how in areas of technology, including medtech. Announced in 2015, the state's plan for its future highlights the importance of domestic manufacturing in key technological areas, elevating medical technology to crucial status. This has geared the market toward homegrown Chinese companies, while organizations that import goods can expect to face increased examination and approval. The 2022 revision of China's Law on the Progress of Science and Technology also created further financial incentives for domestic companies.

To achieve the aims laid out in the Made in China 2025 plan around being a leader in areas such as robotics, big data, artificial intelligence and digital health care

solutions, the state has created regulation to influence those markets. For example, in August, China's State Council adopted work plans to promote high-quality development of locally manufactured pharmaceutical and medical equipment.

In addition, volume-based procurement (VBP) kicked off in 2018 for pharmaceuticals and 2020 for high-value medical devices. Through this approach, China seeks to lower medical costs within the Chinese health care system by promising large volume procurement to the company that can offer the lowest price.

From 2018 to 2022, China implemented seven rounds of national volume-based procurement (NVBP) that reduced the prices of 294 formulations of multiple drugs by an average of over 50%. While pharmaceutical players have other options for selling their products, medical device companies could be excluded from the market if they don't have access to hospital channels. In 2020, the NVBP list included coronary stents, and it has since been expanded to include other devices, including hip and knee implants, surgical staplers, and intraocular lenses, among others. According to the National Healthcare Security Administration in September 2022, centralized VBP for orthopedic and spinal consumables is expected to reduce prices on average by 84% for selected products.

The program has dramatically curbed the cost of medical devices to the Chinese health care system, but it has also allowed for greater penetration into the market as patients get greater access to once costly procedures.

In a boon to multinational companies, China has also increased the number of medical device products on its National Encouraged List, which encourages foreign investment in the manufacturing of certain products or technologies. These additions included AI-enabled medical aid equipment, high-end radiotherapy and surgical equipment, rehabilitation equipment, and wearable health devices.

While regulation and pricing are certainly challenges for multinational companies that are seeking to compete in China, they aren't insurmountable.

11. "Asia-Pacific (APAC) Medical Devices Industry Outlook 2023," *Frost & Sullivan website*, <https://store.frost.com/asia-pacific-apac-medical-devices-industry-outlook-2023.html>, 18 April 2023.

Crafting the right strategy

For any medical device company that’s looking to enter the Chinese market, leadership will have to find the strategy that best fits the organization’s operational structure and needs. There is no one-size-fits-all approach, but here are several strategies to consider:

1. **Optimize costs.** Lowering supply chain and manufacturing costs can allow a company to better compete during the VBP process, which typically awards the contract to the manufacturer that can offer the most cost savings. These contracts guarantee volume and allow companies to forgo the marketing and commercialization costs typically associated with a launch.
2. **Focus on innovative devices.** The VBP lists focus on high-value products that are older and typically readily available or generic in other mature markets. It is still possible for multinational companies to sell unique medical device products at higher prices, and innovation is less likely to be undercut by local suppliers. Innovative products also garner a fast-track approval status under China’s medical device classification system, allowing these products to get to market more quickly.
3. **Leverage technology licensing.** While this strategy allows multinational companies to gain a rapid foothold for a product in China, it can also present challenges due to the transfer of intellectual property. IP risk can be mitigated by limiting China to more mature technology. Short of out-licensing technology, some companies have found success by creating local iterations of products vs. outright innovation.
4. **Pursue local manufacturing or joint ventures.** Local manufacturing and joint ventures provide foreign multinationals with greater access to the Chinese market, allowing them some of the same privileges as homegrown domestic Chinese companies and avoiding many of the delays associated with importation. In these instances, it is imperative that the workforce consists of local talent who can understand the regulatory system in China and may have stronger relationships with local officials. Daily interactions with local government are fundamental around influencing decisions, forecasting policy trends, and lowering strategic and operational risks.
5. **Invest in local companies.** One way to quickly develop a local presence is to buy a majority stake in a publicly traded company listed on the Hong Kong Stock Exchange. This strategy has the benefits of providing local executive talent as well as a locally based sales network. It also provides cross-selling capabilities for both companies.
6. **Consider best practices for interaction with local government.** Companies should consider Foreign Corrupt Practices Act (FCPA) risks when interacting with other governments and government employees, in addition to assessing local regulations and regulatory trends when entering and expanding in a market. In China, hospital employees, and even doctors, are considered government employees. The Chinese government recently stepped up an antibribery campaign focused on doctors who receive bribes and the companies that offer them.

Entering the Chinese market likely means using some combination of these strategies, and challenges will remain once a company gains access. Further, companies should be cognizant of intellectual property and cybersecurity issues during strategy implementation.





The key to operating successfully in China: integrating into the local ecosystem



Tim Schmid

Company Group Chairman,
Johnson & Johnson MedTech, Asia Pacific





While entering the China market presents many challenges and complexities, keeping some companies on the sidelines, the opportunity to impact patients' lives is enormous. As one of the first multinational health care companies to enter China, Johnson & Johnson MedTech¹² has been dedicated to the market, underscoring our commitment to serving this region. We have amplified our commercial, manufacturing and innovation capabilities to cater to the current and future needs of the Chinese population. While we initially focused on lifting and shifting existing sales and marketing strategies from other markets to China, we soon recognized the need for a distinct approach. We also understood that to succeed in China, immersing in the local ecosystem was not an option but a necessity. This approach essentially meant harnessing local talent; collaborating closely with local stakeholders; and forming partnerships with domestic companies around R&D, manufacturing and commercialization.

China's earlier reputation for producing low-quality or copycat products is outdated. Today, the country is making leaps in innovation, including in medical technology. Matching, if not surpassing, global benchmarks, China's domestic R&D investments often eclipse those of international giants. Local players are emerging with comparable quality and technology in multiple categories, especially in the digital realm, such as AI-assisted diagnostics and surgical robotics.

China's insatiable demand for digital health, coupled with its ability to adopt it swiftly, has been further accelerated by the COVID-19 pandemic. For instance, there are now more than 100 local companies developing surgical robotics and planning products, covering all five major subsegments in orthopedics, laparoscopy, neurology and dental. In 2022 alone, there were at least 15 local surgical robotics and planning products approved by China's National Medical Products Administration (NMPA), compared to less than five each year previously.

To tap into this innovation engine as Johnson & Johnson, we have been deliberately integrating ourselves into the local ecosystem and focusing more on creating partnerships. Chinese biotech and medtech companies are becoming increasingly attractive partners across both our Innovative Medicine and MedTech sectors. Within medtech, we explore various commercial models with our strategic partners and determine whether there's further potential to evolve these relationships into deeper partnerships. Committed to advancing health care innovation, we are continually on the lookout for partners whose unique capabilities complement our strengths and who also share a commitment to building trust through integrity and compliance.



12. Johnson & Johnson MedTech refers to the business conducted by Johnson & Johnson Medical (Shanghai) Co. Ltd. in China.



Translating global efforts into commercial success in China

China stands out as a uniquely intricate marketplace that demands a deep understanding of and adherence to local market dynamics and regulations. In China, technical superiority does not always translate into commercial success. Successful navigation requires technical differentiation coupled with price sensitivity and a strong clinical presence, something achieved only through a grounded, hands-on approach. Additionally, investments in funding and resources need to align with the nuances of local market conditions and flex accordingly.

The landscape in China is continuing to rapidly evolve, especially as local companies set their sights on global ambitions. While not without complexities, China's potential matches few markets today for multinational medtech companies. Put simply, the next China is China.

Prioritizing the development of local talent

We recognize that success in China requires a strong focus on building clinical advocacy with health care professionals and partnering with multiple stakeholders to help accelerate the high-quality development of China's health care system. However, the key to this collaboration lies in local talent.

Language, cultural barriers and highly dynamic market conditions can challenge foreign talent to engage meaningfully within China. We've made strategic investments in identifying, developing and nurturing top talent through a robust process, starting with recruitment from graduate programs. Despite facing heightened competition for talent from local companies, we provide a desirable opportunity for candidates who are interested in global careers. Our multiple development programs offer new MBA recruits exciting roles and a chance to work in various regions around the globe before returning to China.





DATABOOK

Financial performance

Figure 1

Medical technology at a glance (US\$b)

	2022	2021	Change	% change
Public data company				
Total revenue	\$573.4	\$554.0	\$19.4	3.5%
Conglomerates	\$240.9	\$238.7	\$2.2	0.9%
Pure-play companies	\$332.5	\$315.3	\$17.2	5.5%
Commercial leaders	\$309.4	\$292.3	\$17.2	5.9%
Emerging leaders	\$23.1	\$23.0	\$0.1	0.3%
R&D expense	\$29.8	\$27.6	\$2.2	7.8%
SG&A expense	\$107.1	\$100.0	\$7.0	7.0%
Net income	\$14.3	\$39.5	\$(25.3)	(63.9%)
Market capitalization	\$1,572.8	\$2,184.6	\$(611.8)	(28.0%)
Number of employees	1,129,800	1,066,500	63,300	5.9%
Number of public companies	454	453	1	0.2%

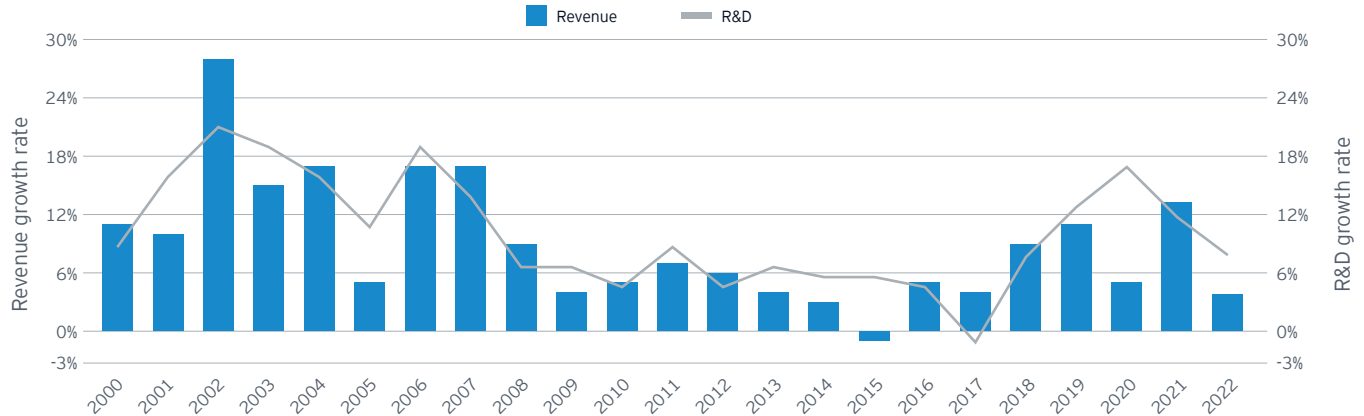
Source: EY analysis, Capital IQ and company financial statement data.

- ▶ Total market capitalization for the sector decreased 28% to nearly US\$1.6 trillion, as the sector saw declines in growth and faced macro headwinds that kept deal activity low.
- ▶ Overall, 58% of pure-play medtechs grew their top line, down from 80% in 2021.
- ▶ Commercial leaders' revenue was up nearly 6% in 2022, but this same group saw a year-over-year decline of 1.1% from the first half of 2023 compared to the first half of 2022.
- ▶ While 64% of conglomerates experienced top-line growth, overall revenue growth within this group fell just short of 1%.
- ▶ Net income dropped nearly 64% to just US\$14.3 billion in 2022, which was largely due to accounting-related charges and not actual operational losses.
- ▶ Just 58% of companies added headcount vs. 77% the year before.

Figure 2

Annual revenue and R&D growth of public medtechs

After reaching its highest level since the financial crisis, revenue growth fell to its lowest levels in years.

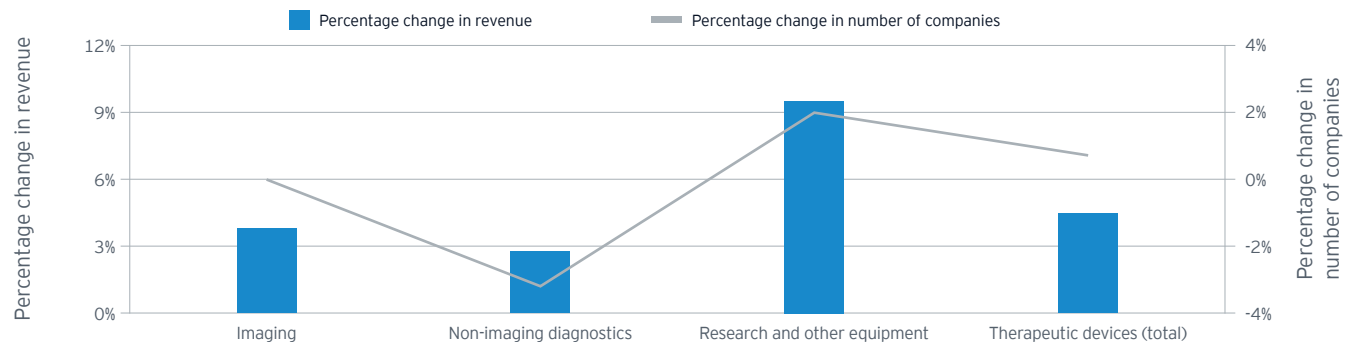


Source: EY analysis, Capital IQ and company financial statement data.
 Note: Medtronic has not reported its FY19 results yet; 9M results included currently.

- ▶ Total 2022 revenue growth was down from a high of 16% in 2021. The 3.5% seen in 2022 tracked more closely with the historical average of 6% seen prior to the recent outlying years.
- ▶ Most medtechs continued to invest in future innovation as total R&D spend increased nearly 8% in 2022, albeit down from the 12% increase seen in 2021. Only 57% of medtechs increased their R&D investment, compared with 71% the year prior.

Figure 3

US and European revenue growth by product group: pure-plays



Source: EY analysis, Capital IQ and company financial statement data.
 Data from public pure-play medtechs only.

- ▶ Only one product segment – research and other equipment – grew by double digits in 2022, compared with more than 20% growth in three out of the four segments in 2021.
- ▶ Research and other equipment increased 10% to US\$78.2 billion, well below the 23% increase seen in 2021.
- ▶ Non-imaging diagnostics, last year’s growth leader, grew only 4% to US\$26.9 billion in 2022, a far cry from the industry-leading 26% seen the year prior.
- ▶ Meanwhile, therapeutic devices jumped more than 4% to US\$200.1 billion (down from 11%), while imaging was also up about 4% to US\$25.3 billion (compared with 6% in 2021).

Figure 4

Change in US and European therapeutic device companies' revenue and net income by disease category: pure-plays

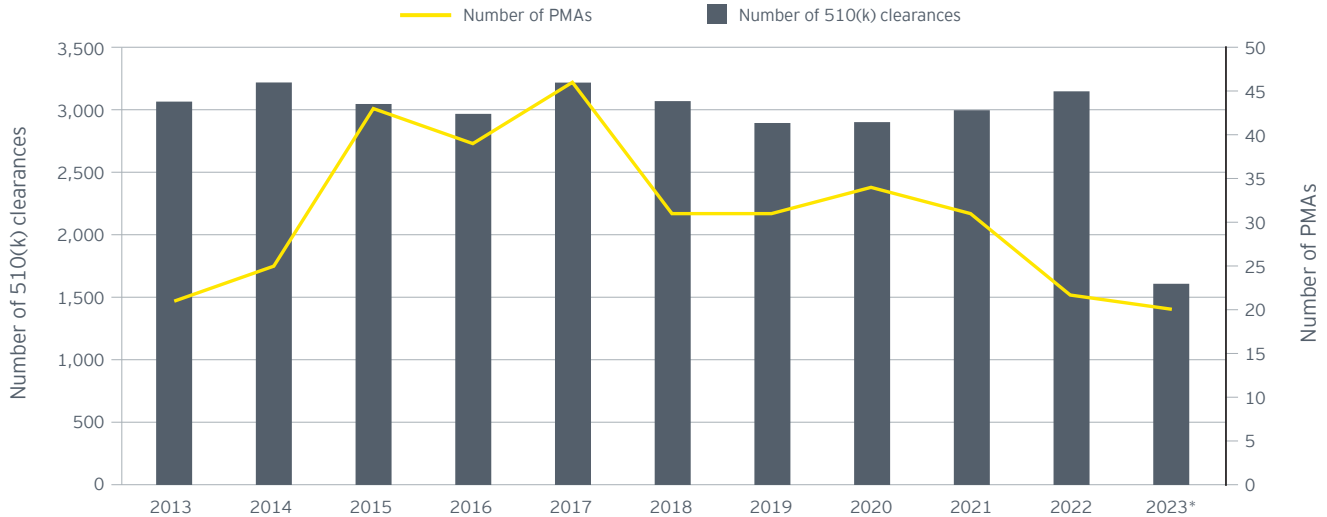


Sources: Capital IQ, company financial statement data and EY analysis.
Data shown for pure-play companies only.

- ▶ Orthopedic had the largest revenue growth of nearly US\$1.8 billion (21%) to US\$35 billion, followed by ophthalmic with US\$901 million (10%) to US\$13.1 billion and cardiovascular/vascular with US\$706 million (8%) to US\$22 billion:
 - ▶ While Stryker was responsible for much of growth in the orthopedic space, several companies, including North Carolina-based Bioventus, also experienced growth. Bioventus grew 19% to US\$512 million primarily due to acquisitions and volume growth within its Surgical Solutions business.
 - ▶ Among ophthalmic players, two of the largest companies drove the growth in the segment: Alcon (+5% to US\$8.7 billion), led by its surgical business, and Cooper Companies (+13% to US\$3.3 billion), led by its contact lens business.
 - ▶ Boston Scientific increased its top line by 7% (to US\$12.7 billion) to secure the largest dollar increase in the cardiovascular/vascular segment. Shockwave Medical had another massive year, gaining 107% to US\$490 million, largely due to the increased sales of its coronary and peripheral catheters.
 - ▶ Within dental, Align Technology grew by more than 60% due to increases in clear aligner volume and the number of iTero intraoral scanners. Dentsply Sirona jumped 27% and Straumann grew 38% – both recovering from pandemic-related drops in elective procedures.
- ▶ From a net income perspective, therapeutic device companies were down 36% to US\$13.6 billion, which comes on the heels of a 98% increase in 2021. However, just as accounting-related charges helped fuel growth last year, they provided headwinds in 2022.

Figure 5

US FDA medical device approvals (2013-23)



*Data for 510(k) clearances and PMA approvals are through June 2023.
Source: FDA website.

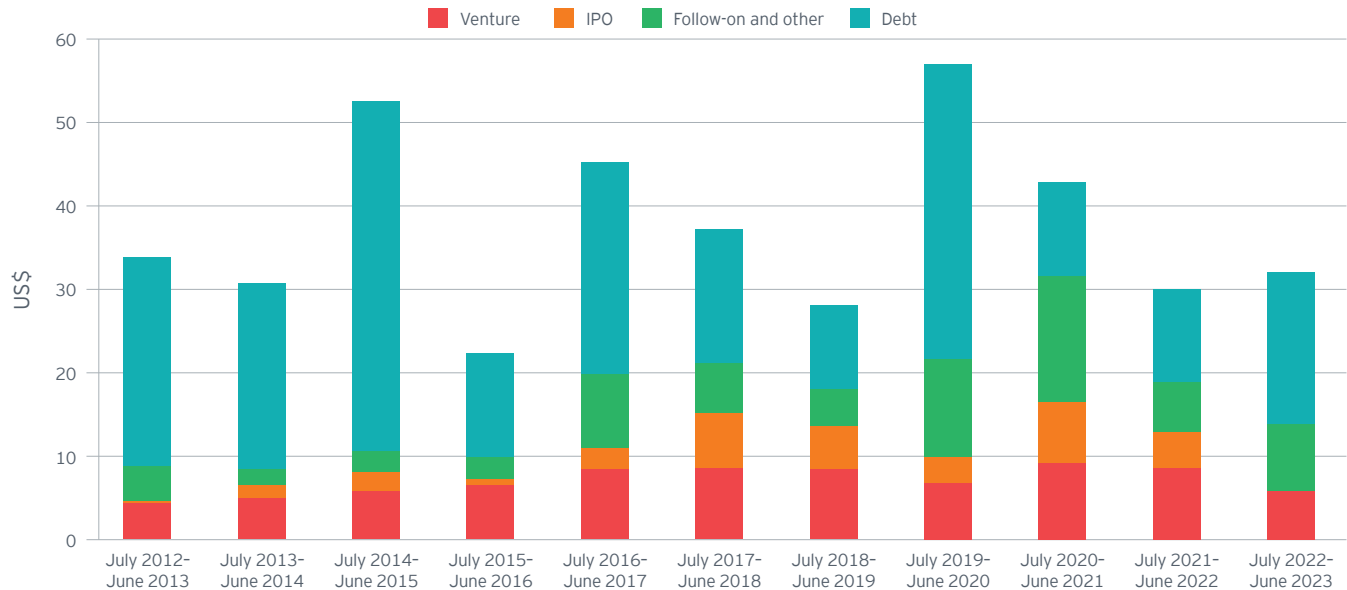
- ▶ In 2022, there were nearly 3,200 510(k) clearances in the US – the highest figure the industry has seen since 2017. However, 2022 saw just 22 pre-market approvals (PMAs), the lowest since 2013.
- ▶ As we noted in the 2021 edition of Pulse, the FDA’s Center for Devices and Radiological Health (CDRH) was overwhelmed by a huge increase in regulatory actions fueled by the pandemic (such as emergency use authorizations for COVID-19 tests). The backlog may have been one of the reasons for lower PMAs in 2022. However, 2023 is on track to reach the highest PMA levels since 2017, with 20 approvals seen through the first half of the year.



Financing

Figure 6

Capital raised in the US and Europe by year (US\$m)

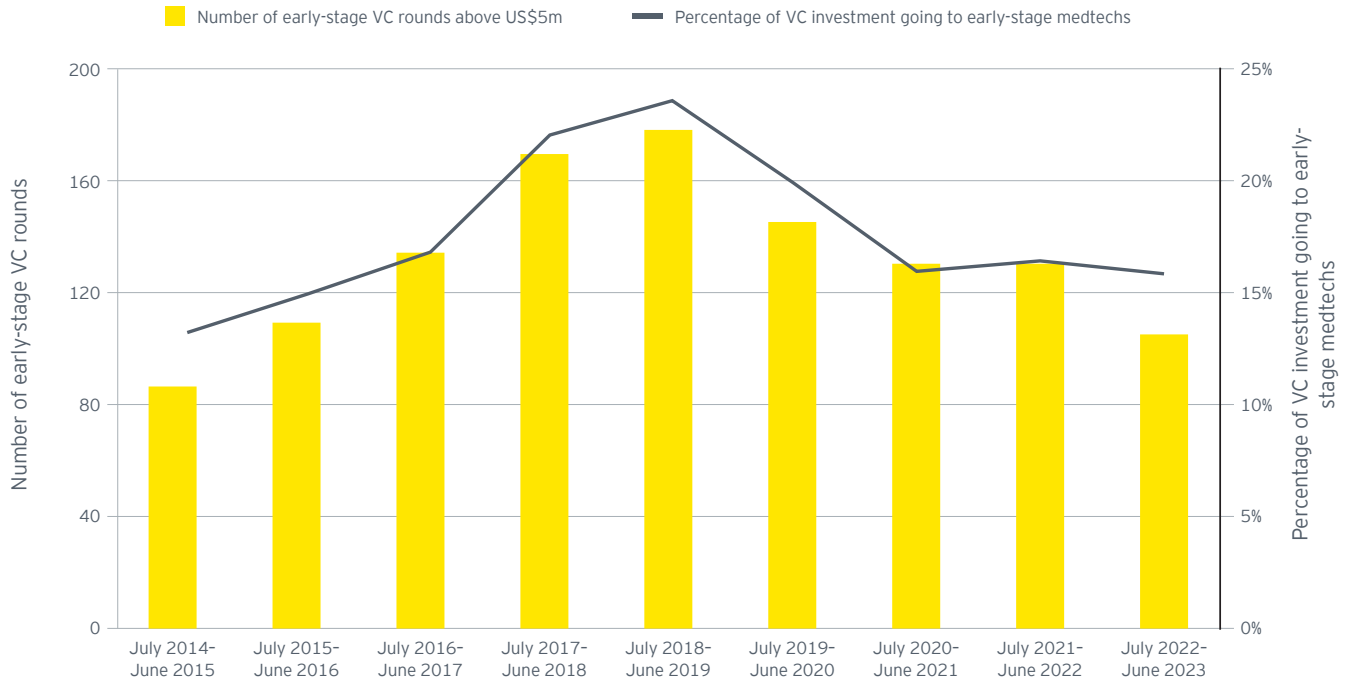


Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ. Numbers may appear to be inconsistent because of rounding. PIPEs included in "follow-on and other."

- ▶ Overall, medtech financing grew to a total of US\$32.8 billion in the 12-month period ending 30 June 2023 (2022/23), a 9% increase over the previous period and the first overall uptick in three years.
- ▶ Driving most of this past year's growth was a 71% increase in the amount of debt issued, which reached US\$19 billion. Of that total, roughly 44% of it (US\$8.3 billion) was due to the January 2023 spinout of GE HealthCare from General Electric (GE). However, GE HealthCare did not receive any proceeds from the offering, with all of the proceeds going back to GE.
- ▶ Unlike previous years, the largest debt offerings in 2022 were used not to fund acquisitions, but rather to repay and refinance existing debt, working capital, stock buybacks and other capital expenditures.
- ▶ Just US\$13.8 billion of equity was raised in the 2022/23 period, the lowest total in seven years and 56% below the US\$31.6 billion raised just two years prior.
- ▶ On the positive side, total value raised via follow-on public offerings increased 19% year-over-year to US\$7 billion; however, like the debt figures, GE's spin of its health care business artificially boosted follow-on capital as GE HealthCare sold 25 million shares of common stock for a total of nearly US\$2 billion. Once again, GE was the beneficiary of this transaction.
- ▶ On the negative side, venture capital and IPOs were down 21% and 99%, respectively.
- ▶ In all, just four companies went public during 2022/23, raising an anemic US\$40 million. The warning signs were first seen in the second half of the previous period (2021 and 2022), when just nine IPOs brought in US\$84 million. These figures stand out starkly against the 39 IPOs that raised US\$4.4 billion the previous year and the even more impressive 43 IPOs that garnered US\$7.3 billion during the 2020/21 period.

Figure 7

US and European early-stage VC rounds above US\$5m



Source: EY analysis, Dow Jones VentureSource and Capital IQ. Early-stage rounds are seed-, first- and second-round VC investments.

- ▶ Just US\$6.7 billion of venture capital was raised in 2022/23, the lowest figure seen since 2015 and 2016. Of that total, 34% (US\$2.3 billion) came from early-stage rounds, which is in line with previous years.
- ▶ There were only 106 venture rounds of US\$5 million or more in 2022/23, the lowest amount in eight years.
- ▶ Figures show that while investors were willing to invest in innovative, private companies, they continued to gravitate toward medtechs that are further along their development cycle.

Figure 8

Top venture rounds, July 2022–June 2023

Company	Region	Product type (disease)	Gross amount raised (US\$m)	Quarter	Round type
Verily Life Sciences	US - Northern California	Other	1,000	Q3 2022	Late stage
Equashield	US - New York	Other	300	Q4 2022	Early stage
HeartFlow	US - Northern California	Therapeutic devices (cardiovascular/vascular)	215	Q2 2023	Late stage
Therabody	US - Southern California	Therapeutic devices (orthopedic)	165	Q3 2022	Late stage
Distalmotion	Switzerland	Therapeutic devices (non-disease specific)	150	Q2 2023	Late stage
HistoSonics	US - Minnesota	Therapeutic devices (oncology)	85	Q4 2022	Late stage
Osler Diagnostics	UK	Therapeutic devices (non-imaging diagnosis)	85	Q4 2022	Late stage
Augmedics	US - Illinois	Therapeutic devices (orthopedic)	83	Q2 2023	Late stage
SetPoint Medical	US - Southern California	Therapeutic devices (neurology)	80	Q1 2023	Late stage
Synchron	US - New York	Therapeutic devices (neurology)	75	Q4 2022	Late stage
Alleviant Medical	US - Texas	Therapeutic devices (cardiovascular/vascular)	75	Q1 2023	Late stage
Medical Microinstruments	Italy	Therapeutic devices (non-disease specific)	75	Q3 2022	Early stage
MicroTransponder	US - Texas	Therapeutic devices (neurology)	73	Q3 2022	Late stage
Cognito Therapeutics	US - Massachusetts	Therapeutic devices (neurology)	73	Q1 2023	Early stage
Presidio Medical	US - Northern California	Therapeutic devices (neurology)	72	Q2 2023	Late stage
Resolve Biosciences	Germany	Research and other equipment	71	Q4 2022	Early stage

Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

- ▶ The majority of the largest venture rounds went to late-stage companies.
- ▶ After many years of non-imaging diagnostic companies attracting the biggest investment, 2022/23 saw investors gravitating toward medtechs that are focused on the development and production of therapeutic devices.
- ▶ The year's largest venture round went to Alphabet's Verily Life Sciences for US\$1 billion in September 2022. This latest round brings the company's total investment to US\$3.5 billion (see table above). Verily's current portfolio includes care solutions for sleep apnea and miniaturized continuous glucose monitors for diabetes. Verily has said the funds may also be used to invest in strategic partnerships and potential acquisitions.
- ▶ After reversing course on a SPAC deal last year, cardiac diagnostic developer HeartFlow picked up US\$215 million to capitalize on a recent FDA clearance for AI-powered software that maps out the heart's coronary arteries and any potential blockages through a 3D CT scan.
- ▶ Therabody, maker of the Theragun massage device, raised US\$165 million to help invest in digital content and acquisitions. The company also announced eight new products, including smart goggles to help relieve facial tension and headaches, as well as a new mini Theragun.
- ▶ Switzerland-based Distalmotion, whose Dexter robot has been used in Europe for daily procedures in gynecology, urology and general surgery, collected US\$150 million in 2022. The latest proceeds will help bring the system to the US market, where it will face FDA approval, the company said in its announcement.
- ▶ In all, five of the top 15 funding rounds went to companies with a focus on neurological conditions, including SetPoint Medical, which raised US\$80 million for its nerve stimulation technology that treats autoimmune disease, as well as US\$75 million for Synchron's catheter-delivered Stentrode BCI implant, which taps into blood vessels to capture signals from the brain.

Figure 9

US and European IPOs, July 2022-June 2023

Company	Ticker	Region	Product type (disease)	Gross raised (US\$m)	Quarter
Monogram Orthopaedics	MGRM	US - New York	Therapeutic devices (orthopedic)	17	Q2 2023
Nexalin Technology	NXL	US - Texas	Therapeutic devices (neurology)	10	Q3 2022
Innovative Eyewear	LUCY	US - Florida	Therapeutic devices (ophthalmic)	7	Q3 2022
Oncosem	ONCSM	Turkey	Research and other equipment	6	Q1 2023

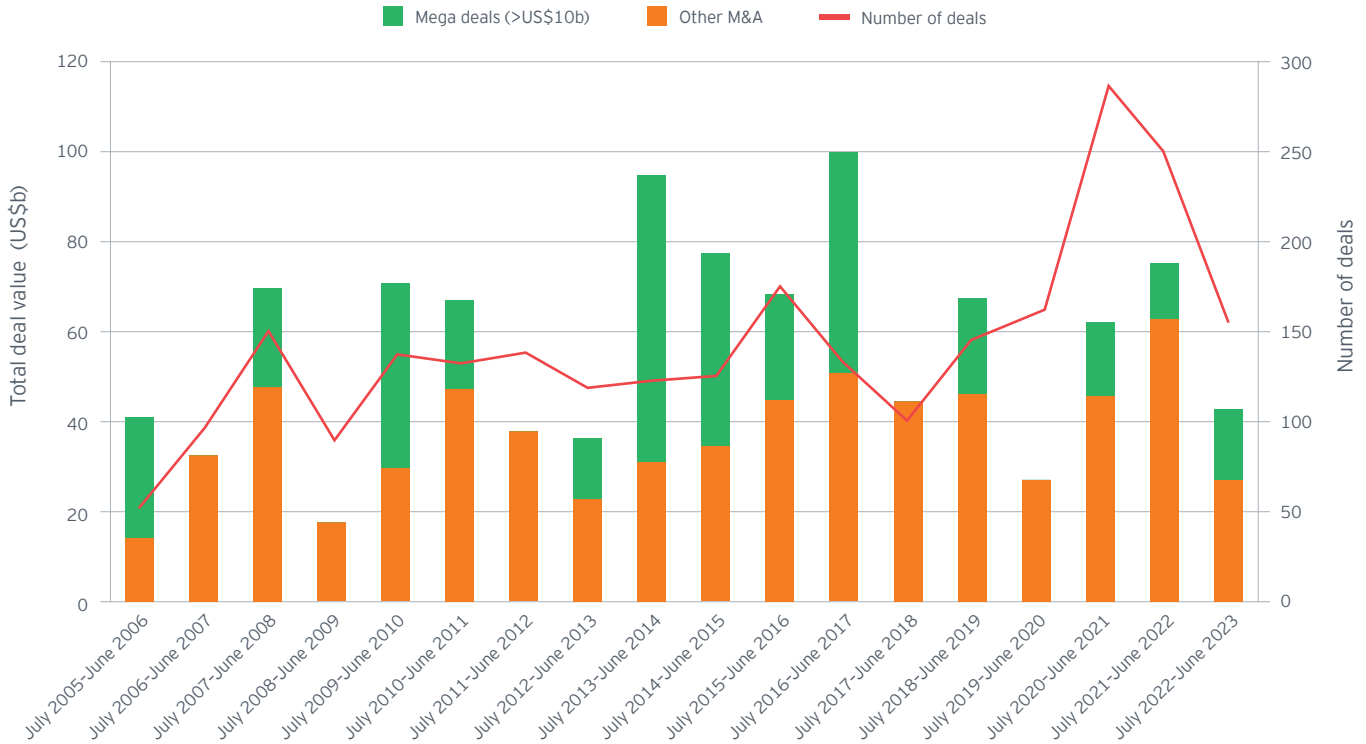
Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

- ▶ Just US\$40 million was raised via IPO in 2022 and 2023, down from US\$4.4 billion the year before and US\$7.3 billion two years prior.
- ▶ Monogram Orthopaedics develops customized orthopedic implants using state-of-the-art 3D printing and robotics technology, coupled with advanced preoperative imaging. The company went public via a Regulation A+ IPO, a type of offering created under the US JOBS Act to give small companies better access to capital.
- ▶ Europe's largest and only IPO went to Turkey's Oncosem, which focuses on the production of consumables, medical devices, diagnostic products and protective equipment.
- ▶ While not a traditional IPO, there was one additional public company to emerge in early January 2023 when the long-anticipated spin-out of GE HealthCare took place. The legacy parent company, General Electric, distributed about 80% of outstanding shares of its health care business to GE shareholders and retained a 20% stake in the firm. GE HealthCare generates about \$18 billion in revenue per year, and its core business focuses on imaging, ultrasound, patient care solutions and pharmaceutical diagnostics.



Figure 10

M&A in the US and Europe by year



Sources: EY analysis, Capital IQ and Thomson ONE
 Chart includes deals with value disclosed (medtech deal where either acquirer or target is located in the US or Europe).

- ▶ Total deal values plummeted 44% year-over-year to US\$44.6 billion in the 12-month period ending 30 June 2023. This figure is down from US\$79.3 billion, which was the third highest total over the past two decades. The US\$44.6 billion in deal value represents the second lowest total in the past decade.
- ▶ Omitting the year's lone megadeal (Johnson & Johnson's acquisition of Abiomed for US\$16.6 billion), the US\$23.5 billion non-megadeal total value for 2022/23 was the lowest in 10 years.
- ▶ Falling in line with the decrease in total value, the number of deals also plummeted 37% year-over-year to 161. The US\$277 million average deal size was slightly higher than the 10-year average of US\$268 million.
- ▶ M&A activity slid as concerns mounted about debt and credit markets and lower valuations. These worries were compounded by headwinds from rising interest rates and continued labor shortages (due to a lack of both workers and skills). Industry experts are mostly optimistic in their forecasts of a resurgence for the sector as public and private investors seek to channel their stockpiles of capital back into market.

Figure 11

Selected M&A (US and Europe), July 2022–June 2023

Acquiring company	Location	Acquired company	Location	Value (US\$m)	Buyer's deal driver
Johnson & Johnson	US - New Jersey	Abiomed	US - Massachusetts	\$16,600	Build scale (cardiovascular/vascular)
Advent International/ Warburg Pincus	US - Massachusetts/ New York	Baxter (BioPharma Solutions)	US - Illinois	\$4,250	Portfolio expansion
Globus Medical	US - Pennsylvania	NuVasive	US - Southern California	\$3,100	Build scale (orthopedic)
Thermo Fisher Scientific	US-Massachusetts	The Binding Site	UK	\$2,600	Build scale (non-imaging diagnostics)
Werfen, S.A.	Spain	Immucor	US - Georgia	\$2,000	Build scale (non-imaging diagnostics)
SD Biosensor/ SJL Partners	South Korea	Meridian Bioscience	US - Ohio	\$1,530	Build scale (non-imaging diagnostics)
Waters	US - Massachusetts	Wyatt Technology	US - Southern California	\$1,360	Build scale (research and other equipment)
Cordis	US - Florida	M.A. Med Alliance	Switzerland	\$1,135	Build scale (cardiovascular/vascular)
Abbott Laboratories	US - Illinois	Cardiovascular Systems	US - Minnesota	\$890	Build scale (cardiovascular/vascular)
Alcon	Switzerland	Aerie Pharmaceuticals	US - North Carolina	\$770	Build scale (ophthalmic)
Boston Scientific	US - Massachusetts	Apollo Endosurgery	US - Texas	\$615	Build scale (gastrointestinal)
STERIS	Ireland	Becton Dickinson (surgical instrument platform)	US - New Jersey	\$540	Build scale (surgical)
Boston Scientific	US - Massachusetts	Acotec Scientific	China	\$523	Build scale (cardiovascular/vascular)
Quest Diagnostics	US - New Jersey	Haystack Oncology	US - Maryland	\$450	Build scale (non-imaging diagnostics)
Orthofix Medical	US - Texas	SeaSpine	US - Southern California	\$328	Build scale (orthopedic)
Teleflex	US - Pennsylvania	Standard Bariatrics	US - Ohio	\$300	Product extension (gastrointestinal)
Zimmer Biomet	US - Indiana	Embody	US - Virginia	\$275	Build scale (orthopedic)
CONMED	US - Florida	Biorez	US - Connecticut	\$250	Build scale (wound care)

Source: EY analysis, Capital IQ and Thomson ONE.

Chart includes deals with value disclosed (medtech deal where either acquirer or target is located in the US or Europe).

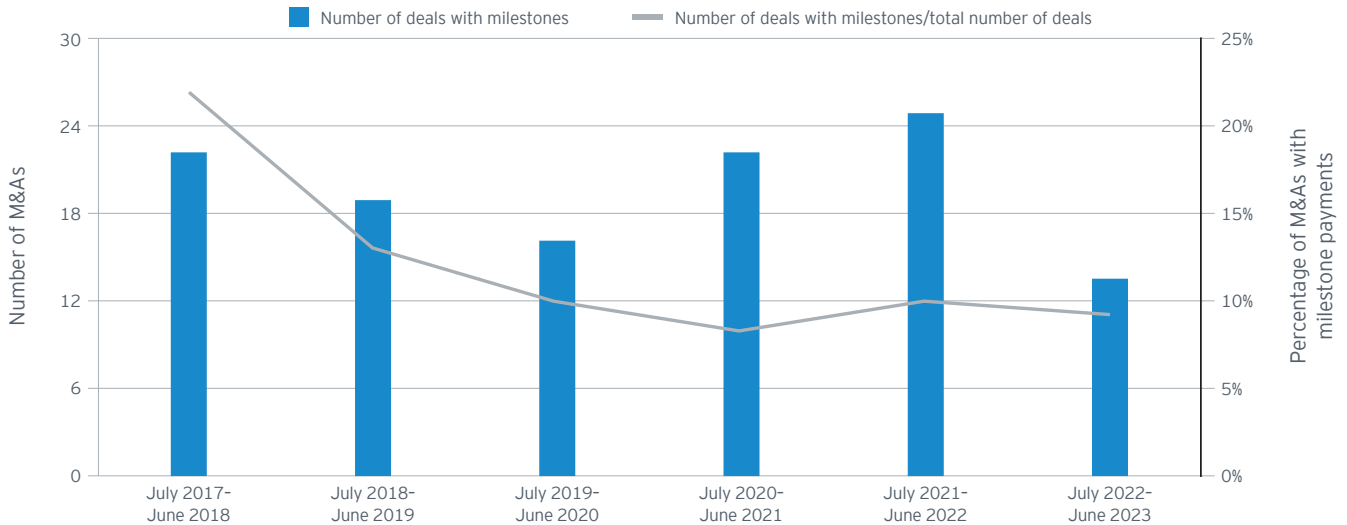
- ▶ The year's top deals gravitated toward both cardiovascular/vascular assets and non-imaging diagnostics.
- ▶ In the largest deal of the year, Johnson & Johnson paid US\$16.6 billion in November 2022 for Abiomed. Abiomed's Impella heart pumps, the smallest in the world, had global revenue totaling US\$985 million in fiscal year 2022. The acquisition adds to Johnson & Johnson's heart recovery solutions, complementing its Biosense Webster electrophysiology business. Abiomed's acquisition comes months after Abbott confirmed that its HeartMate 3 pump could extend a heart-failure patient's life by up to five years.

- ▶ Other notable deals included the following:
 - ▶ Baxter announced its intention to spin off BioPharma Solutions business to private equity firms Advent International and Warburg Pincus for US\$4.3 billion. Proceeds were expected to help reduce company debt, part of which was incurred during \$10.5 billion acquisition of Hillrom that closed at the end of 2021.
 - ▶ Globus Medical/NuVasive for US\$3.1 billion: By annual revenue, the deal combines the world's No. 7 and No. 8 largest orthopedic device companies.
 - ▶ Thermo Fisher spent US\$2.6 billion for oncology diagnostics maker the Binding Site, which develops a range of tests and instruments that detect and monitor various cancers and immune system disorders.
 - ▶ Werfen, a maker of specialized diagnostic instruments, acquired Immucor, a specialist in transfusion and transplant in vitro diagnostics, from private equity firm TPG.
 - ▶ Meridian Bioscience was acquired by SD Biosensor (SDB) and SJL Partners (private equity) (both South Korea-based) for US\$1.5 billion. The deal will help with SDB's entry into the US in vitro diagnostic market.
 - ▶ Abbott spent US\$890 million for artery-cleaning device maker Cardiovascular Systems. It will join Abbott's existing portfolio of catheters, stents, imaging systems and other technologies used to remove plaque buildups from blood vessels.
 - ▶ Boston Scientific made two acquisitions, the first being Apollo Endosurgery for US\$615 million. Apollo makes devices for gastrointestinal surgery, including endoscopic suturing systems and gastric balloons. The second acquisition of Acotec Scientific for US\$523 million includes vascular products such as drug-coated balloons (DCBs), radiofrequency ablation technologies and thrombus aspiration catheters.



Figure 12

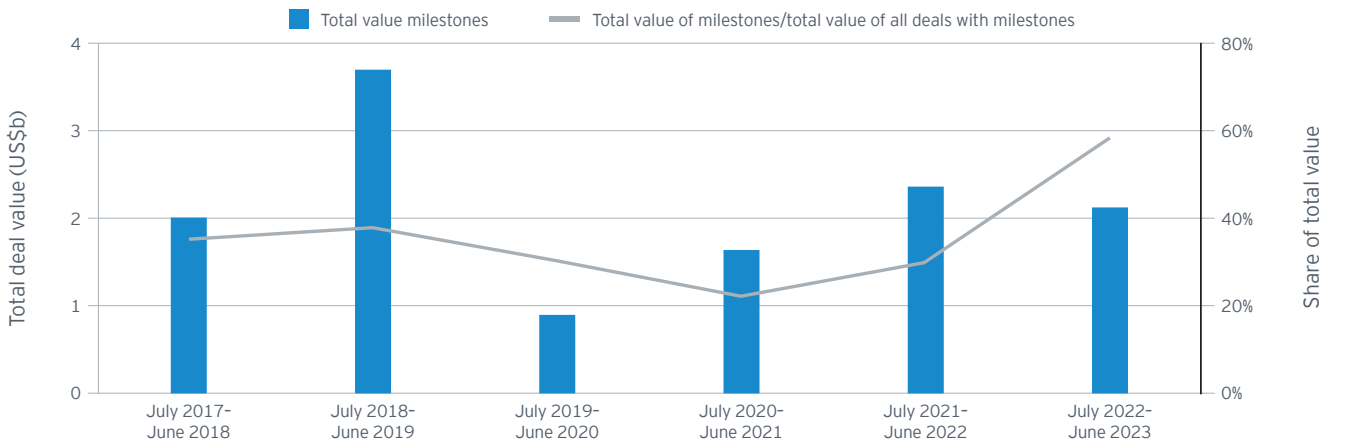
Milestone payments in US and European medtech M&A



Source: EY analysis, Capital IQ and Thomson ONE.

Figure 13

Milestone share in US and European medtech M&A



Source: EY analysis, Capital IQ and Thomson ONE.

- ▶ Just 14 transactions, or 9% of all announced deals, utilized a milestone payment during the period from July 2022 to June 2023, and both were well below the previous five-year averages of 21 deals and 13%, respectively.
- ▶ While the nearly US\$2.2 billion of milestone values in 2022 and 2023 were right on target to the previous five-year average of US\$2.2 billion, the share of total value (58%) was significantly higher than the 31% average.
- ▶ Of the nearly US\$2.2 billion in announced milestones, Cordis' acquisition of MedAlliance accounted for US\$900 million of that total. The agreement includes an initial investment of US\$35 million and US\$200 million payment upon closing in 2023, along with regulatory achievement milestones of up to US\$125 million and commercial milestones of up to US\$775 million through 2029.

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DEFINING MEDICAL TECHNOLOGY

In this report, unless otherwise noted, medical technology (medtech) companies are defined as companies that design and manufacture medical technology equipment and supplies and are headquartered within the United States or Europe. The definition includes therapeutic device, diagnostic, drug delivery and analytical/life sciences tools and digital health companies. It excludes distributors and service providers, such as contract research organizations or contract manufacturing organizations. All publicly traded medtech companies are classified as belonging to one of five broad product groups:

- ▶ **Imaging:** companies that develop products used to diagnose or monitor conditions via imaging technologies, including products such as MRI machines, computed tomography and X-ray imaging equipment, and optical biopsy systems
- ▶ **Non-imaging diagnostics:** companies that develop products used to diagnose or monitor conditions via non-imaging technologies, which can include patient monitoring and in vitro testing equipment
- ▶ **Research and other equipment:** companies that develop equipment used for research or other purposes, including analytical and life sciences tools, specialized laboratory equipment, and furniture
- ▶ **Therapeutic devices:** companies that develop products used to treat patients, including therapeutic medical devices and tools
- ▶ **Other:** companies that develop products that do not fit in any of the above categories; digital health companies included in this product group

In addition to product groups, this report tracks the performance of conglomerate companies that derive a significant part of their revenues from medical technologies. Although we classify conglomerate medtech divisions by product group (e.g., GE HealthCare into imaging and Abbott into therapeutic devices), we report their results separately from pure-play companies. We take this approach because, excepting revenue results, conglomerates do not report full financial numbers for their medtech divisions.

For the purposes of this report, the global data represents combined metrics from US and European medtech companies; Israel's data is analyzed as part of the European market. Foreign exchange rates converted from local currencies to US dollars are calculated on a blended annual rate. Where possible, data is analyzed across a range of dimensions, including product group (e.g., imaging or therapeutic device), therapeutic area focus (e.g., oncology or cardiovascular), company ownership (e.g., public or private) and revenue thresholds. Our taxonomy sometimes segregates companies into thinly populated categories, making it difficult to provide statistically significant results.

As part of its dealmaking evaluation, the EY team's analysis tracks the digital alliances and acquisitions signed by leading pure-play and conglomerate medtechs by therapeutic area, technology capability (e.g., sensors or artificial intelligence) and strategic purpose. Direct investments by medtechs in digital health companies have been excluded from this analysis.

Conglomerate companies

United States

- ▶ 3M: Health Care
- ▶ Abbott: Diagnostics and Medical Devices
- ▶ Agilent Technologies: Life Sciences & Applied Markets and Diagnostics & Genomics
- ▶ Baxter: Medical Products and Therapies, and Healthcare Systems and Technologies
- ▶ Corning: Life Sciences
- ▶ Danaher: Life Sciences and Diagnostics
- ▶ General Electric: GE HealthCare
- ▶ IDEX: Health & Science
- ▶ Johnson & Johnson: Medical Devices & Diagnostics

Europe

- ▶ Agfa-Gevaert: Agfa HealthCare
- ▶ Dräger: Medical Devices
- ▶ DSM: Biomedical
- ▶ Eckert & Ziegler: Medical
- ▶ EN: Biomedical Group
- ▶ EssilorLuxottica: Direct to Consumer
- ▶ Fresenius: Fresenius Medical Care
- ▶ GN: GN Hearing
- ▶ Halma: Healthcare
- ▶ Jenoptik: Advanced Photonic Solutions
- ▶ Lumibird Group: Quantel Medical
- ▶ Merck KGaA: MilliporeSigma
- ▶ Philips: Diagnosis & Treatment and Connected Care
- ▶ Roche: Roche Diagnostics
- ▶ Semperit: Sempermed
- ▶ Zeiss: Carl Zeiss Meditec

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