

Pulse of the industry:
Medical technology
report 2021

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Contents

- 04 The year in review
- 12 Humans at the center
- 16 Leveraging data and digital technologies
- 20 New regulatory and reimbursement models
- 24 Supply chain resilience and agility
- 28 Environmental, social and governance (ESG)

32 Guest perspectives

Giovanni di Napoli, President, Gastrointestinal, at Medtronic

Heather Meade, President, Washington Council Ernst & Young, Ernst & Young LLP

Dr. Jeffrey Krauss, Chief Medical Officer, Hinge Health

Nabil Chegade, Executive Vice President & Chief Clinical Transformation Officer,
MetroHealth in Cleveland, Ohio

40 Databook

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The year in review

US\$446b

Record revenues

Despite COVID-19, MedTech enjoyed its fourth successive year of growth of 6.3% in 2020 and achieved record revenues of **US\$446b**. Growth for 1H21 was over 16%, demonstrating resiliency and opportunity in the sector.

128% ↑

Growth in public valuations

Investor confidence in the industry remains high, with Emerging Leaders particularly favored (**128% growth in public valuations** between January 2020 and August 2021); MedTech valuations >50% outperformed Pharma and Biotech.

US\$23.8b

R&D spending

The industry's innovation engine is back on track, with **R&D spending** recording its highest annual growth rate since before the financial crisis, up 17% to **US\$23.8b**.

US\$34b

Equity investment

Equity investment in the industry reached a new peak **\$34b** (\$9b – VC, \$6b IPO, \$4b SPAC and \$16b Follow-on)



Building data strategies

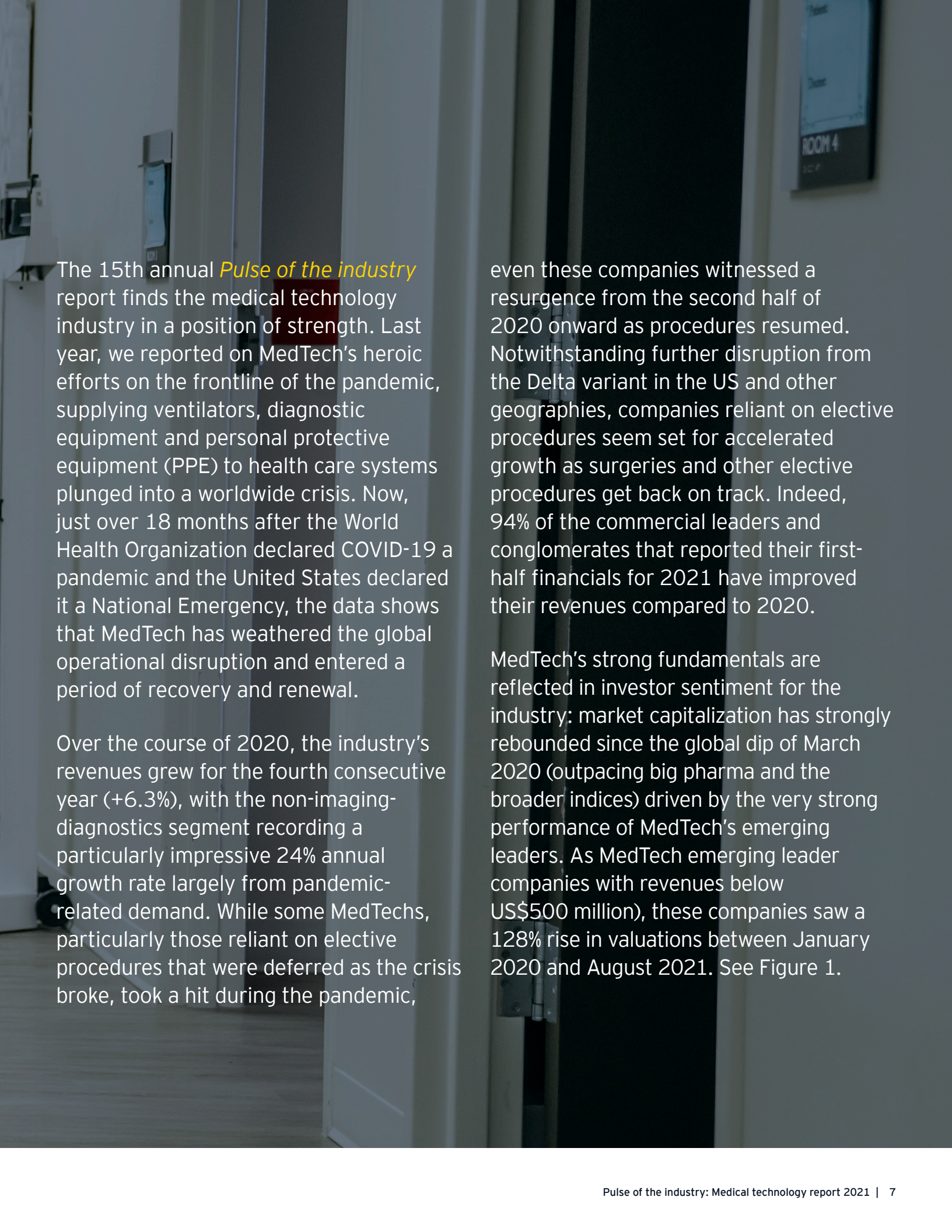
MedTechs now need to prioritize enabling (i) patient-centric care, (ii) outside of the hospital and clinic and (iii) **building data strategies** and capabilities to support this transformation

Going forward

Regulatory and supply chain reform, as well as the ESG agenda, also will be central priorities for MedTech going forward







The 15th annual *Pulse of the industry* report finds the medical technology industry in a position of strength. Last year, we reported on MedTech's heroic efforts on the frontline of the pandemic, supplying ventilators, diagnostic equipment and personal protective equipment (PPE) to health care systems plunged into a worldwide crisis. Now, just over 18 months after the World Health Organization declared COVID-19 a pandemic and the United States declared it a National Emergency, the data shows that MedTech has weathered the global operational disruption and entered a period of recovery and renewal.

Over the course of 2020, the industry's revenues grew for the fourth consecutive year (+6.3%), with the non-imaging-diagnostics segment recording a particularly impressive 24% annual growth rate largely from pandemic-related demand. While some MedTechs, particularly those reliant on elective procedures that were deferred as the crisis broke, took a hit during the pandemic,

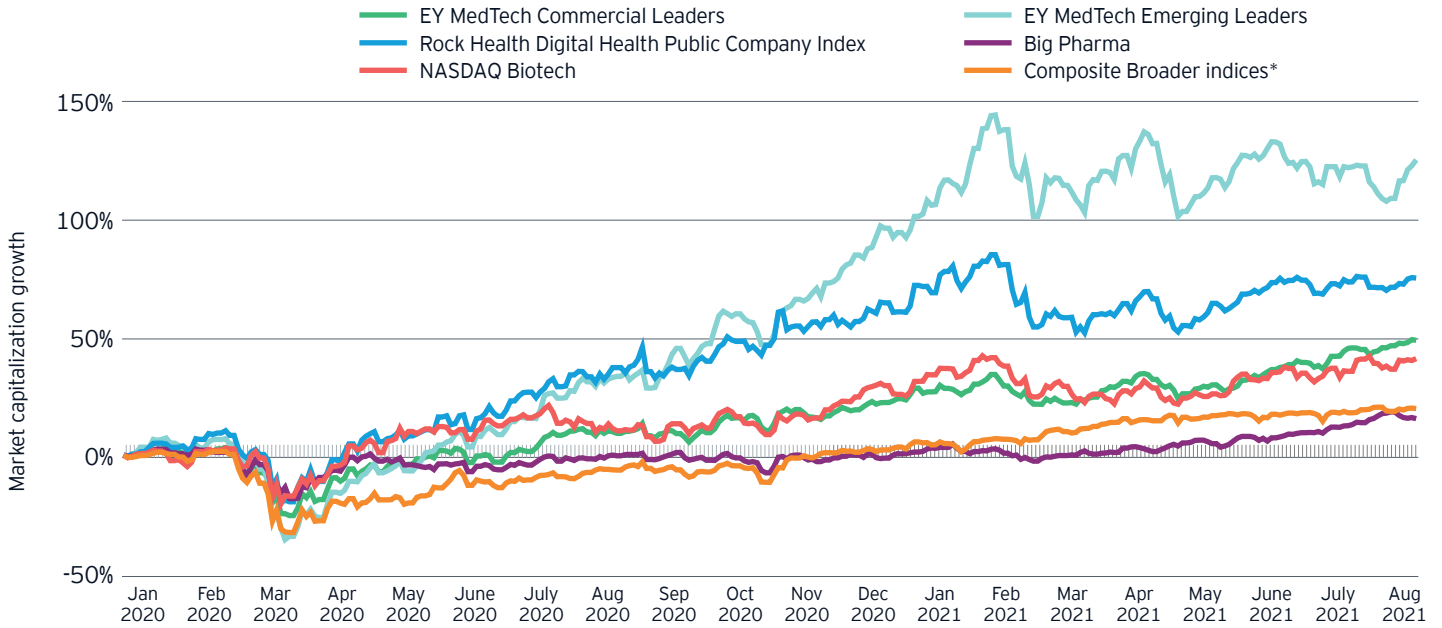
even these companies witnessed a resurgence from the second half of 2020 onward as procedures resumed. Notwithstanding further disruption from the Delta variant in the US and other geographies, companies reliant on elective procedures seem set for accelerated growth as surgeries and other elective procedures get back on track. Indeed, 94% of the commercial leaders and conglomerates that reported their first-half financials for 2021 have improved their revenues compared to 2020.

MedTech's strong fundamentals are reflected in investor sentiment for the industry: market capitalization has strongly rebounded since the global dip of March 2020 (outpacing big pharma and the broader indices) driven by the very strong performance of MedTech's emerging leaders. As MedTech emerging leader companies with revenues below US\$500 million), these companies saw a 128% rise in valuations between January 2020 and August 2021. See Figure 1.

Figure 1. US and European MedTech market capitalization relative to leading indices

Noncommercial leaders outperformed commercial leaders and other industry indices

US and European MedTech market capitalization relative to other sectors



Source: EY analysis and Capital IQ.

Charts include companies that were active on 01 September 2021.

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

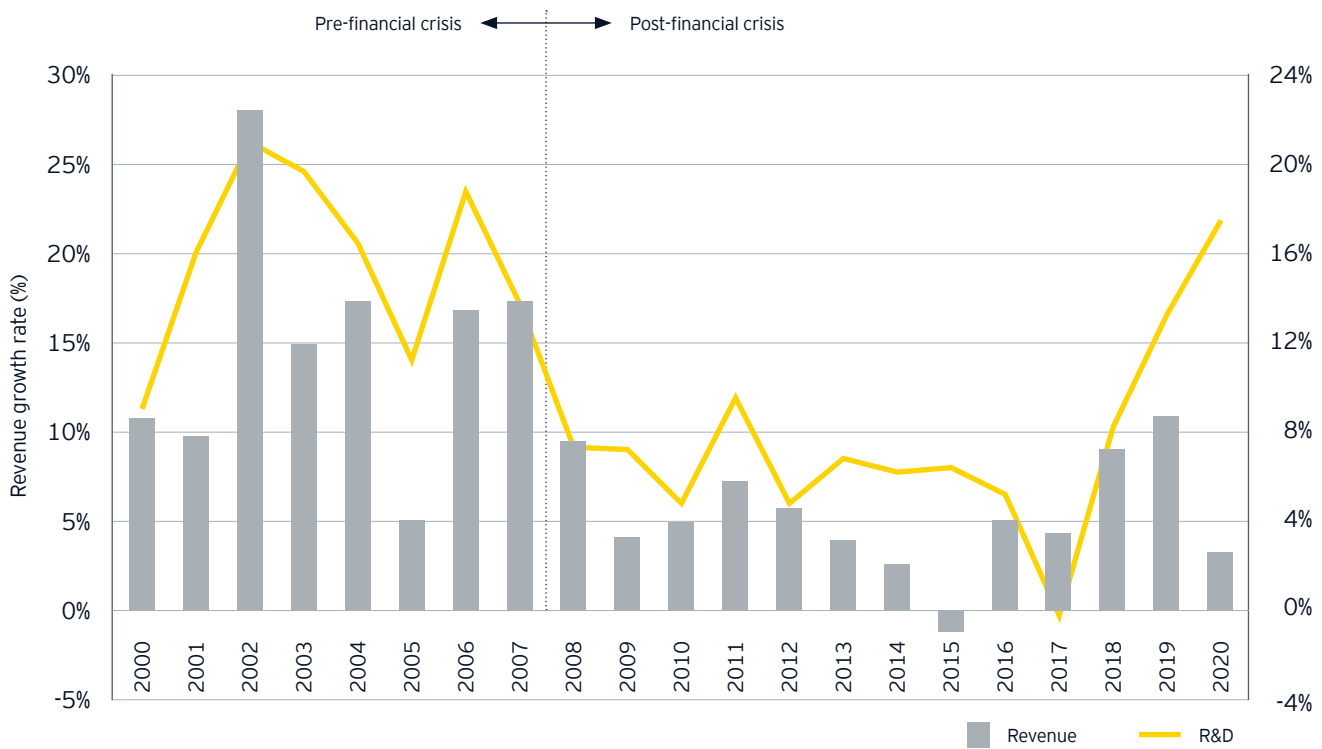


Investors' ongoing confidence in MedTech is validated by data indicating the health of the industry's innovation ecosystem: specifically, the industry's level of investment in the R&D and M&A fields and the level of venture capital (VC) it attracts. Pure-play MedTechs reinvested heavily in R&D in 2020 – recording the largest annual growth rate in R&D spending (+17.2%) since before the financial crisis of 2007 – signaling the industry's confidence in its capacity to keep innovating. See Figure 2.

Figure 2. Pure-play industry revenue and R&D AGRs in the 21st century

R&D growth returned to pre-financial crisis levels

Pure-play MedTech revenue and R&D growth



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

M&A is the other established driver of MedTech innovation, with start-ups traditionally seeking an exit via acquisition after developing a novel product or technology.

“
Over the 12 months ending in June 2021, MedTech companies executed 288 M&A deals – the highest annual number seen since EY researchers began creating the *Pulse of the industry* report in 2007.

See Figure 3.



Figure 3. MedTech M&A July 2020–June 2021

M&A in the US and Europe by year

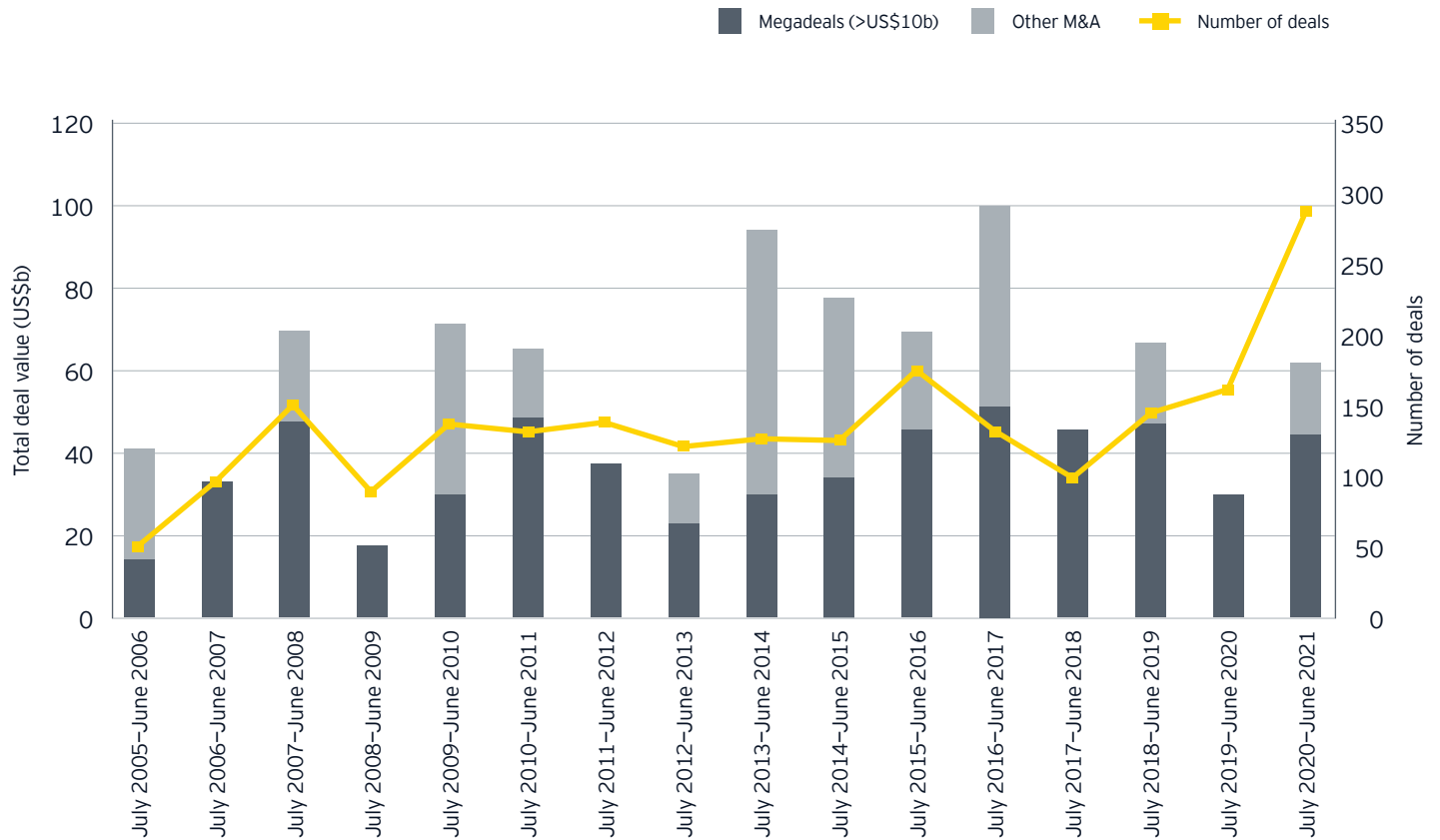


Chart includes deals with value disclosed (MedTech deal where either acquirer or target is located in the US or Europe).

Source: EY, Capital IQ and Thomson ONE.

The innovators that form the standard acquisition targets for MedTech's larger players are dependent on continued funding to support their R&D activities, particularly in the form of VC.

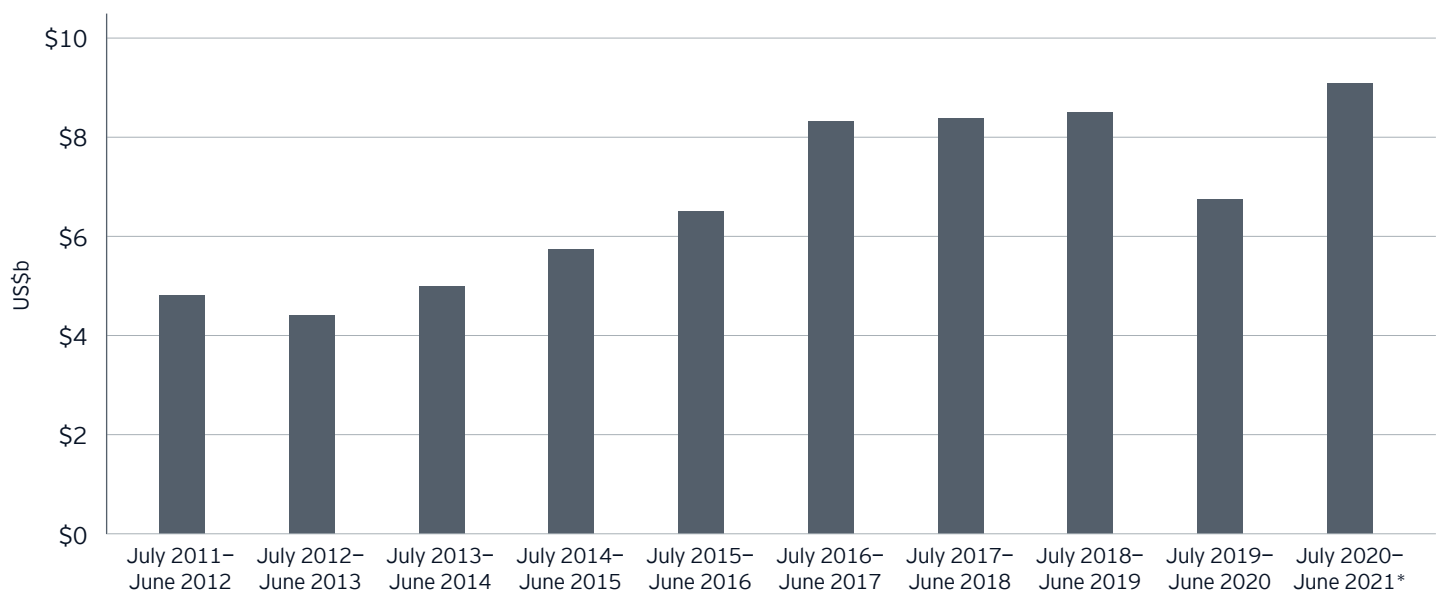


Encouragingly, the industry attracted US\$9.1 billion in VC in the 12-month period to June 2021, up 34% over the previous year and the highest level seen in the past decade.

See Figure 4.

Figure 4. VC investment in MedTech July 2011–June 2021

US and European VC investment reached new heights



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

The crisis has not significantly slowed MedTech's commercial progress – but could it have accelerated the industry's evolution?

A few companies made significant gains from product lines relevant to COVID-19, from PPE to diagnostics. However, the more significant long-term impact of the pandemic may be its effect on the industry's business models. The pandemic has shifted health care's center of gravity in fundamental ways, to which the industry must now respond.

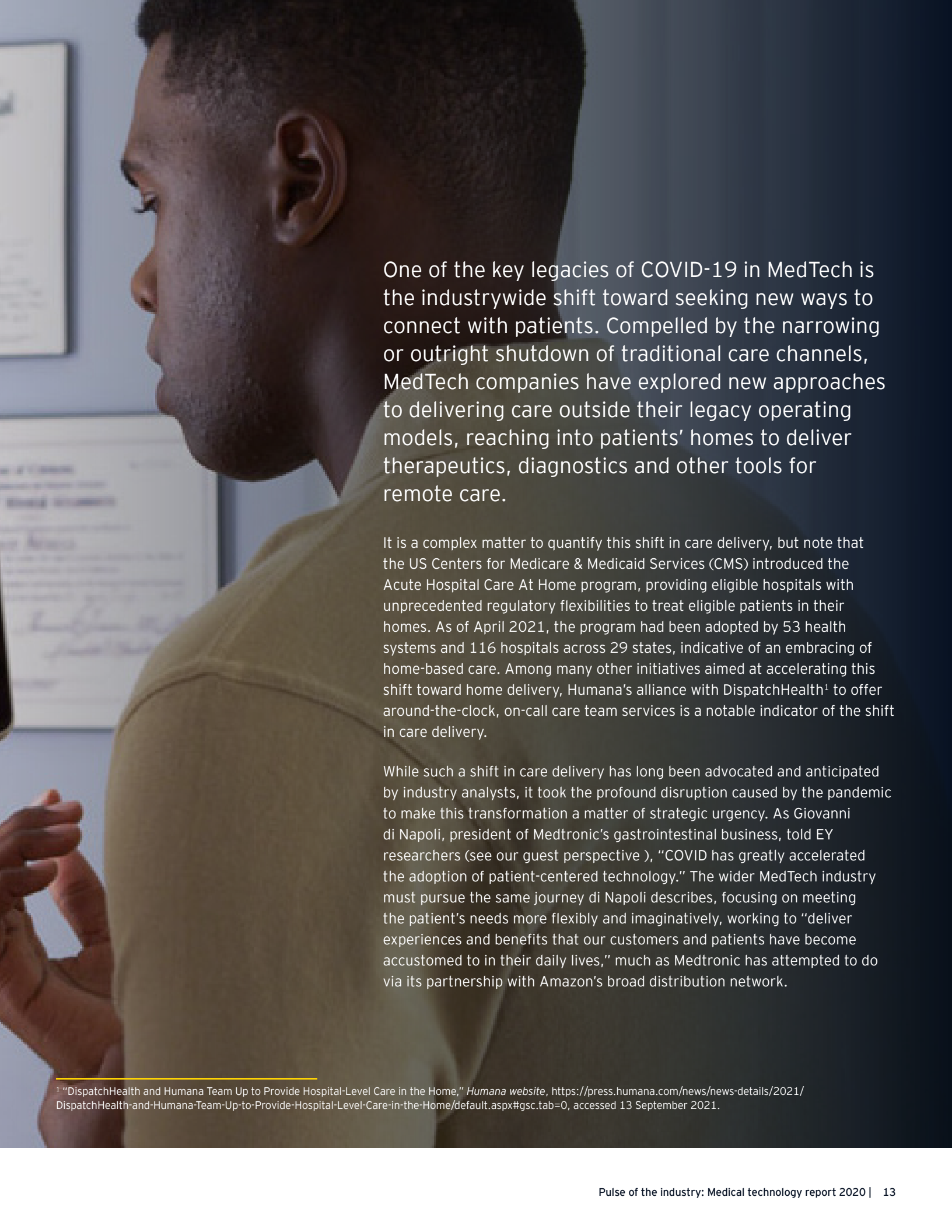
To take one example, COVID-19 has pushed health care outside its standard delivery channels, with providers and patients seeking to move away from traditional clinic and hospital settings and toward the home or telehealth settings. We believe that this shift in care delivery is long overdue, and MedTechs should now prioritize locking in and building on the transformation that the crisis has accelerated.

In all, we identify five key areas where MedTechs should focus on rethinking their business models to deliver care better in the future:

1. Putting "the human at the center" to make care more accessible, convenient and customer-centered
2. Leveraging data and digital technologies to make products smarter and better connected
3. Pushing for regulatory reform to support the industry's ongoing evolution
4. Validating the resilience and agility of their supply chains for the future
5. Improving environmental, social and governance (ESG) measures

1 Humans at the center





One of the key legacies of COVID-19 in MedTech is the industrywide shift toward seeking new ways to connect with patients. Compelled by the narrowing or outright shutdown of traditional care channels, MedTech companies have explored new approaches to delivering care outside their legacy operating models, reaching into patients' homes to deliver therapeutics, diagnostics and other tools for remote care.

It is a complex matter to quantify this shift in care delivery, but note that the US Centers for Medicare & Medicaid Services (CMS) introduced the Acute Hospital Care At Home program, providing eligible hospitals with unprecedented regulatory flexibilities to treat eligible patients in their homes. As of April 2021, the program had been adopted by 53 health systems and 116 hospitals across 29 states, indicative of an embracing of home-based care. Among many other initiatives aimed at accelerating this shift toward home delivery, Humana's alliance with DispatchHealth¹ to offer around-the-clock, on-call care team services is a notable indicator of the shift in care delivery.

While such a shift in care delivery has long been advocated and anticipated by industry analysts, it took the profound disruption caused by the pandemic to make this transformation a matter of strategic urgency. As Giovanni di Napoli, president of Medtronic's gastrointestinal business, told EY researchers (see our guest perspective), "COVID has greatly accelerated the adoption of patient-centered technology." The wider MedTech industry must pursue the same journey di Napoli describes, focusing on meeting the patient's needs more flexibly and imaginatively, working to "deliver experiences and benefits that our customers and patients have become accustomed to in their daily lives," much as Medtronic has attempted to do via its partnership with Amazon's broad distribution network.

¹ "DispatchHealth and Humana Team Up to Provide Hospital-Level Care in the Home," *Humana website*, <https://press.humana.com/news/news-details/2021/DispatchHealth-and-Humana-Team-Up-to-Provide-Hospital-Level-Care-in-the-Home/default.aspx#gsc.tab=0>, accessed 13 September 2021.

Other major MedTechs are investing heavily in capabilities to deliver remote care. In September 2021, Baxter signed a US\$10.5 billion deal to acquire connected care specialist Hillrom. As CEO Jose (Joe) Almeida told Ernst & Young LLP, “patients increasingly want to receive their care at home or nearby, while hospitals and other care providers are increasingly using digital health technologies to expand access, improve quality and lower costs. Baxter and Hillrom are uniting to meet the challenges of a rapidly evolving global health care landscape.” This megadeal falls outside the July 2020–June 2021 period evaluated in this report, but even within the period studied, two other major M&A deals addressed the same need for enhanced remote care options (see Figure 5):

- ▶ Philips purchased BioTelemetry, a maker of digital patient monitoring platforms and AI-based analytics, for US\$2.8 billion.
- ▶ Boston Scientific announced a US\$1.3 billion buy-out of Preventice Solutions, which designs remote monitoring services and mobile health solutions for cardiac arrhythmia patients.

Figure 5. Selected US and European M&As, July 2020–June 2021

Diagnostic and lab equipment assets were in high demand

Selected US and European M&As, July 2020–June 2021

Acquiring company	Location	Acquired company	Location	Value (US\$m)	Buyer’s deal driver
Siemens Healthineers	Germany	Varian Medical Systems	US - California	16,400	Build scale (oncology)
Steris	Ireland	Cantel Medical	US - New Jersey	4,600	Portfolio expansion (multiple)
Philips	Netherlands	BioTelemetry	US - Pennsylvania	2,800	Build scale (patient monitoring)
Roche	Switzerland	GenMark Diagnostics	US - Southern California	1,800	Portfolio expansion (diagnostics)
DiaSorin	Italy	Luminex	US - Texas	1,800	Portfolio expansion (diagnostics/ research & other equipment)
Boston Scientific	US - Massachusetts	Preventice Solutions	US - Minnesota	1,225	Portfolio expansion (diagnostics)
Boston Scientific	US - Massachusetts	Lumenis (surgical business)	Israel	1,070	Build scale (surgical laser solutions)
Avantor Performance Materials	US - Pennsylvania	Ritter	Germany	1,050	Portfolio expansion (diagnostics/ research & other equipment)
Dentsply Sirona	US - North Carolina	Straight Smile	US - California	1,040	Build scale (dental)
Hellman & Friedman	US - Northern California	Cordis	US - Florida	1,000	Portfolio expansion (cardiology)
Tecan Group	Switzerland	Paramit	US - California	1,000	Portfolio expansion (surgical tools/diagnostics)
Steris	Ireland	Key Surgical	US - Minnesota	850	Build scale (hospital/surgical tools)
Hologic	US - Massachusetts	Mobidiag	Finland	808	Build scale (diagnostics)
Patricia Industries	Sweden	Advanced Instruments	US - Massachusetts	780	Build scale (research and other equipment)
Agilent Technologies	US - Northern California	Resolution Bioscience	Finland	695	Build scale (research and other equipment)

Source: EY analysis, Capital IQ and Thomson ONE.



Taking a “humans at the center” approach to care is also a major focus for therapeutic devices companies attracting the most VC funding in 2020-21. For example, Switzerland’s CeQur, which attracted one of the top 10 VC funding rounds, is aiming to make insulin delivery systems that integrate more conveniently into a patient’s everyday life. Outside of surgical robotics, the biggest therapeutic device funding round of the past year went to Quanta Dialysis Technologies, focused on delivering an improved patient experience at home via portable dialysis technology intended to offer greater convenience for the individual.

Using digital technologies to expand home-based care offers MedTechs the prospect of better patient engagement. Analyses suggest that digital health apps and telehealth will play an enlarged role in actively managing chronic conditions from diabetes to mental health for between 30% and 45% of the US patient population in the future.² As Nabil Chegade, Executive Vice President & Chief Clinical Transformation Officer at The MetroHealth System, told EY researchers (see our guest perspective), “The very concept of moving away from an in-person care model to an alternative model of care lends itself

to a MedTech offering, from A-to-Z; it’s going to put more stress on MedTech to develop nimbler, more efficient tools, and figure out how to partner to deliver those capabilities.”


Companies like Comcast’s Quil Health³ offer the suite of technologies needed to build genuinely “smart homes” capable of tracking and monitoring patients’ biometrics via a battery of home sensors. Traditional MedTechs need to insert themselves into this process of transformation and play a key role in putting “humans at the center” long after the final waves of the pandemic have broken and receded.

² “How COVID-19 has triggered a sprint toward smarter health care,” *EY website*, https://www.ey.com/en_us/health/how-covid-19-has-triggered-a-sprint-toward-smarter-health-care, accessed 13 September 2021.

³ “Comcast’s Quil Health exploring how to use smart TVs and sensors to keep patients healthy at home,” *Fierce Healthcare website*, <https://www.fiercehealthcare.com/tech/comcast-s-quil-health-exploring-ways-to-support-patients-at-home-through-smart-devices-and>, accessed 13 September 2021.



Leveraging data and digital technologies

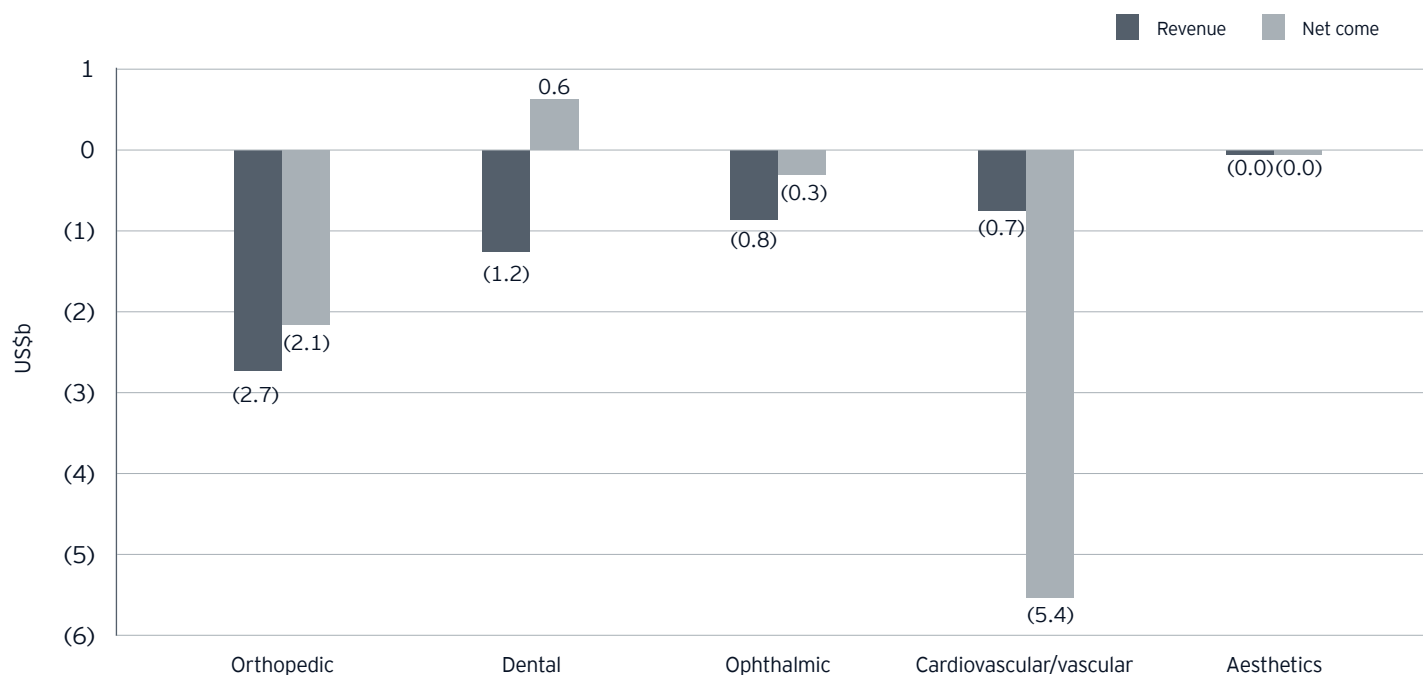
A laboratory setting with a microscope, a computer monitor displaying data, and various lab equipment. The scene is dimly lit with a blue tint. In the foreground, a microscope is positioned on a lab bench. To its left, a computer monitor displays a complex data visualization, including a large image of pinkish, irregular shapes and several smaller charts and graphs. In front of the microscope, there is a rack of test tubes containing red liquid, and several small glass bottles with blue caps. In the background, a person wearing a white lab coat and a yellow head covering is visible, working at a lab bench. The overall atmosphere is professional and scientific.

To deliver care at home and validate its cost-effectiveness, MedTechs will need to capture real-world evidence (RWE). To this end, the Medical Device Innovation Consortium (MDIC),⁴ a public/private consortium, has launched the National Evaluation System for Health Technology (NEST) Coordinating Center,⁵ seeking to take RWE from multiple data sources and use it to support pre or postmarketing. As these expanding data sources become a central element in understanding and treating disease, the device will become just a component in the value that MedTechs deliver.

⁴ MDIC website, <https://mdic.org/>, accessed 13 September 2021.

⁵ NEST website, <https://nestcc.org/>, accessed 13 September 2021.

Figure 6. Financial performance of MedTech's largest therapeutic device disease areas, 2020



Source: EY analysis and CapitalIQ.
Commercial leaders are companies with revenues >=US\$500m.

Take the orthopedics market, which was hit harder in revenue terms than any other MedTech therapeutic area in 2020 (see Figure 6). Orthopedic MedTechs' relationships with patients are traditionally confined to the episode of care, so as the impact of COVID-19 demonstrated, outside such episodes, these MedTechs' access to patients and revenue-generating opportunities alike are extremely limited. In the future, however, orthopedic MedTechs will build far closer ongoing relationships with patients, like what we currently see in chronic disease therapeutic

areas such as diabetes. The key to these strengthened future relationships will be the data captured via sensors embedded within orthopedic implants. This has become a significant area of competition for MedTechs in this space:

- ▶ Zimmer Biomet and Canary Medical won FDA approval in August 2021⁶ for its Persona-IQ implant.
- ▶ Stryker also is pursuing smart-sensor implants with its January 2021 acquisition⁷ of OrthoSensor, which owns the Verasense interoperable sensor technology.

- ▶ Exactech acquired Muvr Labs,⁸ which makes patient wearables and apps, in December 2020, aiming to better monitor patients and connect them with surgical teams.

⁶ "Zimmer Biomet and Canary Medical Announce FDA De Novo Classification Grant and Authorization to Market the World's First and Only Smart Knee Implant," *Zimmer Biomet website*, <https://investor.zimmerbiomet.com/news-and-events/news/2021/08-30-2021-120155075>, accessed 13 September 2021.

⁷ "Hot Off Closing on Wright, Stryker is Back on the M&A Trail," *Medical Device and Diagnostic Industry website*, <https://www.mddionline.com/orthopedic/hot-closing-wright-stryker-back-ma-trail>, accessed 13 September 2021.

⁸ "Exactech Acquires Muvr, Innovative Patient Wearable and Communication Solutions for Orthopaedic Practices," *Exactech website*, <https://www.exac.com/exactech-acquires-muvr-innovative-patient-wearable-and-communication-solutions-for-orthopaedic-practices/>, accessed 13 September 2021.



As Dr. Jeffrey Krauss of Hinge Health notes (see guest perspective), a significant future challenge will be seamlessly combining in-person care with the rapidly expanding range of digital health tools, “integrating these two worlds of care to create a seamless experience for the patient.” The data that connected devices capture will only deliver better outcomes if MedTechs can learn to “fit in” with a broader ecosystem, connecting their data to patients, providers and payers. Application programming interfaces (APIs) will be one key to building this

interoperability and access. Dexcom, for example, announced in July 2021⁹ that it has 510(k) clearance to share its APIs, allowing real-time data from Dexcom CGMs to be integrated into third-party apps and devices. Garmin and Teladoc are already testing the Dexcom APIs.

Data security will be a necessary foundation for the new MedTech ecosystem. As MedTech and its ecosystem partners increase the volumes of data they share, the importance of cybersecurity will

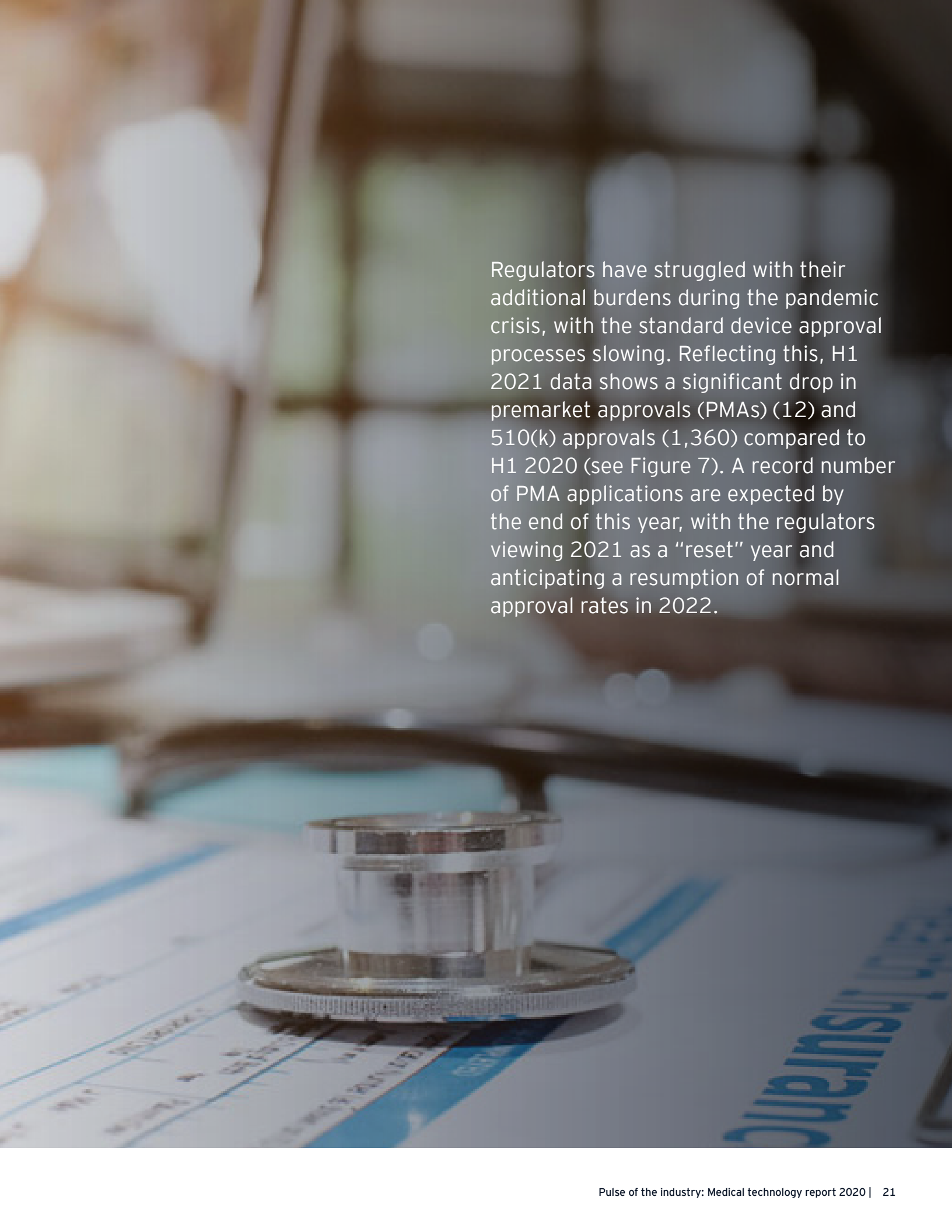
increase in lockstep, with the FDA in August 2021 announcing¹⁰ that it wants to require MedTechs in the future to help ensure their capability to update and patch device security into a product’s design, as well as the ability to require postmarketing disclosure of cybersecurity vulnerabilities as they are identified. This is one of many regulatory changes that MedTech can anticipate in the aftermath of the COVID-19 crisis.

⁹ “FDA Clears Dexcom Real-Time APIs for Third-Party Apps and Devices,” *Dexcom website*, <https://dexcom.gcs-web.com/news-releases/news-release-details/fda-clears-dexcom-real-time-apis-third-party-apps-and-devices>, accessed 13 September 2021.

¹⁰ “FDA seeks more power for medical device cybersecurity mandates,” *MedTechDive website*, www.medtechdive.com/news/fda-seeks-more-power-for-medical-device-cybersecurity-mandates/605107/, accessed 17 August 2021.



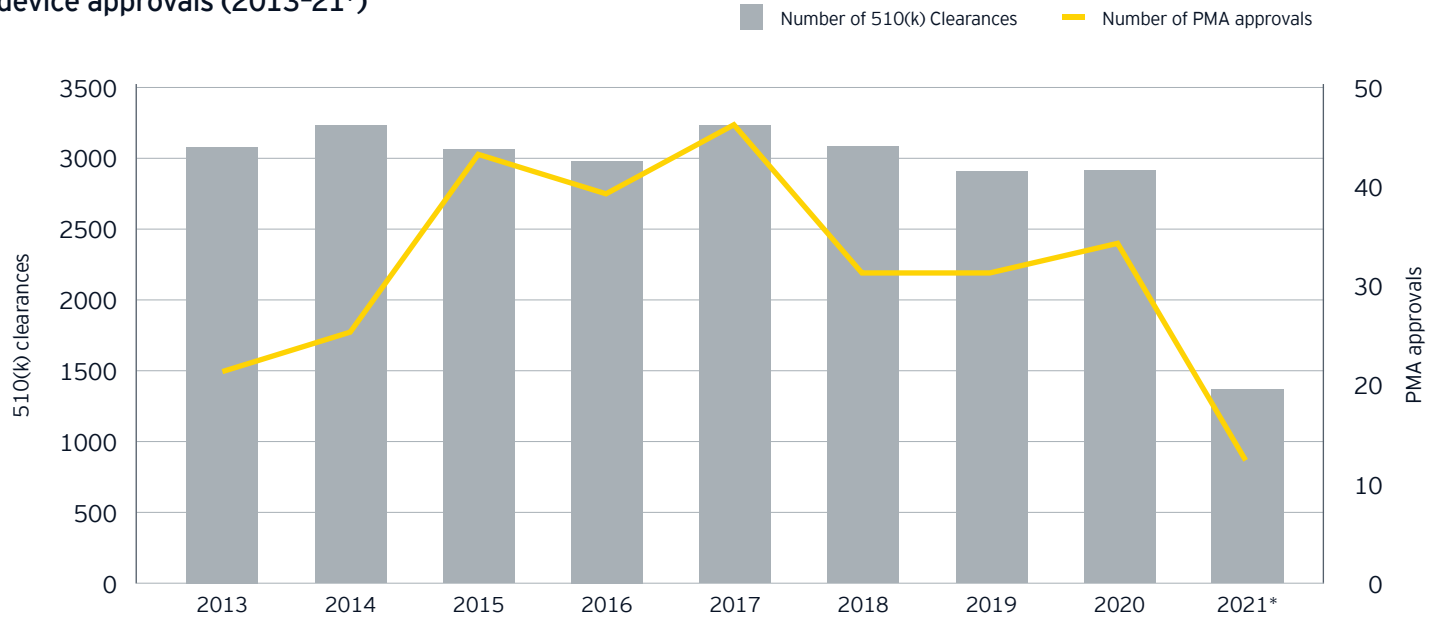
New regulatory and reimbursement models



Regulators have struggled with their additional burdens during the pandemic crisis, with the standard device approval processes slowing. Reflecting this, H1 2021 data shows a significant drop in premarket approvals (PMAs) (12) and 510(k) approvals (1,360) compared to H1 2020 (see Figure 7). A record number of PMA applications are expected by the end of this year, with the regulators viewing 2021 as a “reset” year and anticipating a resumption of normal approval rates in 2022.

Figure 7. US FDA Medical Device Approvals 2013-21

US Food & Drug Administration medical device approvals (2013-21*)



Source: FDA website.

*Data until June 2021 for 510 (k) clearances and approvals.



Yet, the industry now has an opportunity to seek more than just a reset in its regulatory environment. As the industry rethinks business models, it needs to work with regulators to forge a regulatory environment that can support this evolution. During the crisis, regulators showed flexibility to accommodate the expansion of remote care provision and allow a rapid emergency rollout of new products; the challenge for the industry now is to consolidate these changes in legislation to underwrite the ongoing transformation of care delivery.

With the industry currently deep in Medical Device User Fee Agreement (MDUFA) negotiations¹¹ with Congress (intended to reach their conclusion in January 2022), multiple issues are on the table (as discussed in our guest perspective from Heather Meade, Principal, Washington Council Ernst & Young LLP). For example, the possibility of value-based care is on the agenda, as is the funding structure for device review, a potential overhaul of the 510(k) pathway and progress on the Medicare Coverage of Innovative Technology (MCIT) initiative,¹² which is a new pathway for medical device reimbursement that would directly reward breakthrough MedTech innovations with immediate reimbursement.

Also at the forefront is how to widen the “hospital at home” model that has gained such significant traction during the pandemic. The question of whether Congress will support the permanent expansion of telehealth and whether it can allay outstanding concerns about reimbursement rates, fraud, waste and abuse remain, and the US may see uneven national coverage before home care becomes an established permanent policy. With MedTech starting to play

a pivotal role in home-based care, the industry’s advocacy for this long-term transformation is vital.

Other regulatory issues that will help shape MedTech’s future business model include the role of digital therapeutics, classified as software as a medical device (SaMD). Since the FDA’s April 2020 guidance relaxed the entry barriers for digital therapeutics, anticipating that they could meet the need for expanded access to therapies for mental health, approvals for digital therapeutics have followed, including:

- ▶ Akili’s video game EndeavorRx, a prescription-only digital therapeutic for attention deficit hyperactivity disorder (ADHD), was approved by the FDA via the De Novo premarket review pathway¹³ in June 2020.
- ▶ Cognoa’s ASD Diagnosis Aid software for identifying autism spectrum disorders in children aged 18 months through 5 years old was approved¹⁴ in June 2021, also via De Novo.
- ▶ Happify Health’s Ensemble therapeutic for treating major depressive disorder or generalized anxiety disorder won 510(k) approval¹⁵ in July 2021.

However, reimbursement pathways for this emergent class of MedTech products have yet to be clarified, for example, by CMS. In Europe, the situation has progressed more quickly since the German Digital Healthcare Act (DGV) of December 2019¹⁶ went into effect.

One of the industry’s regulatory goals should be to make faster launches a permanent reality by embracing the FDA’s proposed Total Product Lifecycle (TPLC) approach. Outlined in an FDA paper in February 2021,¹⁷ it stated, “The FDA’s traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies.” TPLC can allow AI and SaMD products into market faster if there is a system in place for subsequent postmarketing surveillance. In the future, this accelerated model could become the norm for hardware and software devices, but making it work will depend on the industry’s ability to gather data.

¹¹ “Industry pitches FDA with 26% rise in user fee funding in MDUFA V negotiations,” *MedTechDive website*, <https://www.medtechdive.com/news/industry-pitches-fda-with-26-rise-in-user-fee-funding-in-mdufa-v-negotiations/605166/>, accessed 13 September 2021.

¹² “CMS Delays MCIT Initiative,” *Policy & Medicine website*, <https://www.policymed.com/2021/07/cms-delays-mcit-initiative.html>, accessed 13 September 2021.

¹³ “FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD,” *FDA website*, <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd>, accessed 13 September 2021.

¹⁴ “FDA Authorizes Marketing of Diagnostic Aid for Autism Spectrum Disorder,” *FDA website*, <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-diagnostic-aid-autism-spectrum-disorder>, accessed 13 September 2021.

¹⁵ “Happify Health Launches Prescription Digital Therapeutics to Treat Depression or Anxiety,” *Medtech Insight website*, <https://medtech.pharmaintelligence.informa.com/MT144260/Happify-Health-Launches-Prescription-Digital-Therapeutics-To-Treat-Depression-Or-Anxiety>, accessed 13 September 2021.

¹⁶ “Germany’s digital health changes will boost digital therapeutics in Europe,” *Deep Dive website*, <https://deep-dive.pharmaphorum.com/magazine/digital-health-innovation-2020/germanys-digital-health-changes-will-boost-digital-therapeutics/>, accessed 13 September 2021.

¹⁷ “Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan,” *FDA website*, <https://www.fda.gov/media/145022/download>, accessed 13 September 2021.



Supply chain resilience and agility



The COVID-19 crisis highlighted concerns that the supply of key devices may be vulnerable in times of global disruption. It's another area where regulatory involvement in the industry is intensifying, with lawmakers discussing the potential need for onshoring or nearshoring certain operations to bolster resilience ahead of future challenges. The FDA's 2022 budget request includes US\$21.6 million in funds for a new Resilient Supply Chain and Shortages Prevention Program¹⁸ intended to allow the agency to track device supply and anticipate and preclude shortages. The program builds on the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act's extension of FDA authority into MedTech supply chain security. FDA Acting Commissioner Janet Woodcock blogged that "the pandemic has exposed great weaknesses in the medical device supply chain,"¹⁹ with the agency intending in the future to apply "state-of-the-art supply chain intelligence" to increase surveillance and transparency of MedTech's supply networks.

¹⁸ "FDA's Budget: Medical Device Supply Chain and Shortages Prevention Program," FDA website, <https://www.fda.gov/news-events/fda-voices/fdas-budget-medical-device-supply-chain-and-shortages-prevention-program>, accessed 13 September 2021.

¹⁹ Ibid.

Ernst & Young LLP Managing Director John Polowczyk, a retired US Navy Rear Admiral and former Vice Director for Logistics to the Chairman of the Joint Chiefs of Staff who served as the White House Supply Chain lead on the Coronavirus Task Force, notes that the US struggled to meet PPE demand during the early stages of the pandemic, due to its heavy reliance on overseas production. The federal government deployed the Defense Production Act (DPA) to build domestic capacity, and Polowczyk anticipates that MedTech will continue to see DPA awards as the federal government aims to transform the Strategic National Stockpile “from a static warehouse to a distributed system resident in the commercial segment backed up by US surge production.”

As Polowczyk comments, “Congress is likely to legislate additional authorities to the US Department of Health and Human Services (HHS) to formalize an end-to-end visibility system to understand supply versus demand in real time.”

Yet, while this government-mandated focus on increasing responsiveness and resilience will inform the future development of MedTech supply chains, the industry has its own internal

imperatives to overhaul supply chain operations. If the industry continues to embrace a “humans at the center” model of decentralized care, it will need to evolve its supply chain operations to build agility outside the traditional channels of care delivery.

At present, MedTech supply chains operate in an asset-heavy business model. They typically hold a significant amount of redundant inventory, from orthopedic spare parts to unutilized loose instruments. If the industry can better translate demand signal into supply chain reality (cutting out, for example, distortions caused by salesforce overoptimism), embrace AI analytics for better forecasting, and build greater flexibility – in addition to other innovations such as using smarter use of imaging to anticipate the size of implants required – the industry could significantly downsize its redundant inventory. On the distribution side, there may be more scope for MedTechs to work directly with suppliers and cut out the sales companies they now rely on as intermediaries. Upstream of these operational changes, MedTechs could incorporate integrated business planning into supply chain strategies to accommodate the industry’s long lead times for supply.

Beyond these opportunities, other supply chain challenges loom, and many MedTechs already are engaging with the need to update supply chain strategy, including:

- ▶ Baxter has deployed a cloud-based digital infrastructure²⁰ to simulate demand patterns for its renal therapy devices, using data modeling to understand the location of critical patients, increase manufacturing capacity and accelerate shopping times.
- ▶ Siemens Healthineers signed a July 2020 agreement²¹ with logistics giant DHL, focusing on digital technology, robotics and the goal of building “end-to-end, digitally-enabled supply chain solutions.”
- ▶ Fresenius Medical Care signed a July 2021 deal²² with UPS-owned Polar Speed to help bring dialysis solutions to homes and hospitals in the UK.

With providers and regulators apparently supporting a move away from traditional clinical settings toward data-driven, home-delivered health care, MedTechs will need to build smarter, more agile supply chain strategies to deliver care to a patient’s front door.

²⁰ “Baxter Advances Enterprise Digital Transformation in Collaboration With AWS,” *Business Wire website*, <https://www.businesswire.com/news/home/20210802005596/en/Baxter-Advances-Enterprise-Digital-Transformation-in-Collaboration-With-AWS>, accessed 13 September 2021.


²¹ “Siemens Healthineers and DHL Supply Chain Team Up to Target Innovation and Efficiency in Americas Supply Chain,” *Siemens website*, <https://www.siemens-healthineers.com/en-us/press-room/press-releases/dhl.html>, accessed 13 September 2021.

²² “UPS Healthcare Announces Agreement with Fresenius Medical Care, Expanding Service in the UK,” *Polar Speed website*, <https://www.polarspeed.com/ups-healthcare-announces-agreement-with-fresenius-medical-care-expanding-service-in-the-uk/>, accessed 13 September 2021.





Environmental, social and governance (ESG)

The background of the page is a photograph of a waiting area. In the foreground, there is a modern, silver metal bench with black armrests and legs. Behind the bench is a large window with a grid pattern, looking out onto a building and some green plants. The lighting is soft and natural, suggesting an indoor setting with large windows.

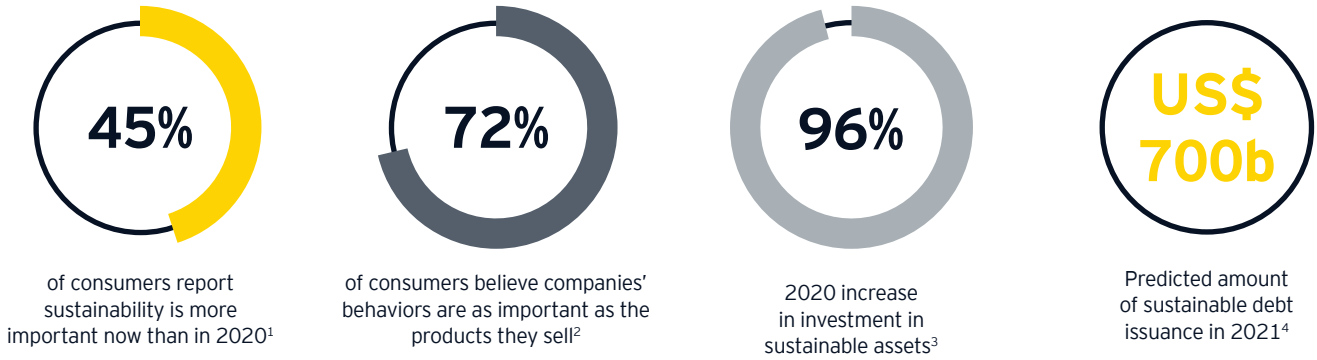
The progress made in evolving the MedTech business model in 2020–21 should be just the start of a long journey. Yet, as we have seen, MedTech faces challenges to put the gains made in human centered care, data access, and supply chain and regulatory reinvention on a more sustainable footing. More broadly, however, MedTech needs to think strategically about helping to ensure its own sustainability – and committing to measuring this. Global recognition of the need to define best practices for measuring sustainability has increased over the past two decades. That’s because sustainability is no longer seen as a marginal concern but as a core aspect of a company’s market value.

Consumers increasingly prioritize sustainability when assessing a company’s business practices, and investors share the sentiment, with Larry Fink’s 2021 letter to CEOs noting a 96% increase in mutual funds’ and ETFs’ investments in sustainable assets in the first 11 months of 2020 compared to the entirety of 2019 (see Figure 8).

¹⁸ “FDA’s Budget: Medical Device Supply Chain and Shortages Prevention Program,” FDA website, <https://www.fda.gov/news-events/fda-voices/fdas-budget-medical-device-supply-chain-and-shortages-prevention-program>, accessed 13 September 2021.

¹⁹ Ibid.

Figure 8. The growing importance of sustainability



Source:

^{1,2} EY Future Consumer Now Survey, January 2021. | ³ BlackRock, "Larry Fink's | letter to CEOs," 2021. | ⁴ S&P Global Ratings.



Sustainability should be a central concern for MedTech. A 2020 Health Affairs analysis²³ suggested that the global health industry generated 4.6% of all greenhouse emissions (twice as much as the aviation industry²⁴), with medical device supply chains presenting major opportunities to increase sustainable practice. (In 2018 alone, device reprocessing in the US, Europe and Canada reduced hospital waste generation by 7,100 tons.) Many leading MedTechs are embracing sustainability initiatives:

- ▶ Medtronic, Illumina, Becton Dickinson, Boston Scientific, Edwards were included on the S&P Dow Jones Sustainability North America Index in November 2020.
- ▶ Johnson & Johnson collected 1.6 million medical devices and reprocessed 670,000 in 2020 alone as part of its broad-ranging Health for Humanity sustainability initiative.

- ▶ Phillips, in February 2021, announced it had achieved carbon neutrality across its operations, with all of its electricity generated renewably, 90% of its operational waste recycled and 15% of its sales coming from circular revenues.

Yet overall, MedTechs have been slower than companies in other sectors to respond to the demands of sustainability. As devices increasingly incorporate digital and electronic components, issues of waste move beyond single-use plastics and become more pressing. From manufacturing processes to packaging and recycling of products at the end of their shelf life, there are significant areas for MedTechs to focus on reducing not only CO2 but the broader environmental consequences of their products.

It's now acknowledged that environmental degradation creates global public health challenges, such as respiratory disease from air pollution and elevated cancer risks from chemical contaminants in the food chain. For companies in the business of delivering better health outcomes, there is a greater need to walk the talk. That includes not building their operations on supply chains associated with outsize carbon footprints or pollutant by-products. Instead, companies need to embrace sustainable manufacturing, potentially sharing capacity and infrastructure to reduce wastage.

In 2021, the MedTech industry already has rebounded strongly from the impact of COVID-19. To sustain that momentum into the future, it needs to focus on ensuring it has patient-centric business models, the tools to capture and use data effectively, an optimal regulatory environment and resilient supply chains. It also needs to focus on ensuring it is simply – sustainable. This will be the final and critical component in locking in long-term value for MedTech into the future.

²³ "Transforming the Medical Device Industry: Road Map to A Circular Economy," *Health Affairs website*, <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2020.01118>, accessed 13 September 2021.

²⁴ "Single-Use Medical Device Reprocessing: Towards a Circular Economy," *Yale University Sustainability in Health Care Symposium*, Dan Vukelich, Esq., 27 May 2021.



Giovanni di Napoli

President

Gastrointestinal, at Medtronic

Detect Early, Treat Early: improving the care experience for patients and physicians

We can summarize our approach in four words: Detect Early. Treat Early.

That's the key to better outcomes. Any innovation we bring to market must measure up to this goal and to the core tenets of the Medtronic mission – to alleviate pain, restore health and extend life.

We're working to solve major challenges in health care. In gastroenterology, one area where we've achieved this is in our advancement of colonoscopy. Colorectal cancer (CRC) is the second deadliest cancer worldwide.¹ But it doesn't have to be. Screening can lead to early detection and diagnosis of earlier stage disease – when it's most treatable – and help detect and remove precancerous polyps, preventing their progression to cancer. Yet despite dire warnings and hopeful solutions, each year, there are still approximately 22 million people in the US who should – but don't – get screened, including a disproportionate number from ethnic and racial minorities at greater risk of colon cancer.²

Using AI to disrupt screening

Medtronic believes that AI will supercharge the speed, accuracy and quality of diagnostic and therapeutic decision-making – ultimately giving patients the individualized care they deserve. Earlier this year, Medtronic introduced the gastrointestinal GI Genius™ intelligent endoscopy module – the first FDA-approved computer-aided detection system using artificial intelligence (AI) for identifying colorectal polyps to become commercially available.

GI Genius™ serves as a second set of eyes during colonoscopies. The system scans every frame of the procedure by leveraging the power of AI, providing real-time image analysis in milliseconds, and alerts physicians to the presence of lesions – including small, flat polyps that the human eye could easily miss.

The AI was trained on 13 million polyp images of various shapes and sizes, enabling it to achieve a 100% sensitivity³ in detecting colorectal polyps – robust clinical evidence shows polyp detection increases by up to 14% when using GI Genius™ when compared to the average endoscopist.

Today, GI Genius™ is used to detect precancerous polyps in the colon, but in the future, it also could size and characterize them, helping to determine whether a polyp should be removed and unlocking the even greater potential for making the physician's job easier and faster.

This is a unique and innovative technology, and we're committed to a unique and innovative approach to bringing it to customers: with the GI Genius™ Membership, we're helping physicians access this leading AI technology through a subscription plan. As our AI continues to evolve, new software upgrades will continue to unlock new features and add value each quarter.

Empowering patients and challenging suboptimal care standards

The PillCam™ platform is another first-of-its-kind product, helping to personalize care and change the way in which patients experience medicine. It's an ingestible capsule offering physicians comprehensive digestive tract imaging while giving patients the type of minimally invasive test they prefer. We invented capsule endoscopy 20 years ago. Now, we are reinventing it by changing where it takes place. Last month, we received FDA 510(k) approval for the PillCam™ Small Bowel (SB) capsule that can be administered by the patient in their own home.

At-home diagnostic tests are an increasingly preferred option for many patients, as they require less time and logistics than visiting a care site. In the future, we will offer additional at-home PillCam™ tests, such as for colorectal cancer screening, to empower patients to take ownership of their health care.

Enabling this future requires a broad distribution network, cloud services and other technology solutions to help make PillCam™ more readily accessible and deliver experiences and benefits that our customers and patients have become accustomed to in their daily lives.

Of course, COVID-19 has greatly accelerated the adoption of this patient-centered technology. As elective procedures in GI were being canceled and backlogs grew, we were able to show how our PillCam™ small bowel (SB) product could be used in the patient's home rather than the doctor's office. In Europe, PillCam™ COLON provided a way to risk stratify patients and determine who should receive a colonoscopy faster, helping to ease accessibility challenges. Feedback from doctors using the remote PillCam™ COLON procedure in the UK during the pandemic showed that the technology has helped offset a huge drop in volume at surgical centers and has received exceptionally positive feedback from patients.

Another example of how we're challenging suboptimal standards of care in GI comes into play when a lesion like a colorectal polyp is found and needs removal. Another of our new technologies, ProdiGI™ traction wire, an innovative endoscopic resection platform, could enable clinicians to remove those lesions, without open surgery, during a procedure called Endoscopic Submucosal Dissection (ESD).

This is a proven procedure to remove lesions completely – but it's technically challenging to perform even for experienced clinicians. ProdiGI™ will help them more easily remove these lesions – endoscopically – with more control and fewer tools.

We believe that improving care requires disruptive innovation, which can only be achieved through a deep understanding of the patient – their needs, journey and experience. So, when we're faced with a new opportunity, we ask ourselves: will this improve patient outcomes? Will it set a new standard of care? Does it increase access to care? Does it empower patients to take ownership of their health care? If it fits in with these criteria, we know we're on the right path.

Views expressed in this article are those of the author and do not necessarily represent the views of Ernst & Young LLP or other members of the global EY organization.

¹ "World Health Organization Cancer Today Fact Sheets," World Health Organization, website, www.who.int/news-room/fact-sheets/detail/cancer, accessed September 16, 2021.

² "Colorectal Cancer Facts & Figures 2020-2022," American Cancer Society website, www.cancer.org/research/cancer-facts-statistics/colorectal-cancer-facts-figures.html, accessed September 16, 2021.

³ GI Genius™ instructions for use (IFU).



Heather Meade

President

Washington Council Ernst & Young,
Ernst & Young LLP

The MedTech Minute: What to watch in Washington

Over the past year, COVID-19 has dominated the MedTech and wider health care agenda in Washington, as hundreds of billions of relief dollars flowed into the industry while the resiliency of supply chains and decision-making of regulators came under scrutiny. As public health challenges continue, the Democratically controlled US Congress and Biden administration wants to deliver on campaign promises to expand health benefits, reduce prices and address the cost of care, spurred further into action as the clock ticks down to the 2022 US midterms (and the possible end of their control).

While the policy changes under consideration undoubtedly will have implications for the MedTech industry (i.e., drug pricing and coverage expansion), there are other smaller changes under consideration that could affect the industry as we round out 2021.

Here are three potentially important stories largely flying under the radar:

1. MDUFA V negotiations

With authorization for the current Medical Device User Fee program (MDUFA) expiring in September 2022, negotiations for FY 2023–27 are well underway, and an agreement is due to Congress by January 2022. While the industry is mainly looking for targeted improvements to the program, the FDA wants more money to fund its operations. The agency proposes using leftover user fee money for its Digital Transformation Initiative, which involves updating the medical device center's IT system and making reporting data more accessible. However, device industry officials contend that any carryover funds be used to lower user fees, improve premarket reviews and eliminate application backlogs.

The FDA also is proposing a new program – the Total Product Lifecycle Advisory Program (TAP) – to increase premarket communication among the FDA, device sponsors, payers and physicians. But the industry has argued that such a program would over-complicate the approval process and cause the FDA to overstep its authority.

While industry and regulators hash it out in the coming months, other congressional priorities inevitably will get attached to the negotiations. One prime suspect: cybersecurity. The FDA is considering seeking additional legislative authority to bolster medical device cybersecurity amid growing ransomware and other cyber attacks on health care organizations. Provisions from the bipartisan “CURES 2.0” legislation proposed by Rep. Diana DeGette (D-CO) and Rep. Fred Upton (R-MI) also are being considered, including proposals aimed at improving how Medicare covers innovative health technologies and better incorporates real-world evidence and consumer feedback.

2. CMS coverage decisions

In September, CMS issued a Notice of Proposed Rulemaking (NPRM) that proposes to repeal the Trump-era Medicare Coverage of Innovative Technology (MCIT) initiative, which would have provided automatic reimbursement for breakthrough devices once approved by the FDA. MCIT was celebrated by the industry and supported by many in Congress, who saw the pathway as addressing a critical delay between FDA approval of a breakthrough device and coverage by Medicare. However, Biden’s CMS noted concerns that the new pathway could lead to coverage of devices that lack adequate value and safety assessments – a sentiment shared by some insurer and provider groups – and that the MCIT pathway could disincentivize the development of innovative technologies that do not meet “breakthrough device” criteria and, thus, do not qualify for MCIT. CMS will now try to thread the needle in future rulemaking, leveraging existing statutory authorities to create a more flexible coverage pathway to speed access to new technologies while also prioritizing beneficiaries’ health and outcomes.

Lawmakers also are considering how best to address the coverage of telehealth in Medicare, with CMS recently proposing to extend the coverage of certain services added during the pandemic to allow more time for evaluation, in addition to continued expansion of remote monitoring codes.

CMS, however, needs Congressional action to permanently expand telehealth in many regards – including removing restrictions on site of care, eligible providers, and non-rural areas. Congress agrees that action is needed, but issues of reimbursement, equity and the hefty costs of a potential package remain sticking points in the discussions.

3. Changing care and reimbursement models

The Biden administration also is focused on broadening access to value-based, equitable care. President Biden is particularly focused on enhanced access to home- and community-based care, which could lead to new or expanded models for the delivery of home-based primary care, behavioral health and chronic disease management, as well as an expansion of programs providing hospital-level care at home. Proposals may include expansion of the “Acute Hospital Care at Home” program, which provides eligible hospitals with unprecedented regulatory flexibilities to treat eligible Medicare patients in their homes, enabled by virtual care and remote monitoring technology combined with in-home visits.

Unfortunately, the state of the Medicare Trust Fund, which is set to run dry in 2026, may mean that cost-cutting will be part of the overarching calculus. Proposals include a potential emphasis on site-neutral payment, enhanced primary care models and population-based reimbursement methodologies such as capitation – potentially leaving it up to providers to determine how best to flex their payments to meet quality metrics and patient needs.

With health policy changes large and small under consideration, communicating the perspective of the MedTech industry will continue to be important for both Congress and the administration through the fall and into next year.

The views expressed by the author are not necessarily those of Ernst & Young LLP or other members of the global EY organization.



Dr. Jeffrey Krauss

Chief Medical Officer
Hinge Health

How digital health is creating a frictionless health care experience

In 2020, the COVID-19 pandemic fundamentally shifted the way we delivered health care from a brick-and-mortar approach to more virtual care. At Hinge Health, we saw an increasing number of employers and health plans partner with us to offer our innovative Digital Musculoskeletal (MSK) Clinic as an alternative to elective surgeries or in-person physical therapy.

The pandemic drove this widespread adoption of digital care, but employers, health plans and patients recognize its lasting benefits. In fact, according to the Business Group on Health, over 70% of large employers plan to add a digital MSK benefit over the next few years.¹

Tackling the fragmented health care experience

While back, neck, shoulder, hip, knee and other joint pain affect over half of Americans today, the current member experience is often poorly coordinated.

According to our 1,000 US office workers, over half of respondents with moderate or severe MSK pain saw two or more providers for their MSK care; 50% of respondents felt their history got lost in between different providers and 87% felt their MSK care would benefit if their provider looked at their whole picture.²

Here are four ways digital health technologies can provide a more frictionless health care experience.

1. Integrated digital teams providing seamless care

Fragmented care occurs because care is spread out across a large number of poorly coordinated providers. Coordinating holistic care teams across specialties can be a headache when specialists aren't located in the same office. But with the advent of virtual care and digital technologies, integrated care teams are becoming the new standard of care.

We have pioneered delivering digital care with a comprehensive, holistic clinical care team of physicians, physical therapists, health coaches, nutritionists and other specialists to look at a member's whole body and lifestyle, not just one injury. When it comes to chronic pain, our team can address both patients' physical therapy plan and their exercise, sleep, diet and self-management strategies.

2. Digital tools empower patients

Changing the paradigm from a traditional doctor-patient relationship to a patient-centered approach also is key to creating a better member experience in an integrated world of care. The goal is to empower the patient with the tools to better manage their own care.

Our Digital MSK Clinic provides advanced digital technologies like motion sensors and an easy-to-use app to allow patients to self-manage their care and perform their exercise therapy from the comfort of their homes. We also provide one-on-one health coaches and physical therapists to further support the member's recovery.

3. Wearable technologies provide pain management

Just as robots can now perform surgeries, new wearable technologies offer care remotely. We recently announced Enso, our wearable technology using high-frequency pulses to provide non-addictive, non-invasive and long-lasting pain relief. The wearable can be worn while a member is exercising or going about their daily life, enabling them to do their exercise therapy and get on a recovery path.

4. Bridging the divide between physical and digital care

While the pandemic prompted a surge in digital care, it also exposed a lack of coordination between in-person and digital

providers, resulting in a poor participant experience, lower-quality care, and higher costs. The next challenge will be integrating these two worlds of care to create a seamless experience for the patient (sometimes referred to as "click-and-mortar"). For some treatments, in-person care is necessary; for others, digital care is better.

At Hinge Health, we are continuously innovating to improve the participant experience across the worlds of digital and physical care. We recognize participants in our program have in-person providers as well. We recently launched HingeConnect, which leverages data intelligence to set a new standard for personalized care via electronic medical record (EMR) integration, real-time interventions and robust care coordination across digital and in-person providers.

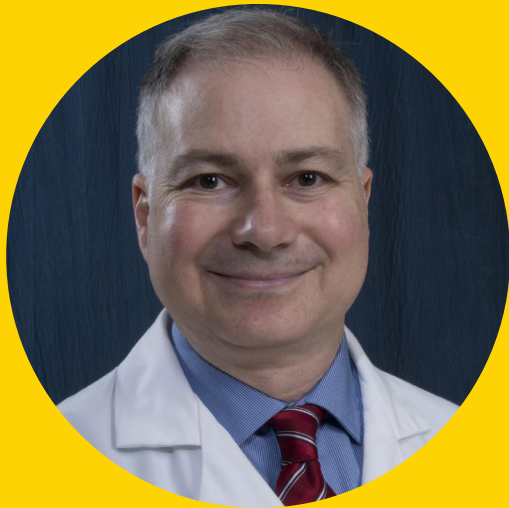
Another way we've integrated the two worlds of care this year is through our partnership with Carrum Health and SurgeryPlus Centers of Excellence, offering high-quality and low-cost surgery when surgery is the right option.

We're only at the tip of the iceberg when it comes to innovations in the digital health space. While 2020 was a watershed year, the floodgates are now open, and we are continuing to invest in R&D and innovation to redefine how we deliver MSK care.

Views expressed in this article are those of the author and do not necessarily represent the views of Ernst & Young LLP or other members of the global EY organization.

¹ "2021 Large Employers' Health Care Strategy and Plan Design Survey," Business Group on Health website, www.businessgrouphealth.org/resources/2021-large-employers-health-care-strategy-and-plan-design-survey, accessed September 16, 2021.

² "Creating a Frictionless Healthcare Experience: What Members Want in Musculoskeletal Care," Hinge Health website, www.hingehealth.com/creating-a-frictionless-healthcare-experience-report/, accessed September 16, 2021.



Nabil Chehade

Executive Vice President & Chief
Clinical Transformation Officer
MetroHealth in Cleveland, Ohio

MetroHealth is a public health system where we have always been focused on health equity. Over the past several years, we have been taking on risk to manage costs and provide access to care most effectively. We worked hard for many years, with limited success, to introduce the concept of virtual care. But we could not move the needle within our own system despite our best efforts; virtual care made up less than 1% of our encounters.

Then, in March 2020, came COVID-19, and overnight, things changed.

Within a week, virtual care made up 75% of our visits. Prior to the crisis, we had been working with a third-party vendor to offer a virtual urgent care app. We were getting 60–80 calls per month. Now we range from a hundred to several hundred each day, and about half of these lead directly to virtual urgent care visits with providers. Suddenly, there was mass acceptance of telehealth in general and, more specifically, for on-demand virtual urgent care. Today, health care CEOs will tell you they are never going back to traditional care delivery.

Unfortunately, I believe that many health systems will ultimately reduce their virtual care focus. Everybody understands where we need to go. But despite those best intentions, the reality is that health systems have bricks and mortar that they must pay for, hospital beds to fill and outpatient facilities still in place. That inertia is going to drag them back to what they know. The burning platform of one year ago is no longer present, and the rules and regulations that the Centers for Medicare & Medicaid Services (CMS) and state medical boards passed at the onset of the pandemic (covering reimbursement and scope of practice) are very quickly evaporating.

Nevertheless, I also believe that virtual care is here to stay.

Traditionally, it's been very difficult for new entrants to penetrate the health market, but the price of entry for virtual and home care is much lower. We will see many offerings based on nontraditional care entering the market. In the end, health systems will have to adopt those technologies and solutions, even if it potentially cannibalizes revenue from their

own services. Quite simply, if they don't offer these virtual care models, somebody else is going to do it instead. Whether it's payers, employers, large tech companies or some combination of these partnering to offer an alternative to the traditional provider network, it's going to happen. It's a scary prospect for the health systems that aren't able to adapt quickly and become the first movers.

As many players queue up to offer virtual care, the question for MedTech companies is how they can insert themselves into these new ventures. The very concept of moving from an in-person care model to an alternative model of care lends itself to a MedTech offering, from A to Z. In any scenario where you are providing care at the patient's home, you need the assistance of devices that can transmit data and assist the remote provider who's interpreting the data. It's going to put more stress on MedTech to develop nimbler, more efficient tools, figure out how to partner to deliver those capabilities and prove the value of those capabilities.

There are many MedTech innovations created that end up having limited use in broader practice. MedTechs need to offer solutions that are practical, affordable, easy to use and solve problems at scale. For example, we have digital disparities in this country around issues like Wi-Fi availability – but devices can bypass those problems. MedTech could improve the LTE digital connectivity of the most common devices, build them to continuously transmit 5G data directly from your home to your provider and without relying on the intermediary of a third-party app that the patient has to download on their phone or tablet. This would help ensure that the digital divide doesn't come between us and the care we're trying to provide. In this revolution, there is so much opportunity, even in simple things.



A person wearing a white lab coat is pointing with a blue pen at a computer monitor displaying an ECG (heart rate) graph. The monitor is the central focus, showing multiple traces of heart activity on a grid. The person's hands are visible, one holding the pen and the other resting on a desk. The background is a bright, out-of-focus window, suggesting a clinical or laboratory setting. The word "Databook" is overlaid in large white text on the left side of the image.

Databook





Financial performance

Medical technology at a glance

(US\$b, data for pure plays except where indicated)

Public company data	2020	2019	Change	% change
Total revenue	\$446.0	\$419.7	\$26.4	6.3%
▸ Conglomerates	\$201.8	\$183.0	\$18.7	10.2%
▸ Pure-play companies	\$244.3	\$236.6	\$7.6	3.2%
▸ Commercial leaders	\$223.7	\$218.0	\$5.7	2.6%
▸ Noncommercial leaders	\$20.5	\$18.6	\$1.9	10.2%
R&D expense	\$23.8	\$20.3	\$3.5	17.2%
SG&A expense	\$82.6	\$81.5	\$1.1	1.3%
Net income	\$20.4	\$24.8	\$(4.4)	(17.8)%
Market capitalization	\$1,662.4	\$1,286.4	\$376.0	29.2%
Number of employees	878,900	840,100	38,800	4.6%
Number of public companies	446	435	11	2.5%

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

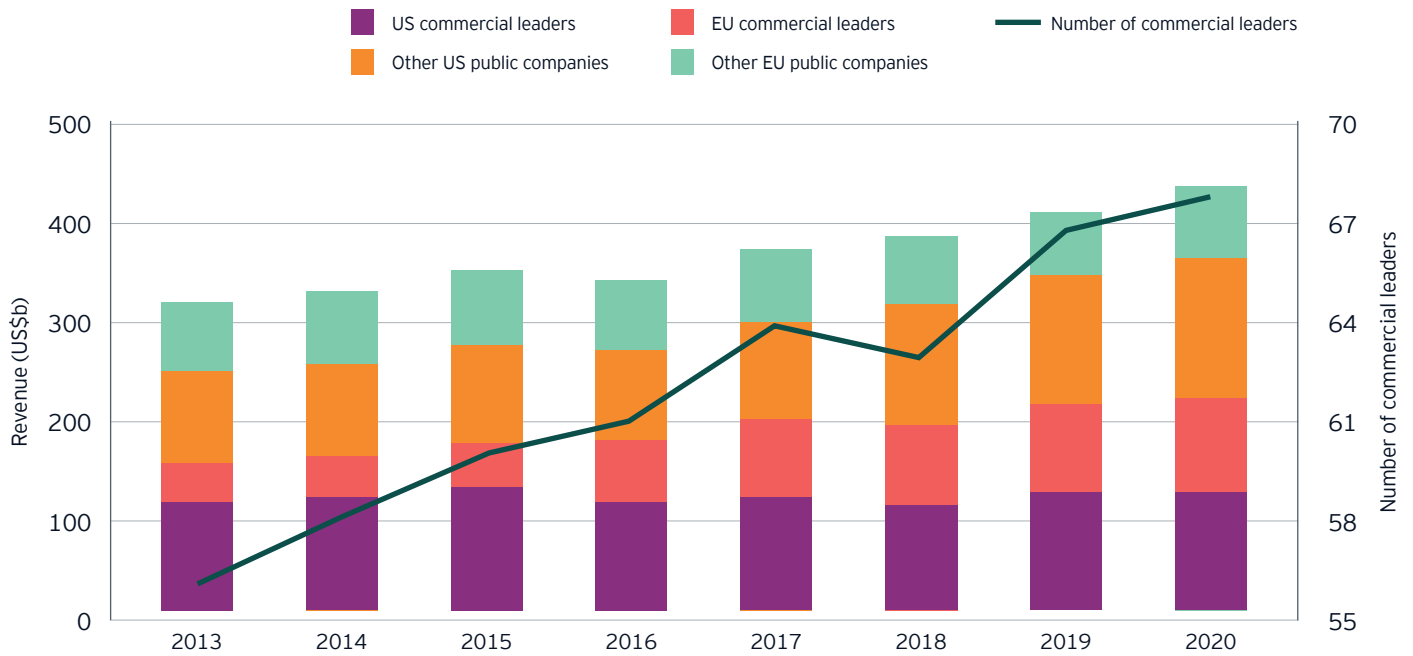
Numbers may appear to be inconsistent due to rounding.

Data shown for US and European public companies.

Market capitalization data is shown for December 31, 2020.

- Despite the disruptions of 2020, industry revenue grew 6.3%, essentially unchanged from revenue growth rates in 2019 (6.2%) and 2018 (6.3%).
- Conglomerates were the strongest performing segment, with 10.2% growth (vs. 1% in 2019). Seven conglomerates (Fresenius, Danaher, Avantor, Abbott, Roche, Merck KGaA and Philips) saw revenue growth of at least US\$1.5 billion as COVID-19 spurred investment in testing and treatment, diagnostics, PPE, and remote screening and monitoring technologies.
- However, other conglomerates saw revenues hit by canceled or delayed elective surgeries and reduced overall patient visits. For instance, Johnson & Johnson experienced a US\$3 billion drop in revenues, while Essilor's ophthalmic business experienced a US\$487 million decline.
- Pure-play MedTechs also suffered from the impact of COVID-19, with net income falling 18% to US\$20 billion, following a 40% increase (mostly driven by accounting charges, credits and other tax/legal adjustments) in 2019. In all, 55% of pure-play MedTechs saw incomes fall, and 7 of the 10 largest pure-plays saw declining revenues, with only Medtronic, Siemens Healthineers and Edwards Lifesciences growing revenues.
- Despite COVID-19, there was an increase in the number of public pure-play MedTechs (rising 3% to 446) and the number of people working for them; pure-plays added nearly 40,000 employees, with two-thirds of all companies increasing headcount.
- Of the commercial leaders and conglomerates that released H1 2021 earnings, their collective top lines grew 30% vs. the same period in 2020 and 25% vs. 2019.
 - 94% of the companies grew their revenue, with Align Technology (+111%), Hologic (+96%) and PerkinElmer (73%) leading the way.

US and EU MedTech public company revenues

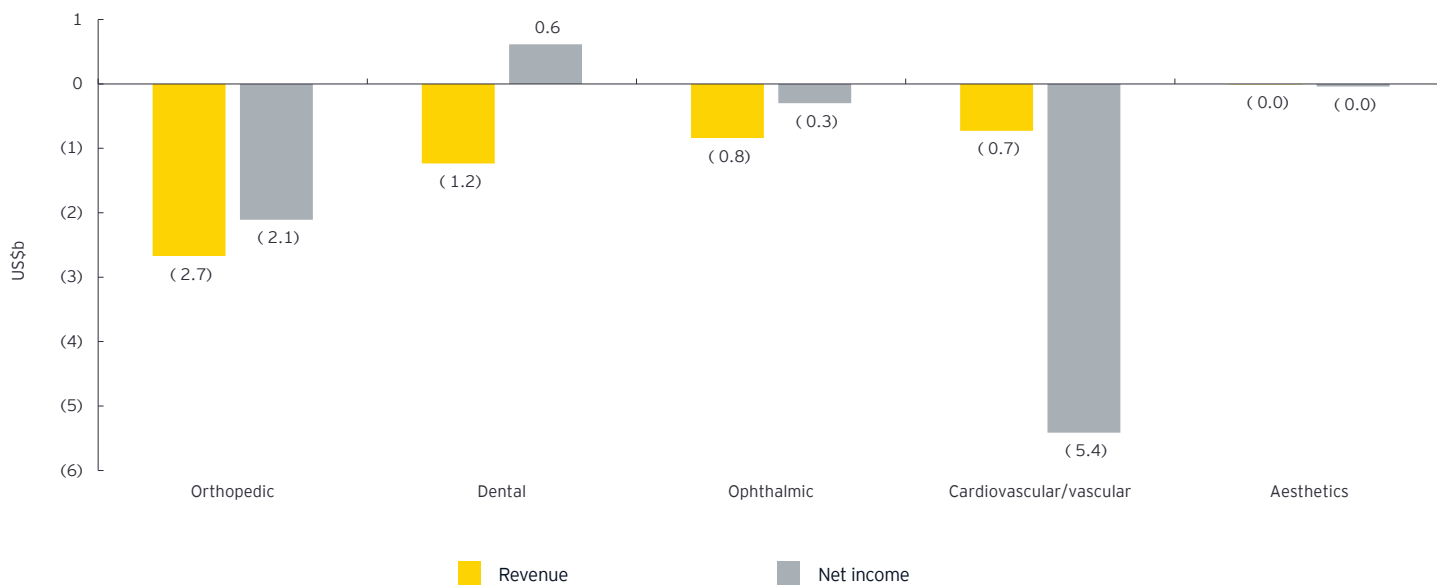


Source: EY analysis and Capital IQ.

Commercial leaders are companies with revenues \geq US\$500m.
Other companies include figures for conglomerates.

- ▶ Of the industry's US\$446 billion total, US public companies accounted for 63% of that revenue, generating a total US\$274 billion (up 5%). European public company revenue rose 8%, reaching US\$172 billion.
- ▶ There were 68 commercial leaders (defined by EY research as pure-play MedTechs with revenues greater than US\$500 million) in 2020, with 44 of these companies based in the US.
- ▶ Europe had 24 commercial leaders, with one addition in 2020 – Denmark's Ambu A/S, which focuses on single-use endoscopy solutions, diagnostic and life-supporting equipment, saw its revenues climb 37% to US\$563 million in 2020.

Financial performance of MedTech's largest therapeutic device disease areas, 2020



Source: EY analysis and Capital IQ.

Commercial leaders are companies with revenues >=US\$500 million.

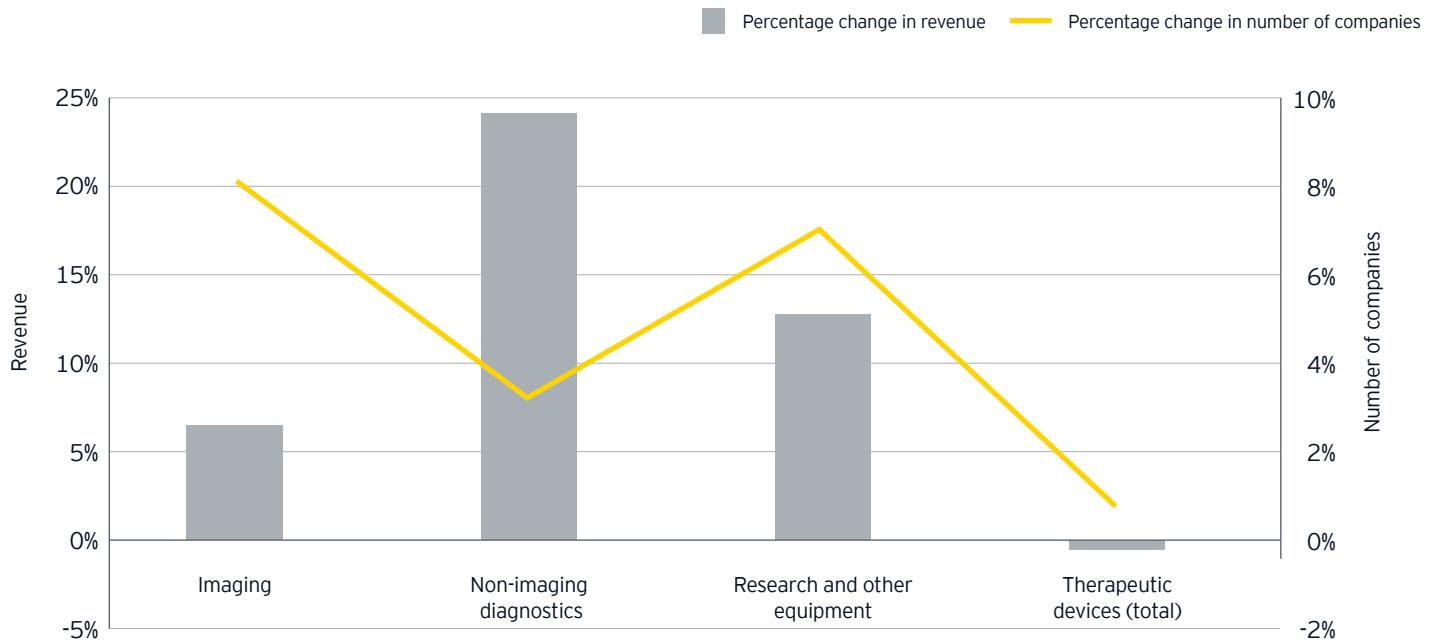
► The therapeutic areas worst affected by the pandemic were:

- Orthopedic, which saw the most significant drop in annual growth rate (-8.2%) and dollar (-US\$2.7 billion) terms. In all, 68% of orthopedic companies saw a decline, with Zimmer Biomet revenues dropped -12% (-US\$958 million), largely through deferral of elective surgical procedures; Smith & Nephew fell 11% (-US\$578 million) for similar reasons), and Stryker also declined 4% (-US\$533 million).
 - However, there was a notable improvement in H2 2021, as these same companies saw their top lines grow by 29%, 28% and 30%, respectively, vs. H1 2020.
- Dental (-10.3%; -US\$1.2 billion): with customer demand plunging in H1 2020 and professional dental associations recommending practitioners perform only emergency procedures, leaders like Dentsply Sirona experienced a 17% (US\$687 million) revenue decline, with Envista Holdings also taking a 17% hit. In all, 75% of dental companies saw revenues contract, though the sectors' second-largest player, Align Technology, grew 3%.
 - Again, H1 2021 provided significant relief as revenues of Dentsply, Envista and Align grew 53%, 59% and 111% vs. H1 2020.

- Ophthalmic (-8%; -US\$840 million): with delayed orders, lack of patient access and lower use of contact lenses during social distancing, 70% of ophthalmic companies saw revenues fall, including the two leaders Alcon (down -9%, a drop of US\$675 million) and Cooper Companies (-8%; US\$222 million).
 - Once again, H1 2021 results far outpaced H1 2020, as Alcon's revenue surged 32% while Cooper's increased 20%
- Cardiovascular (-4.2%; -US\$787 million): 71% of companies saw revenue contractions because of COVID-19, though the worst-affected, Boston Scientific, fell largely because its 2019 revenues included US\$2.5 billion of after-tax credits.
 - In the first half of 2021, Boston Scientific's top line jumped 28%.
- In absolute revenue terms, Respiratory grew more than any other therapeutic area (up US\$492 million, a 13% rise), with companies such as GVS (a 2020 IPO) and ResMed at the forefront of delivering masks, ventilators and filters.

Driven by the impact of COVID-19, non-imaging diagnostic revenues surged nearly 25%

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



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

Data shown for pure-play companies only.

- ▶ With the negative impact of COVID-19 on the two biggest therapeutic areas (orthopedic and cardiovascular), overall therapeutic device revenue remained almost flat, falling 0.4% to US\$176 billion (though still accounting for over 72% of all revenues for pure-play MedTechs).
- ▶ All other product segments grew in 2020, with the pandemic often acting as a driver rather than a constraint; the imaging segment grew 6%, with 58% of imaging companies recording top-line growth; Siemens Healthineers led the way with 9% growth.
- ▶ The Research & other equipment segment grew 13%, with COVID-19 fueling growth; in all, 70% of companies in the segment grew, with PerkinElmer revenues rising US\$900m and Sartorius by US\$807 million, in both cases driven by product offerings relevant to COVID-19 diagnostics, vaccines and other R&D.
- ▶ The urgent need for COVID-19 diagnostics saw non-imaging diagnostics perform more impressively than any other product segment, hitting US\$21 billion, with 60% of companies increasing their revenues, and 28 seeing top-line growth of over US\$200 million. While the pandemic accelerated growth, the diagnostics segment has performed strongly in recent years and established itself as a key driver for the industry even prior to 2020.
- ▶ Prominent among the non-imaging diagnostics companies making significant revenue gains were Quidel (up US\$1.1 billion, with 70% of revenues coming from six different COVID-19 immunoassay and molecular diagnostic products for which it won emergency use authorization), Biomerieux (up US\$813 million on the basis of COVID-19 testing, and Exact Sciences (up US\$615 million after expanding its cancer screening franchise and adding COVID-19 tests).

A lot has changed in 15 years

The fastest-growing MedTechs since the inaugural EY Pulse report in 2007 (US\$m)

Company	Segment	Region	Revenue (2006)	Revenue (2020)	CAGR (2006-20)
Dexcom	Non-imaging diagnostics	US - Southern California	\$2	\$1,927	57%
Exact Sciences Corporation	Non-imaging diagnostics	US - Wisconsin	\$5	\$1,491	47%
Insulet	Therapeutic devices (drug delivery)	US - Massachusetts	\$4	\$904	44%
Abiomed	Therapeutic devices (cardiovascular/vascular)	US - Massachusetts	\$44	\$841	22%
Illumina	Research and other equipment	US - Southern California	\$185	\$3,239	21%
Quidel	Non-imaging diagnostics	US - Southern California	\$106	\$1,662	20%
Align Technology	Therapeutic devices (dental)	US - Northern California	\$206	\$2,472	18%
Intuitive Surgical	Therapeutic devices (multiple)	US - Northern California	\$373	\$4,358	18%
NuVasive	Therapeutic devices (orthopedic)	US - Southern California	\$98	\$1,051	17%
Hologic	Therapeutic devices (women's health)	US - Massachusetts	\$463	\$3,776	15%
Danaher: Life Sciences & Diagnostics and Dental	Research and other equipment	US - District of Columbia	\$2,220	\$17,979	15%
Livanova	Therapeutic devices (multiple)	UK	\$123	\$934	14%
Merck KGaA: EMD Millipore	Research and other equipment	Germany	\$1,255	\$9,193	14%
ICU Medical	Therapeutic devices (non - disease - specific)	US - Southern California	\$202	\$1,271	13%
Cantel Medical	Research and other equipment	US - New Jersey	\$192	\$1,016	12%

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

- ▶ Many of today's MedTech commercial leaders were mere startups when we first published the *Pulse of the industry* report in 2007.
- ▶ Technologies like continuous glucose monitoring, precision diagnostics, automated drug delivery platforms, surgical robots and rapid genetic sequencing were all in their infancy. Today, they are at the core of MedTech innovation and growth.
- ▶ Founded in 1999, Dexcom's revenue has grown an astronomical 88,688% since 2006. In 2006, Dexcom received US FDA approval and launched the Dexcom STS Continuous Glucose Monitoring (CGM) System, a three-day sensor that provided up to 288 glucose measurements for every 24 hours. Fast-forward 15 years, and the flagship G6

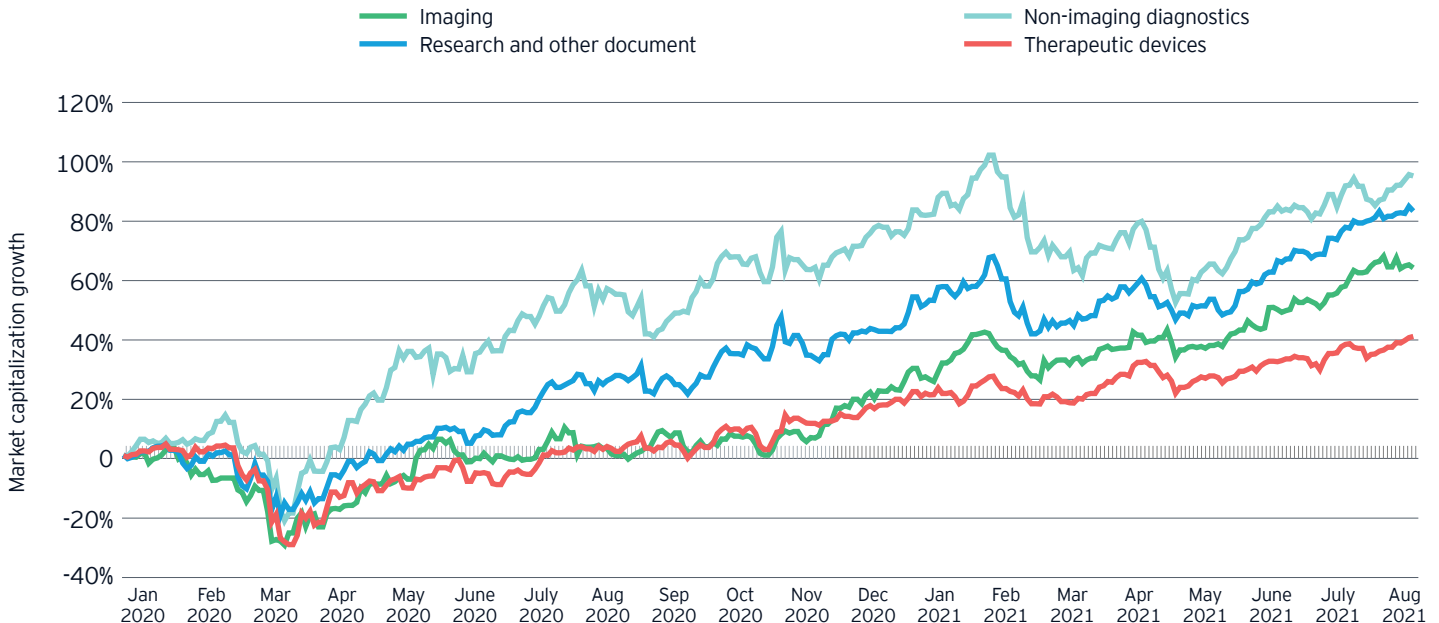
CGM System – which uses a small wearable (remote) sensor and transmitter to measure and send real-time glucose values wirelessly – fueled nearly US\$2 billion of revenue for Dexcom in 2020.

- ▶ With a growth rate of more than 31,000%, Wisconsin-based Exact Sciences was the second-fastest-growing MedTech over the past 15 years. Founded in 1995, the company is a leading provider of cancer screening and diagnostic tests, marketing Cologuard® (a multitarget stool DNA test) and Oncotype DX (an individualized oncology diagnostic test)
- ▶ Rounding out the top three is Insulet, maker of Omnipod®, a tubeless, automated insulin pump that provides 72 hours of continuous insulin delivery to diabetic patients and which has recorded a 24,590% revenue increase in the past 15 years.



Non-imaging diagnostic companies were handsomely rewarded by public investors

US and European MedTech market capitalization by product type



Source: EY analysis and Capital IQ.

Charts includes companies that were active on 01 September 2021.

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

- ▶ As well as outstripping the other segments of the market in revenue growth terms, the non-imaging diagnostics segment also led the rebound in MedTech company valuations, with company valuations rising 95% in the 20 months from January 2020 to the end of August 2021. The other MedTech product segments all saw their valuations climb in this period, though less spectacularly. Research and other equipment company valuations grew 83%, imaging 64%, and therapeutic device 41%.
- ▶ Overall, since dropping 36% when the market bottomed out on March 22, 2020, MedTech valuations have recovered to a record growth of 55% since January 2020, outperforming big pharma (16%), NASDAQ biotech (42%) and the composite broader indices (21%).
- ▶ MedTech's recovery indicates the importance of its offerings to the global effort to contain COVID-19, from PPE and ventilators to novel diagnostic tests. For example, Quidel received a EUA for its Lyra SARS-CoV-2 Assay rapid point-of-care test as early as March 17, 2020. However, it is notable that Rock Health's digital health index has rebounded even more strongly (up 77% since January 2020), suggesting the growing perception of digital health's vital role in health delivery during the pandemic crisis and beyond.

Top 10 changes in the US+EU market capitalizations, H2 2016-H1 2021 (US\$m)

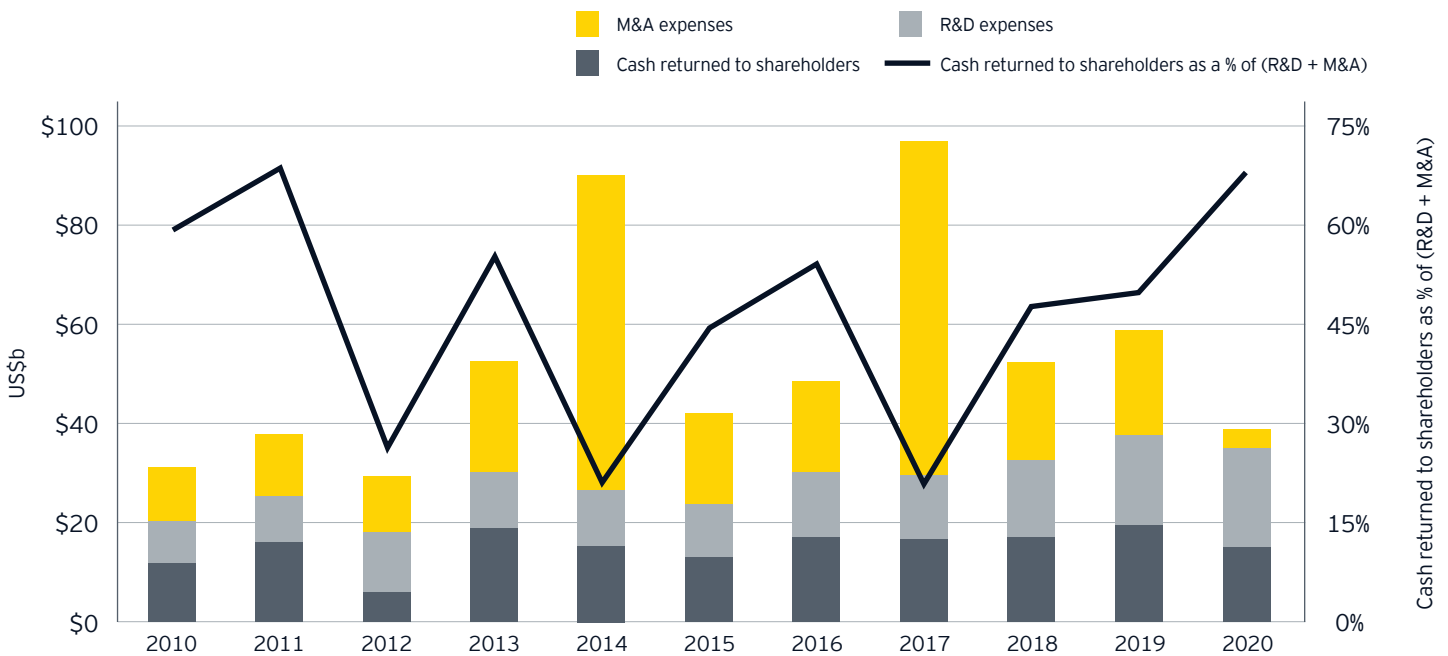
Company	Market cap as of July 1, 2021	Market cap as of July 1, 2016	US\$ change	CAGR (H2 2016-H1 2021)
Intuitive Surgical	\$109,823	\$25,360	\$84,463	34%
Stryker	\$98,972	\$45,031	\$53,941	17%
Medtronic	\$169,507	\$121,384	\$48,123	7%
Illumina	\$68,716	\$20,715	\$48,001	27%
IDEXX Laboratories	\$54,490	\$8,333	\$46,157	46%
Edwards Lifesciences	\$65,154	\$20,876	\$44,278	26%
Align Technology	\$48,982	\$6,618	\$42,364	49%
Becton Dickinson and Company	\$71,765	\$35,998	\$35,768	15%
DexCom	\$41,278	\$6,648	\$34,630	44%
Boston Scientific	\$61,611	\$31,764	\$29,846	14%
Total	\$728,687	\$290,962	\$437,725	20%

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

CAGR = Compounded Annual Growth Rate.

- ▶ Since the second half of 2016, cumulative MedTech market caps have recorded a median CAGR of 24%. Notably, the bulk of the top 10 companies by valuation change achieved growth without making significant M&As during this period.
- ▶ The biggest growth in market cap (in terms of US dollars) was recorded by Intuitive Surgical (up US\$84.5 billion), which has pioneered the robotic surgery space with its first-in-class da Vinci surgical system. Though Intuitive suffered from the pandemic slowdown, its stock has performed strongly since elective procedures began to return in the second half of 2020.
- ▶ Market leader Medtronic joins the list of MedTechs with the biggest cap growth this year – as does Align Technology, the dental specialists that manufacture the Invisalign system, iTero intraoral scanners and software for digital orthodontics and restorative dentistry, which cleared US\$1 billion in Q2 2021 revenues (up 187% on the previous year).

US and Europe MedTech commercial leaders spending trend, 2010-20



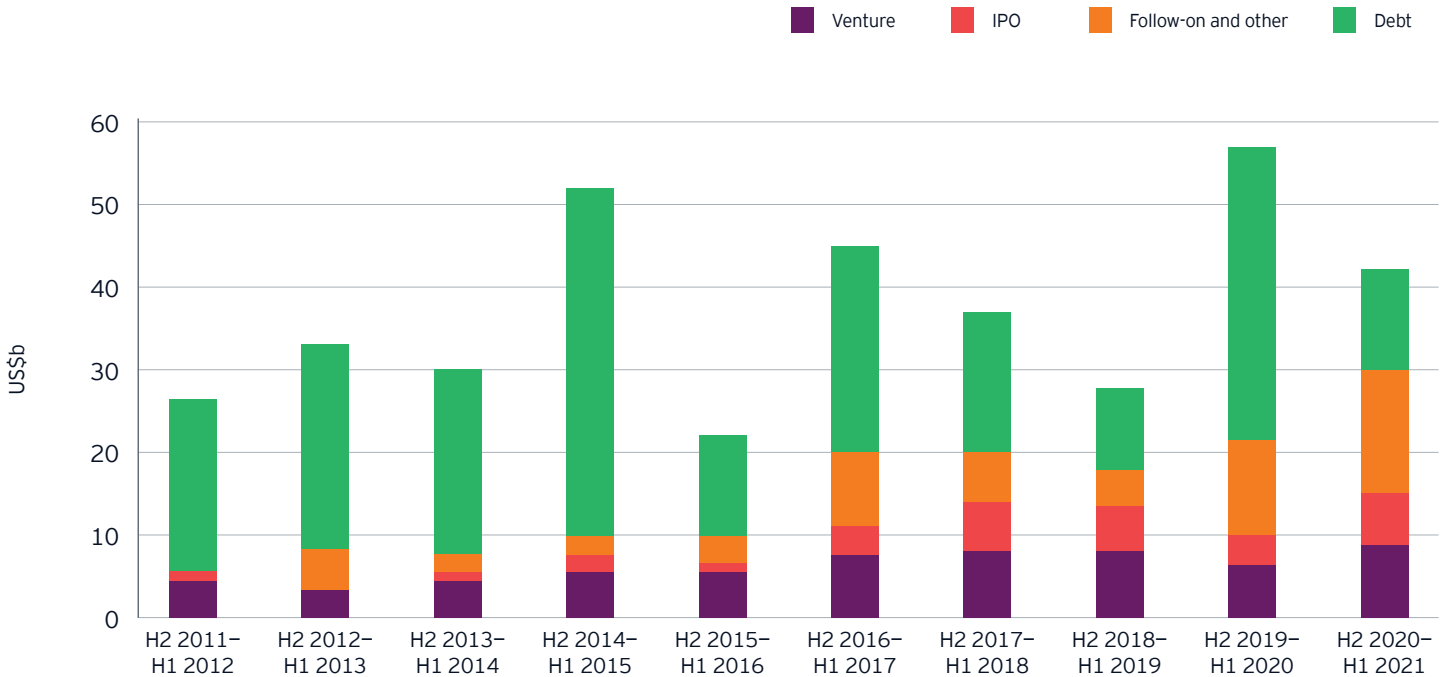
Source: EY analysis, Capital IQ, company financial statement data.

- ▶ With a relative decrease in M&A activity in 2020, MedTech commercial leaders opted to return US\$14.1 billion to shareholders (in the form of stock buybacks and dividends) – this represented 61% of deployable capital, the highest rate since 2011 (71%).
- ▶ In all, 9 of the 10 largest MedTechs carried out stock buybacks or paid dividends, with the total shareholder return rising 5% to US\$10.4 billion, led by Boston Scientific, which returned US\$563 million to shareholders (almost entirely via buybacks).
- ▶ Though MedTech largely avoided large-scale M&As in 2020, the industry did heavily invest in R&D. R&D spending hit a record US\$19.6 billion – with 8 of the top 10 allocating more capital to R&D than to shareholder returns – suggesting a readiness to invest in organic growth rather than seeking acquisitions. However, H1 2021 did witness a resurgence in MedTech M&A as a more stable market left companies searching for a quicker avenue to growth.

Financing

Equity investment in MedTech reached new heights

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. Private investments in public equity (PIPEs) included in "Follow-on and other."

- ▶ Total MedTech funding fell 25% to US\$42.8 billion in the H2 2020-H1 2021 period; however, this decline is entirely accounted for by a drop of over US\$22 billion in debt funding that reached record levels in the previous 12-month period as large MedTechs looked to secure themselves against disruption from COVID-19.
- ▶ Excluding debt, financing rose by 41% in the 12-month period, reaching US\$30.4 billion, its highest in the past decade.
- ▶ Around half of this total came from follow-on public offerings, which rose 29% to US\$15.0 billion – its highest level in a decade – representing the largest single source of financing in the H2 2020-H1 2021 period. Yet, venture capital also hit US\$9.1 billion, which once again was the highest level in a decade, and IPO financing doubled.



Diagnostic, remote-enabled and robotic-focused MedTechs attracted significant venture capital

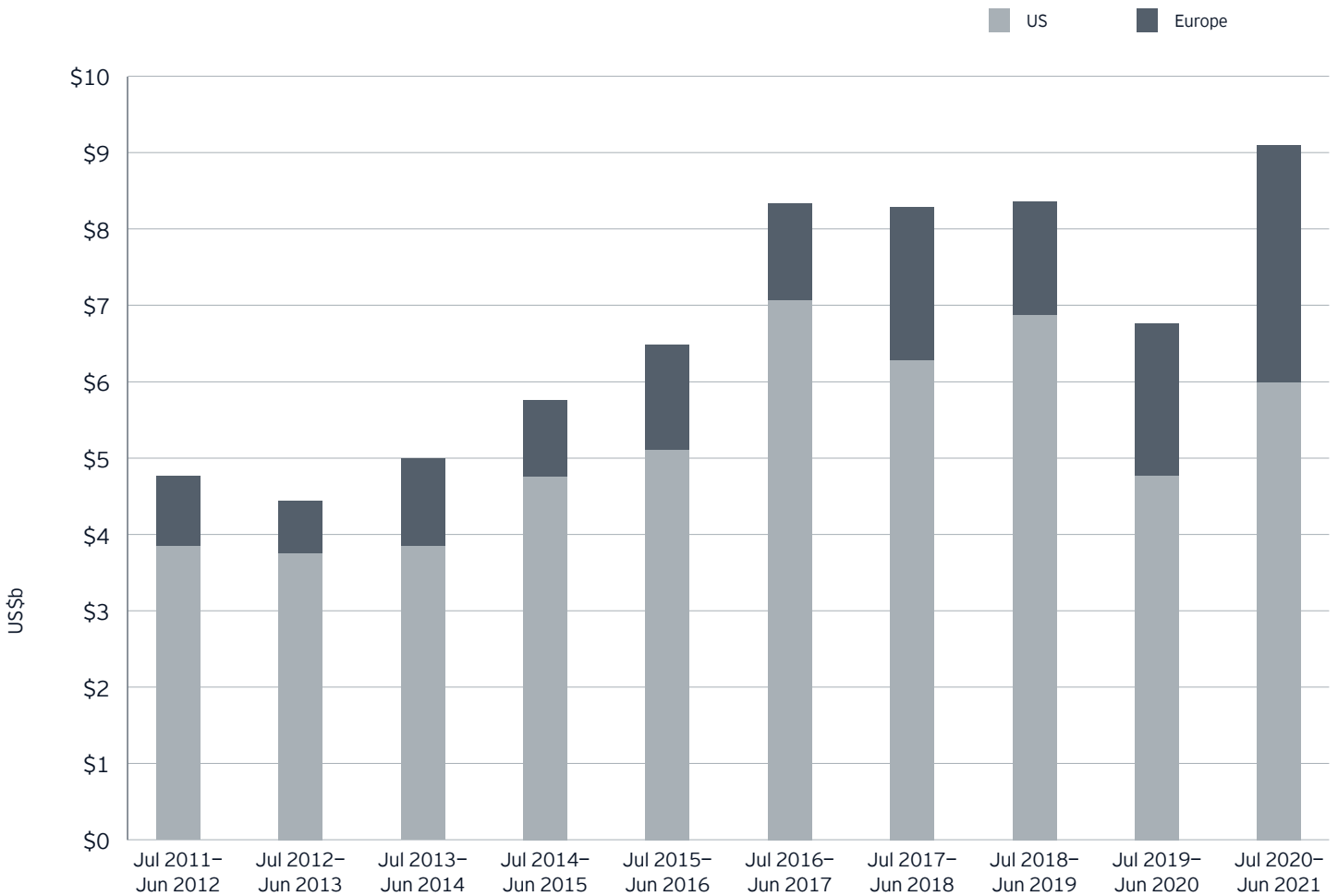
Top US and European venture rounds, July 2020–June 2021

Company	Region	Product type (disease)	Gross raised (US\$m)	Quarter	Round type
Verily Life Sciences	US - Northern California	Other	700	Q4 2020	Late stage
CMR Surgical	UK	Therapeutic devices (non-diseases specific)	600	Q2 2021	Late stage
Element Biosciences	US - Southern California	Research and other equipment	276	Q2 2021	Late stage
Quanta Dialysis Technologies	UK	Therapeutic devices (hematology/renal)	245	Q2 2021	Late stage
PathAI	US - Massachusetts	Research and other equipment	165	Q2 2021	Late stage
eCential Robotics SAS	France	Imaging diagnostics	121	Q1 2021	Late stage
Warby Parker	US - New York	Therapeutic devices (ophthalmic)	120	Q3 2020	Late stage
CeQur SA	Switzerland	Therapeutic devices (hematology/renal)	115	Q2 2021	Late stage
Mainstay Medical Holdings	Ireland	Other	108	Q1 2021	Late stage
Truvian Sciences	US - Southern California	Non-imaging diagnostics	105	Q1 2021	Late stage
Binx Health	UK	Non-imaging diagnostics	104	Q2 2021	Late stage
Inflammatix	US - Northern California	Non-imaging diagnostics	102	Q1 2021	Late stage
Maxter Healthcare	US - Delaware	Other	100	Q4 2020	Early stage
Delfi Diagnostics	Maryland	Non-imaging diagnostics	100	Q1 2021	Early stage
Fractyl Health	US - Massachusetts	Therapeutic devices (hematology/renal)	100	Q2 2021	Late stage
Memic Innovative Surgery	Israel	Therapeutic devices (women's health)	96	Q2 2021	Late stage
Dutch Ophthalmic Research Center	Netherlands	Therapeutic devices (ophthalmic)	94	Q3 2020	Early stage
Hyperfine Research	US - Connecticut	Imaging diagnostics	90	Q1 2021	Late stage
Conformal Medical	US - New Hampshire	Therapeutic devices (cardiology)	85	Q3 2020	Late stage
PROCEPT BioRobotics	US - Northern California	Therapeutic devices (hematology/renal)	85	Q2 2021	Late stage

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



US and European VC investment reached new heights



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

- ▶ The impact of COVID-19 was felt in the diversion of VC funding toward late-stage ventures. The top 12 funding rounds all went to late-stage companies, while the number of early-stage VC rounds >US\$5 million fell to its lowest level in five years, capturing only 16% of VC investment.
- ▶ Verily Life Sciences captured the largest single VC round of the H2 2020-H1 2021 period with US\$700 million in Q4 2020. The Alphabet-owned company has R&D investments in multiple areas of MedTech, attracting attention for its Baseline platform for COVID-19 research and joint venture with Johnson & Johnson in the surgical robotics space.
- ▶ Also focused on surgical robotics, CMR Surgical of the UK, which manufactures the Versius system, raised US\$600 million in a Series D round in June 2021; another European robotics company, eCential Robotics SAS, also drew US\$121 million to fund its surgical robotics system, incorporating 2D/3D imaging.
- ▶ Once again, diagnostics loomed very large in VC funding, with companies such as Truvian Sciences, Binx Health, Inflammatrix and Delfi Diagnostics all among the top 15 VC rounds overall. Companies like Element Biosciences (focused on genetic analysis) and PathAI (using machine learning in pathology) also indicate the high level of investment in disruptive diagnostic technologies.



Maravai LifeSciences and Ortho Clinical Diagnostics led a resurgent MedTech IPO market

US IPOs, July 2020–June 2021

Company	Ticker	Region	Product type (disease)	Gross raised (US\$m)	Quarter
Maravai LifeSciences	MRVI	US - Southern California	Research and other equipment	1,863	Q4 2020
Ortho Clinical Diagnostics	OCDX	US - New Jersey	Non-imaging diagnostics	1,486	Q1 2021
Outset Medical	OM	US - Northern California	Therapeutic devices (hematology/renal)	278	Q3 2020
Olink Holding AB	OLK	Sweden	Research and other equipment	265	Q1 2021
Pulmonx	LUNG	US - Northern California	Therapeutic devices (respiratory)	219	Q3 2020
Berkeley Lights	BLI	US - Northern California	Research and other equipment	205	Q3 2020
Seer	SEER	US - Northern California	Research and other equipment	201	Q4 2020
Nano-X Imaging	NNOX	Israel	Imaging	190	Q3 2020
Acutus Medical	AFIB	US - Southern California	Therapeutic devices (cardiovascular/vascular)	183	Q3 2020
Lucira Health	LHDX	US - Northern California	Non-imaging diagnostics	176	Q1 2021
Eargo	EAR	US - Northern California	Therapeutic devices (ear, nose and throat)	163	Q4 2020
CVRx	CVRX	US - Minnesota	Therapeutic devices (cardiovascular/vascular)	145	Q2 2021
Implantica AG	IMP A SDB	Switzerland	Therapeutic devices (gastrointestinal)	142	Q3 2020
Codex DNA	DNAY	US - Southern California	Research and other equipment	123	Q2 2021
Bioventus	BVS	US - North Carolina	Therapeutic devices (orthopedic)	120	Q1 2021
Treace Medical Concepts	TMCI	US - Florida	Therapeutic devices (orthopedic)	118	Q2 2021
NeuroPace	NPCE	US - Northern California	Therapeutic devices (neurology)	117	Q2 2021

Continued to next page

Company	Ticker	Region	Product type (disease)	Gross raised (US\$m)	Quarter
Nyxoah	NYXH	Belgium	Therapeutic devices (respiratory)	100	Q3 2020
Human Xtensions	HUMX	Israel	Therapeutic devices (non-disease-specific)	48	Q4 2020
Pulsenmore	PULS	Israel	Imaging diagnostics	42	Q2 2021
Femasys	FEMY	US - Georgia	Therapeutic devices (women's health)	34	Q2 2021
Affluent Medical SA	AFME	France	Therapeutic devices (non-diseases specific)	30	Q2 2021
Abingdon Health	ABDX	UK	Non-imaging diagnostics	30	Q4 2020
Belluscura	BELL	UK	Therapeutic devices (respiratory)	25	Q2 2021
Vivos Therapeutics	VVOS	US - Colorado	Therapeutic devices (respiratory)	24	Q4 2020
GBS	GBS	US - New York	Non-imaging diagnostics	22	Q4 2020
Audientes	AUDNTS	Denmark	Therapeutic devices (ear, nose and throat)	12	Q3 2020
ENvizion Medical	ENVM	Israel	Therapeutic devices (non-diseases specific)	6	Q2 2021
Luxbright AB	LXB	Sweden	Imaging	4	Q4 2020

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

- ▶ IPO funding grew by 100% in the 12 months to June 2021, generating US\$6.4 billion, with over half of the value generated by just two deals.
- ▶ “Research and other” equipment player Maravai LifeSciences, which provides reagents and services, completed a US\$1.9 billion IPO in November 2020.
- ▶ Ortho Clinical Diagnostics raised US\$1.5 billion in a Q1 2021 IPO. The company is focused on non-imaging diagnostics.

Several MedTechs took advantage of a new funding mechanism: Special-purpose acquisition companies (SPAC)

Sample of MedTech SPACs

SPAC company	Company type	Location	SPAC investor	Quarter	Valuation (US\$)	Total Up-front investment	Up-front investment as % of valuation	PIPE/debt (US\$)
LumiraDx	Non-imaging diagnostics	US - Massachusetts	CA Healthcare Acquisition	Q2 2021	5,000	545	10.9%	400
23andMe	Non-imaging diagnostics	US - Northern California	VG Acquisition Corp.	Q1 2021	3,500	592	16.9%	250
Butterfly Network	Imaging	US - Connecticut	Longview Acquisition Corporation	Q4 2020	1,500	589	39.3%	175
Quantum-Si	Research and other equipment	US - Connecticut	HighCape Capital Acquisition Corp.	Q1 2021	1,460	425	29.1%	425
SomaLogic	Research and other equipment	US - Colorado	CM Life Sciences II	Q1 2021	1,230	651	52.9%	375
Vicarious Surgical	Therapeutic devices (non-disease-specific)	US - Massachusetts	D8 Holdings	Q2 2021	1,100	425	38.6%	115
HydraFacial	Therapeutic devices (aesthetics)	US - Southern California	Vesper Healthcare Acquisition Corporation	Q4 2020	1,100	975	88.6%	350
Nautilus Biotechnology	Research and other equipment	US - Washington	ARYA Sciences Acquisition Corp III	Q1 2021	900	350	38.9%	200

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

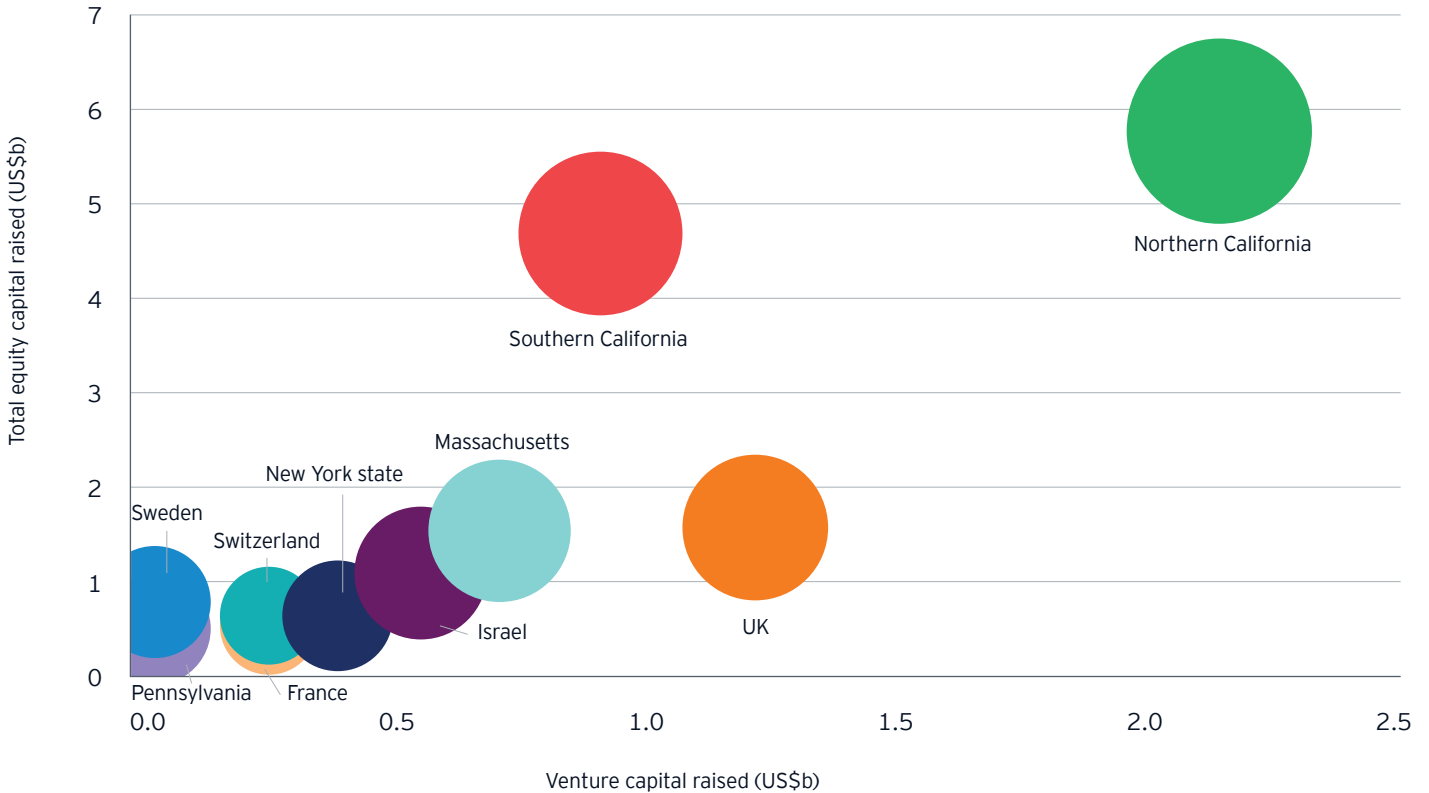
- ▶ As an alternative to an IPO, growing numbers of MedTechs are making deals with special purpose acquisition vehicles (SPACs). SPACs are formed with the sole purpose of raising capital and then merging with a target private company, which takes on the public listing and so gains rapid and straightforward access to public markets. During the COVID-19 pandemic, the SPAC route to market has gained appeal as IPOs became logistically more difficult. (For example, virtual roadshows are less effective at generating investor attention).
- ▶ Once again, non-imaging diagnostics have been an important focus area, with the first half of 2021 seeing two significant SPAC financing deals: CA Healthcare Acquisition

Corporation (CAHC), a Boston-based SPAC, merged with LumiraDx (a London-based maker point-of-care diagnostics for COVID-19 antigens and antibodies, among others), and Richard Branson's VG Acquisition Corporation merged with personalized genetic testing company 23andme.

- ▶ Other SPAC deals of 2020-21 have offered routes to market for companies innovating in the proteomics space, including next-generation protein sequencing innovators Quantum-Si; SomaLogic, a specialist in AI-driven proteomics assays; and Nautilus Biotechnology, which is developing a novel platform for rapid human proteome analysis and has a partnership with Genentech.

California once again dominated the MedTech funding landscape

Capital raised by leading US and EU regions excluding debt, July 2020–June 2021



Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.
Size of bubbles shows relative number of financings per region.

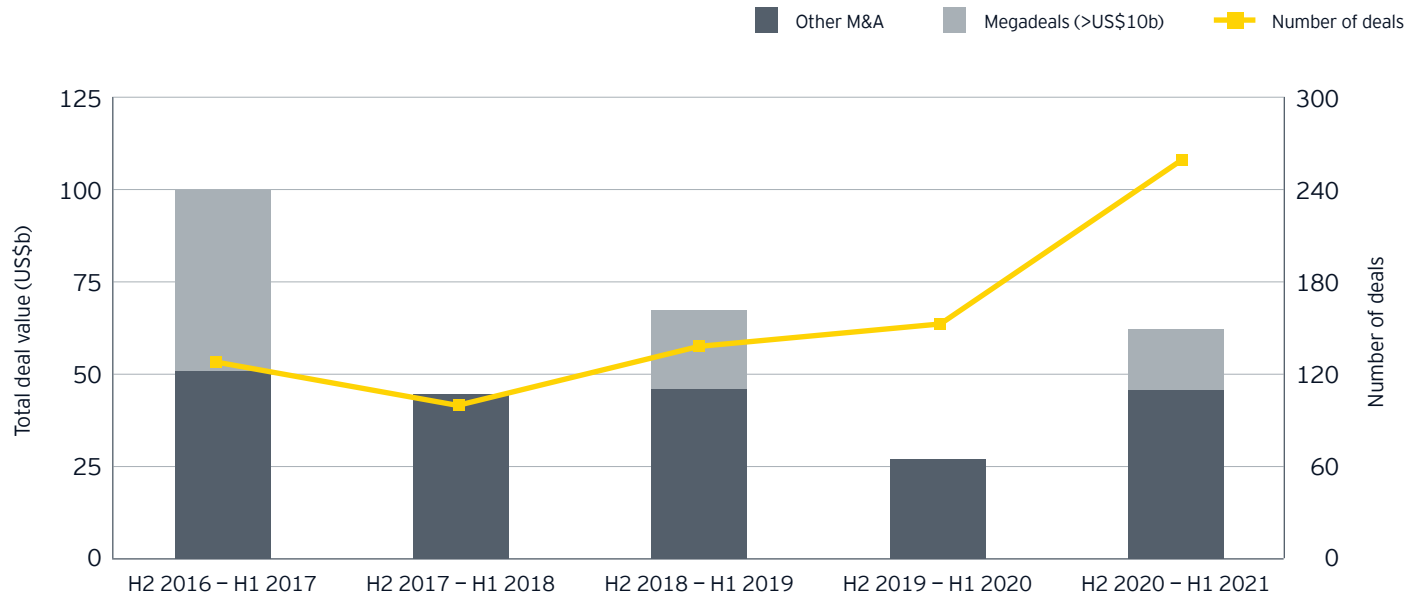
- ▶ California continued to dominate the overall MedTech financing landscape in terms of both VC and overall capital raised. Outside of the US, the UK generated the highest levels of MedTech funding, yet this amounted to barely one-seventh of the volume raised in California alone, which attracted 35% of all MedTech equity investment.



Mergers & acquisitions

The number of MedTech M&As reached unprecedented heights, while the value of deals stayed flat

M&A in the US and Europe, by year



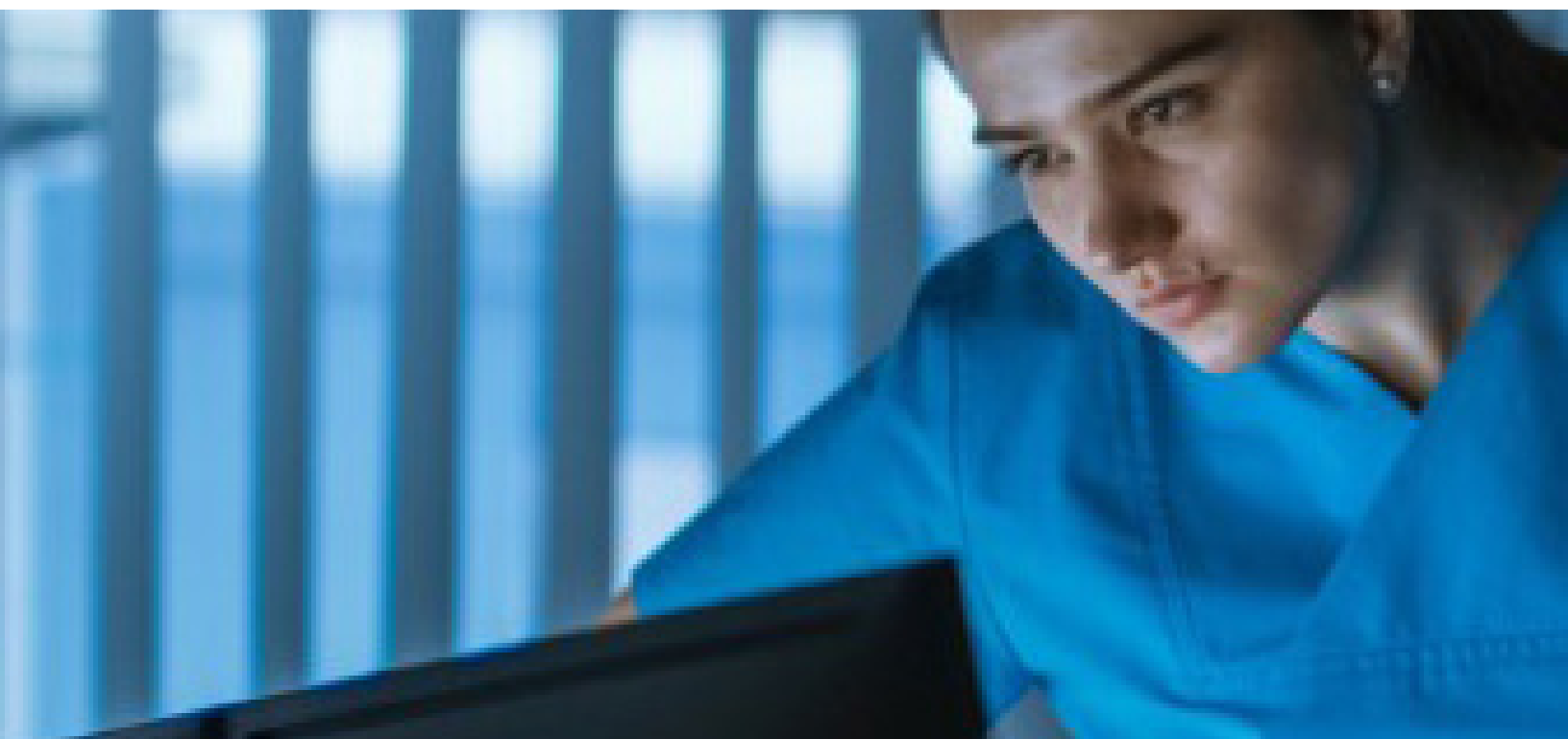
Source: EY analysis, Capital IQ and Thomson ONE.

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



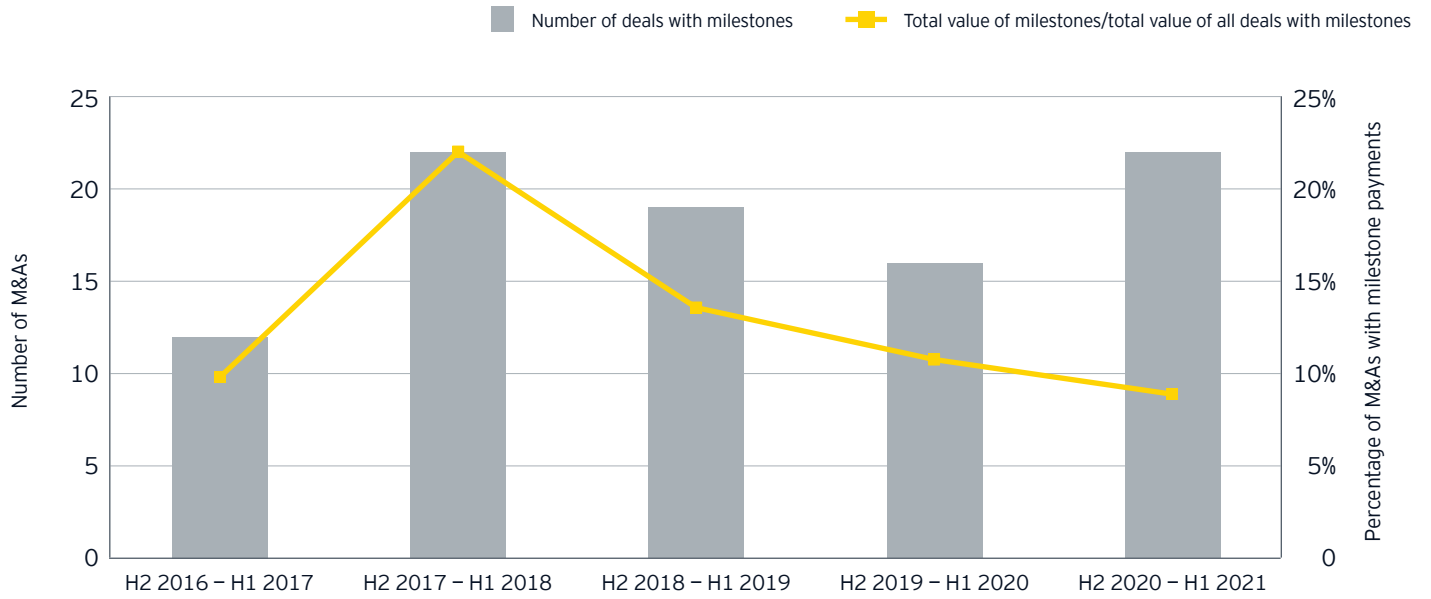
- ▶ In the H2 2020-H1 2021 period, MedTech companies executed 288 deals – the highest annual number seen since EY research began creating the *Pulse of the industry* report in 2007 and a 77% rise over the previous 12 months.
- ▶ Many of these deals were small-scale: 200 of them (69%) were valued at under US\$100 million, and the average deal size of US\$282 million was well below the previous four-year average of US\$455 million.

- ▶ In all, the total value of M&A activity was US\$63.3 billion (with 79% of the spend going to US-based targets), up 129% on the previous 12-month period. In part, this reflects the fact that the first six months of 2020 saw a hiatus in M&A activity due to the pandemic, while the second half of the year saw a recovery.
- ▶ In particular, the second half of 2020 saw Siemens Healthineers close a megadeal (defined by EY research as any M&A transaction worth over US\$10 billion) in acquiring Varian Medical for US\$16.4 billion, representing over a quarter of all the MedTech M&A investment in the H2 2020 – H1 2021 period). While industry attention focused on Siemens' addition of Varian's radiation hardware to its oncology portfolio, Varian's digital software business was also a significant component of the acquisition for Siemens.
- ▶ Outside the scope of this data, September 2021 saw a further megadeal, with Baxter acquiring Hillrom for US\$10.5 billion. Baxter will add Hillrom's suite of products and services (including monitoring and diagnostic technologies, smart beds and advanced surgical equipment) to its core portfolio of essential hospital products, covering dialysis, IV solutions and other categories.
- ▶ Elsewhere, therapeutic devices attracted less M&A attention than other device segments, with MedTechs more focused on research and lab equipment, surgical tools and disposables. Non-imaging diagnostics was once again at the forefront, accounting for seven of the top 15 M&A deals. Notably, Roche and DiaSorin each paid US\$1.8 billion to acquire companies (GenMark Diagnostics and Luminex, respectively) with COVID-19 diagnostic capabilities.
- ▶ Private equity played a role in 5 of the top 15 deals over the 12-month period, appearing on both the seller side (Boston Scientific spending US\$1.1 billion to acquire Lumenis from a private equity portfolio), the buyer side (with the Hellman & Friedman PE syndicate paying US\$1 billion to buy Cardinal Health's Cordis business) and on both sides in the Patricia Industries (part of Investor AB) and Windjammer Capital for the acquisition of the Advanced Instruments for US\$780 million.

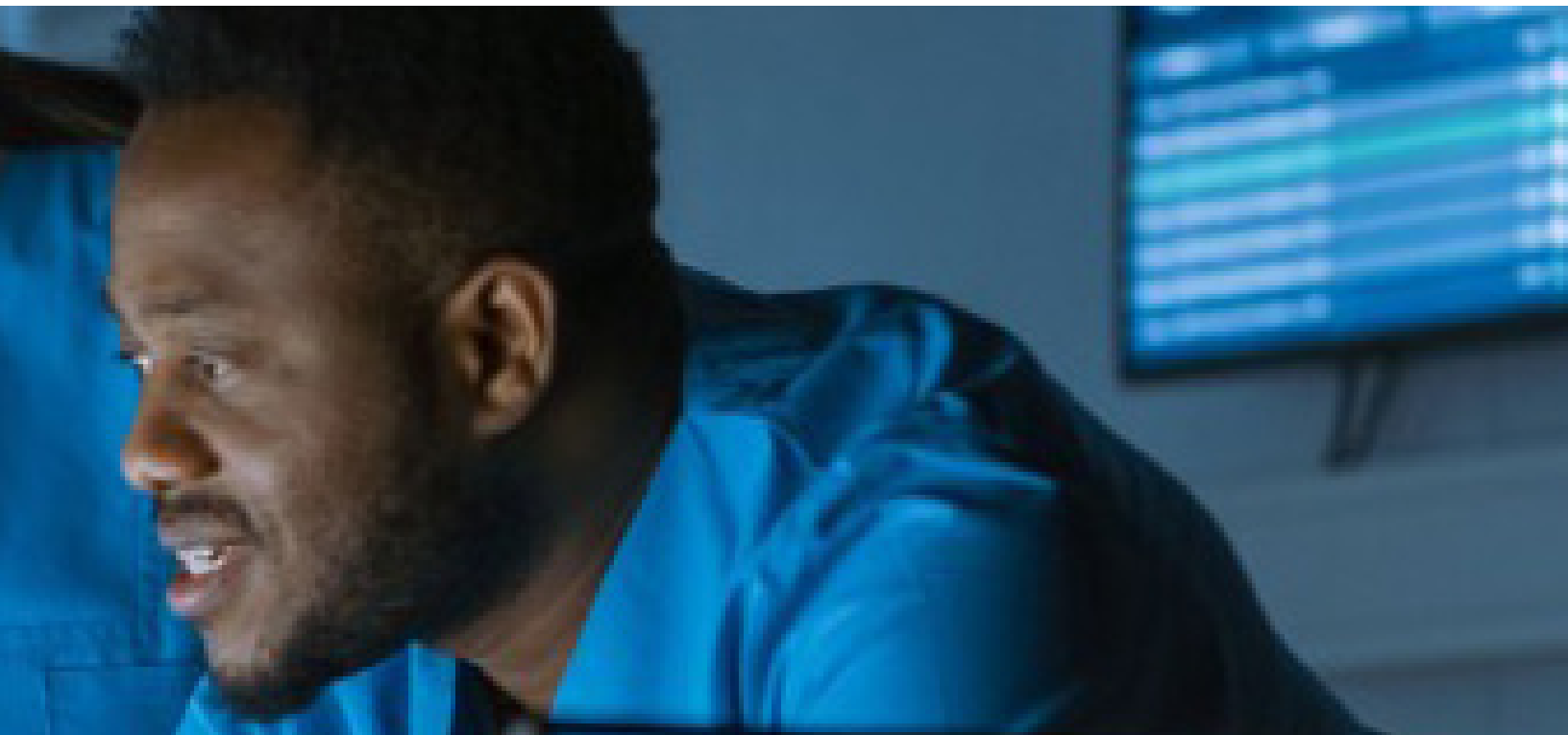


Milestone payments in US and European MedTech M&A

Milestone payments used in US and European MedTech M&As

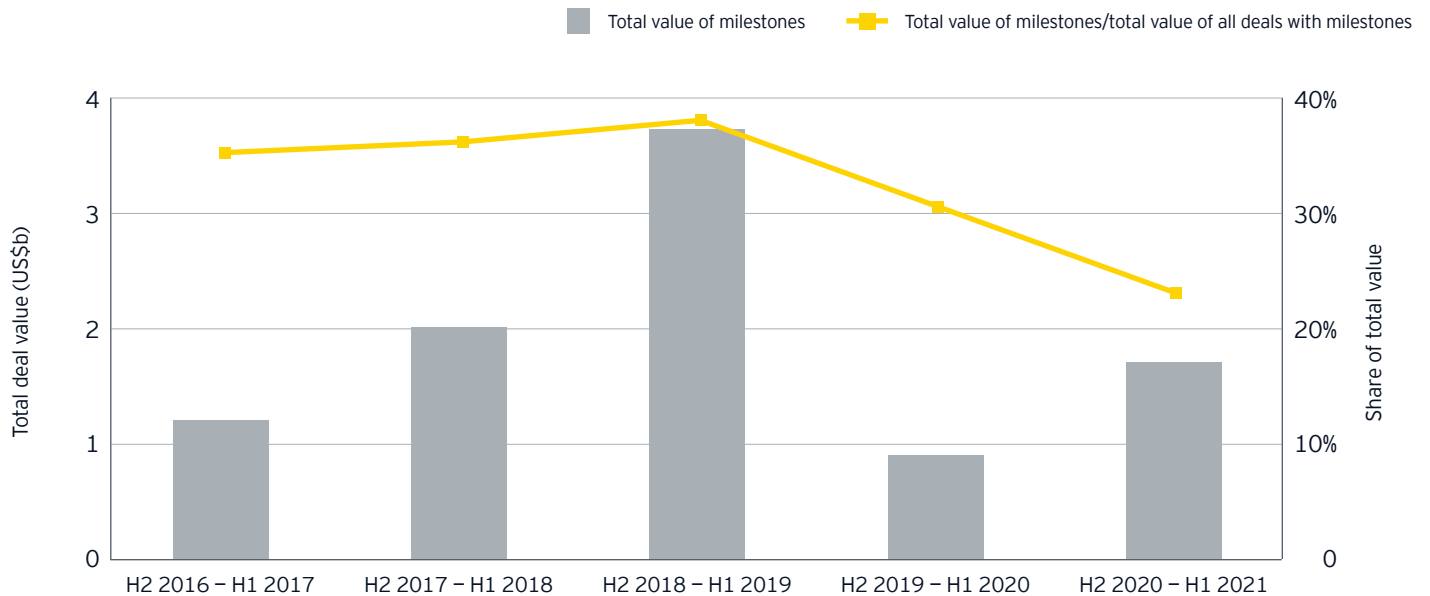


Source: EY analysis, Capital IQ and Thomson ONE.



Milestone share in US and European MedTech M&A

Milestone shares among US and European MedTech M&As



Source: EY analysis, Capital IQ and Thomson ONE.

- ▶ After dropping in the previous 12-month period, the number of M&A deals involving milestone payments rose to 22% between July 2020 and June 2021. However, the percentage of deals involving milestones fell to 8%, the lowest rate in the past five years.
- ▶ At US\$1.7 billion, the total value of potential milestones was also below the three-year average of US\$2.3 billion; nevertheless, this represented an 85% increase in the potential milestone value from the previous 12 months.
- ▶ Total milestone value as a percentage of overall deal value hit a five-year low of 22%. In all, MedTech seems currently disinclined to explore novel deal structures in its M&A activity.



Notes

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As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 23,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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