



Pulse of the industry:
Medical technology
report 2020

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To EY clients and friends

As EY teams began the planning for the 14th annual *Pulse of the industry* report in late fall 2019, little did we imagine how different this year would be for all of us. EY teams' initial plan was to take stock of the industry, focusing this edition on the roughly 10-year period following the financial crisis and how the fundamentals of the industry have evolved over that time frame. As with the previous 13 editions, the basis for comparison always starts in the quantitative realm. Leading with valuations, transactions, capital allocation and investments has always been the basis for our perspective on the industry.

As we publish this report in fall 2020, the story is much more about medtech as a community, not an industry. While we still look to metrics and comparisons for insight, the community aspects of our existence are where we find not only insight, but inspiration. Confronted with the advance of this major pandemic, medtech has stepped up to the clinical front line and played a critical role in the attempts to defuse the crisis. From mass-producing ventilators, sterilizing equipment, face masks and other protective personal equipment, to inventing and distributing the rapidly expanding range of diagnostic tests now reaching the market, the industry has achieved an incredible amount in the first half of 2020. Medtech's work has saved lives, allowed medical facilities to keep running, enabled patients to be treated in hospitals or at home, and overall made it possible for normal operations to be maintained, while simultaneously also helping health systems, governments and the general public wage a global health battle on a scale not previously seen this century.

In August 2020, Ernst & Young Global Limited co-hosted two CEO panels with our colleagues at AdvaMed, and the first question to the group was, "what are you most proud of over the last six months?" The groups spoke passionately about the innovation, collaboration and determination that have characterized medtech's response to COVID-19 pandemic. It was clear that this community is truly connected by a universal sense of purpose in the extraordinary care shown for patients, clinicians and employees. It is also evident that helping to solve this crisis as a community has provided an opportunity to accelerate much needed and lasting change across the industry.

So, today, our perspective is centered on the 10 years between two crises, with the second one yet unresolved. As the ongoing high valuations for medtech in 2020 show, investors continue to recognize the importance of medtech. The industry demonstrated its resilience over the decade of steady growth and solid valuations, and even though 2020 looks to have delivered a negative (though possibly very transient) financial blow to some sectors of the industry, other areas, such as the diagnostics segment, have surged over the past few months. Moreover, this most recent crisis will help illuminate the way to a brighter future for the industry, by demonstrating the need to futureproof business models, strengthen supply chains and ecosystem relationships, and accelerate the progress of digital technology and data. The COVID-19 pandemic has shown us that we can accelerate progress in all of these areas and that by delivering innovation through the use of data and digital technology, we will secure the future of this industry, and our community.

We firmly believe that individuals and groups show their true colors under pressure, and medtech has risen to the challenge of the pandemic, demonstrating its medical, economic and societal value, and showing why it is an essential industry for the whole world. In closing, I'd like to take the time to express a strong vote of confidence toward the industry for the vital role it has played in the efforts to contain COVID-19 pandemic, both in the United States and across the globe.

In this, the 14th annual *Pulse of the industry* report, we attempt to take stock of an extraordinary year for the medtech industry and for the rest of the world.



Jim Welch

EY Global Medical Technology Leader



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The year in review

↑ 6.3%
(2019)

In 2019, total US and European medtech revenues grew 6.3%, slightly less than the 6.7% recorded in 2018. However, during the first half of 2020, revenues of US commercial leaders and conglomerates declined 5.0%, as many medtechs were negatively impacted by the COVID-19 pandemic.

-5.0% ↓
(H1 2020)

↑ 11.5%

R&D spending in 2019 grew 11.5% (compared with an increase of 8.1% last year), marking a return to the double-digit rates common in the industry before the 2007-08 financial crisis.

But the industry returned a record US\$19.6b to shareholders in 2019.

US\$19.6b

US\$57.1b

Financing levels more than doubled from July 2019 to June 2020 compared with the previous 12 months – with over 40% resulting from debt financing.

US\$3.2b

Medtechs garnered US\$3.2b in IPO values – the third highest on record – however, just 3 deals represented 5% of the total, and the number of deals (14) was the lowest in a decade.

22% ↓

After three straight years of record investment, venture capital funding fell 22%, with Q2 2020 being particularly anemic.

US\$40.5b ↓

Total M&A deal values plunged 60% from US\$67.6b the year before to US\$27.1b, partially reflecting the loss of the year's largest announced deal.

41% ↓

The total value of non-megadeals (those under US\$10b) dropped 41%, while average deal value across the industry shrank from US\$463m in the prior 12-month period to US\$167m.

A new decade, new disruption – and a new dawn? Where medtech stands in the Now





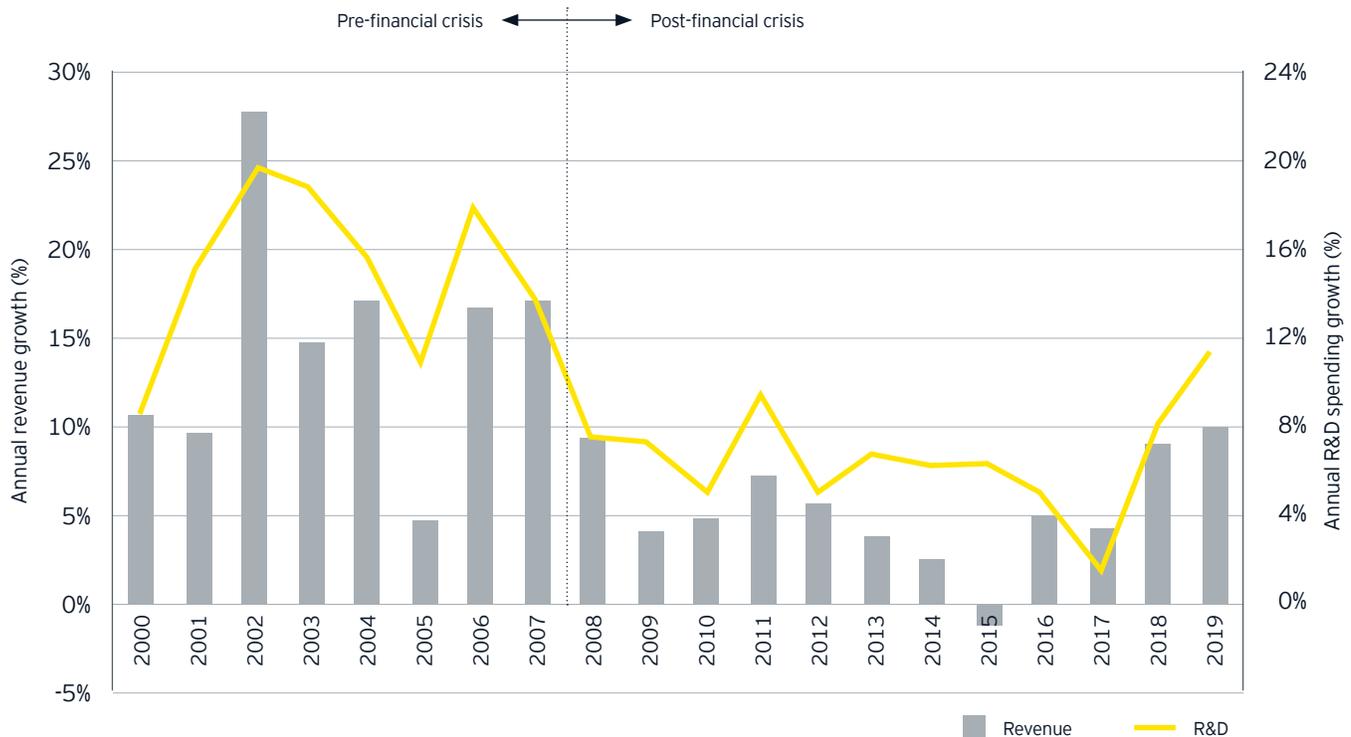
It's too early to assess the ultimate effect of COVID-19 on the medtech industry. Throughout this report, we have considered some of the early signs around changes the pandemic is currently bringing to the industry's business models, supply chain operations, regulatory regime, and embrace of digital and data-led transformation. First, however, we will take stock of the key metrics for medtech: the industry's financial performance, financing situation and M&A activity. The activity seen in these metrics across 2019 and into 2020 gives us perspective on the state of the industry before and during the current crisis, and it provides us with a basis to assess medtech's prospects after the pandemic is past.

Between the financial crisis and the pandemic: medtech's years of steady growth

Throughout the 2010s, the medtech industry maintained its solid financial performance year after year. While the financial crisis of 2007 and 2008 was a heavy blow to medtech and many other industries, the following decade witnessed a medtech resurgence due to strong fundamentals and investors' high confidence in the sector (see Figure 1). Though annual growth in revenues had yet to recapture the heights of the early years of the 21st century, 2019 saw the industry earn one more year of respectable single-figure growth (6.3%).

In another encouraging sign, medtech's 2019 R&D investment grew by 11.5% compared to 8.1% in 2018, marking a return to the double-digit R&D growth rates regularly recorded before the financial crisis. For an industry driven by research, this is a positive sign, suggesting confidence in medtech's ability to keep creating innovative and profitable new products.

Figure 1. Medtech 2000-19



Source: EY, company reports.

Then came COVID-19.

Though we don't have full-year 2020 financial data to assess the impact of the pandemic (and the socioeconomic chaos it has brought in its wake) on medtech, we can already recognize that the industry's financials in 2020 will look nothing like 2019 or any other year over the previous decade.

An analysis of Q1 and Q2 2020 financial reporting indicates that roughly two-thirds of US commercial leaders (pure-play medtech companies with more than US\$500 million in annual revenue) and conglomerates have experienced an aggregate revenue decline of 5%. However, this figure conceals wide variations.

Among companies focused on elective procedures, the impact has been higher, as patients have stayed away from hospitals where COVID-19 dominated clinical priorities in the second quarter of 2020. By contrast, companies focused on diagnostics saw topline rise significantly with the heightened demand the pandemic brought (see Figure 2).

However, the immediate financial effects, good or bad, are only half of the story unfolding in 2020. While COVID-19 has hit revenue growth, there are signs that the industry may rebound rapidly in the second half of the year. Some early data suggests a "V-shaped" recovery in the elective space, as

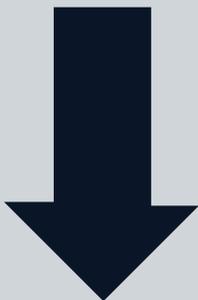
surgeries resume and surgeons advise patients to undergo procedures sooner rather than later with the future course of the pandemic still unpredictable.

Beyond this, COVID-19 has brought significant opportunities, as well as challenges, in medtech. The industry has been at the forefront of efforts to fight the outbreak (see Figure 3), raising its profile and consolidating its reputation as a good partner and "a must-have industry," as one participant described it at the first Ernst & Young LLP/AdvaMed medtech CEO roundtable in August 2020. As this roundtable series revealed (see *Insights from the first and second Ernst & Young LLP/AdvaMed medtech CEO roundtable* below), medtech has adapted creatively during the



Figure 2. COVID-19 impact on US medtechs* during the first half of 2020

Aggregate revenue decline is **5%**.
2/3 of medtechs report revenue drop in H1 2020.
7 of the top **10** companies by revenues report H1 2020 downturns vs. H1 2019.



Eight companies, primarily focused on elective procedures, saw revenues fall by 15% or more ...

- Envista Holdings: -34%
- Dentsply Sirona: -30%
- Zimmer Biomet: -24%
- NuVasive: -18%

... but diagnostic companies surged, accounting for four of the six biggest revenue increases:

- Exact Sciences: +70%
- Quidel: +47%
- Dexcom: +39%
- Masimo: +24%



Source: EY and public company filings.

*Includes US-based commercial leaders and conglomerates.

Figure 3. Selected examples of medtech's role in the COVID-19 response



As of August 2020, there were **448** COVID-19-related diagnostics launched in market or in development; **219** were from US manufacturers; **187** from Europe.

232 were focused on viral in-vitro diagnostics; 148 were antibody in-vitro diagnostics.

There were **219** FDA-cleared COVID-19 tests;

155 focused on diagnostic – molecular PCR tests; **39** focused on serology.

452 partnerships have been identified – the vast majority were driven by biopharmas (270), but medtechs did have **56** – mostly focused on digital, diagnostic testing development, scaling manufacturing and telemedicine and virtual care.

There are **734** drugs and vaccines in development (544 drugs and 190 vaccines).

Among these vaccines, **152** are preclinical; only **8** are in Phase III.

crisis, strengthening its relationships with its customers and accelerating the progress of its next-generation technologies into clinics and homes.

Medtech's response to the events of 2020 has important implications in at least four major areas: business model evolution; supply chain resilience; regulatory relationships; and the accelerated advancement of digital technologies that can capture, analyze and use data. The impact of COVID-19 in each of these areas is explored further later in this report.

First, however, we turn our focus to the industry's fundamentals, as shown in the data for 2019 and 2020 to date.

Is medtech in a position to ride out the disruptions of 2020 and regain or even surpass its performance across the 2010s? Examining the industry's most recent financial performance, financing and M&A data gives us a mostly affirmative answer – though not without some underlying causes for concern, too.

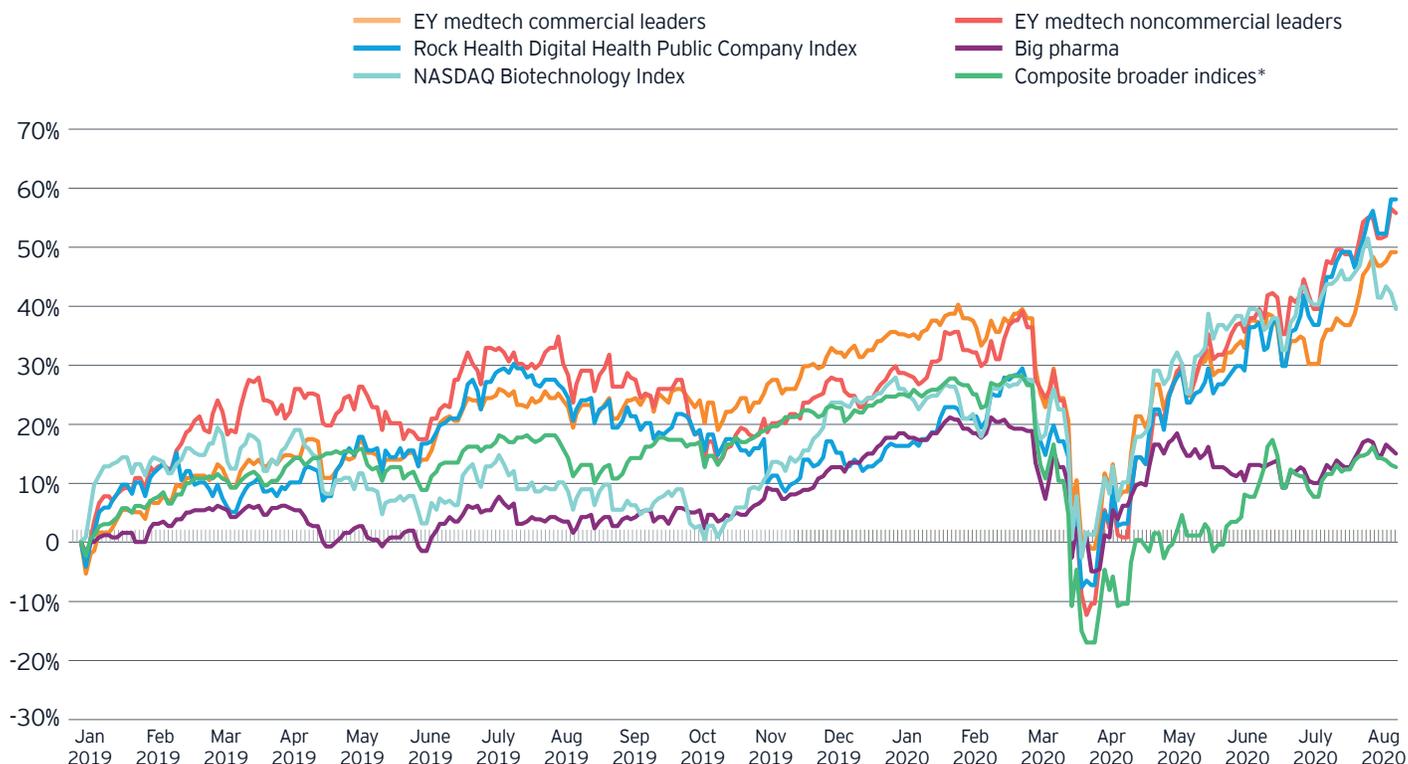
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... a key driver of medtech's high valuations was the non-imaging diagnostics segment ...

Medtech valuations rise again in 2020

When we look at medtech's key metrics in 2020 to date, one reassuring measure stands out: investor confidence. Though medtech's valuations fell along with the broader market (bottoming out in late March 2020), they recovered strongly in the subsequent months (see Figure 4). By the end of August 2020, medtech's valuations were up 50% compared to January 2019; much stronger than the rebound for broader composite indices such as the New York Stock Exchange (NYSE) and the S&P 500 (up 15% and 40%, respectively, over the same period).

Figure 4. Medtech's valuations resurgent in Q2 and Q3 2020

US and European medtech market capitalization relative to leading indices



Though digital health companies rebounded even more strongly (up 65%, likely due to investor excitement over enhanced use of virtual health and other remote technologies during the COVID-19 pandemic), medtech's commercial and noncommercial leaders both comfortably outperformed big pharmaceutical companies (which saw valuations rise 18% compared to January 2018) and biotech companies (up 40%). This highlights the perceived reliability of medtech as an investment, free from the controversies over pricing, for example, that generate political headwinds for big pharma.

When we dig deeper into these numbers, it is clear that a key driver of medtech's high valuations was the non-

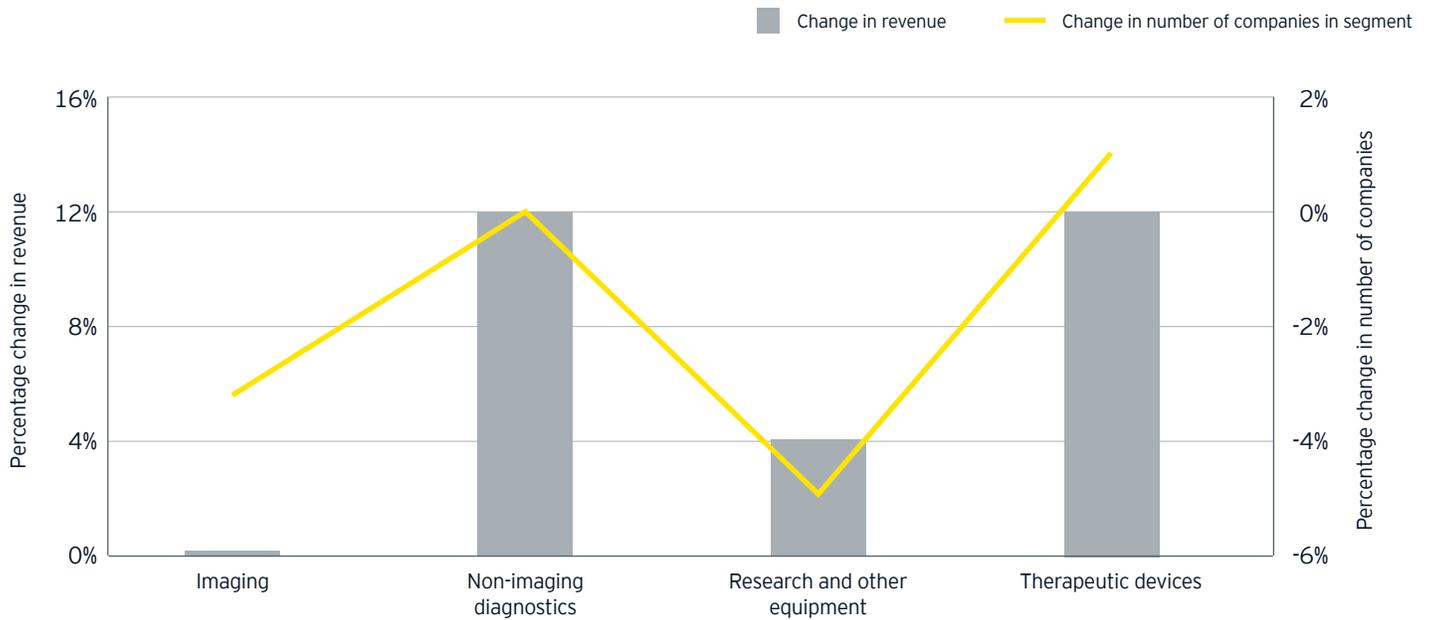
imaging diagnostics segment, which saw valuations rise 116% between January 2019 and August 2020, more than twice as much as for any other segment. In part, this reflects the urgent need for new diagnostic tools to combat COVID-19: For instance, Quidel, saw its overall valuation jump 331% between January 1, 2019 and June 30, 2020, partially aided by the U.S. Food and Drug Administration's (FDA) emergency use authorization (EUA) approval for its Sofia® SARS Antigen FIA rapid point-of-care test for COVID-19 in early June 2020. Yet the strong performance of diagnostics predates the pandemic and reveals an important underlying trend within medtech.

Revenues: diagnostics on the front line

The high levels of waste in health care spending are a matter of record, and the inefficiency (in terms of cost) and ineffectiveness (in clinical terms) of treating patients with a "one-size-fits-all" approach are widely acknowledged. Recognition of these facts has increasingly prompted calls for a more personalized approach to medical treatment. Of necessity, diagnostic tools are at the heart of this new approach, since they offer means to build a detailed and individualized understanding of patient health and

Figure 5. Non-imaging diagnostics at the forefront in 2019

Non-imaging diagnostics led all product categories in revenue growth



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

Data shown for pure-play companies only.

illness. In recent years, this vital role for diagnostics has been reflected in the performance of this segment of the medtech market.

In 2019, the non-imaging diagnostics segment recorded 12.2% revenue growth (see Figure 5). This would make diagnostics the strongest performer in medtech, with therapeutic devices, the next strongest, recording only 7.7% growth. However, when Novartis' spinoff of Alcon as a stand-alone company is accounted for (causing a large shift of revenue from the conglomerates category into pure-play therapeutics), the therapeutic devices segment's growth rate climbs to 12.5% for the year.

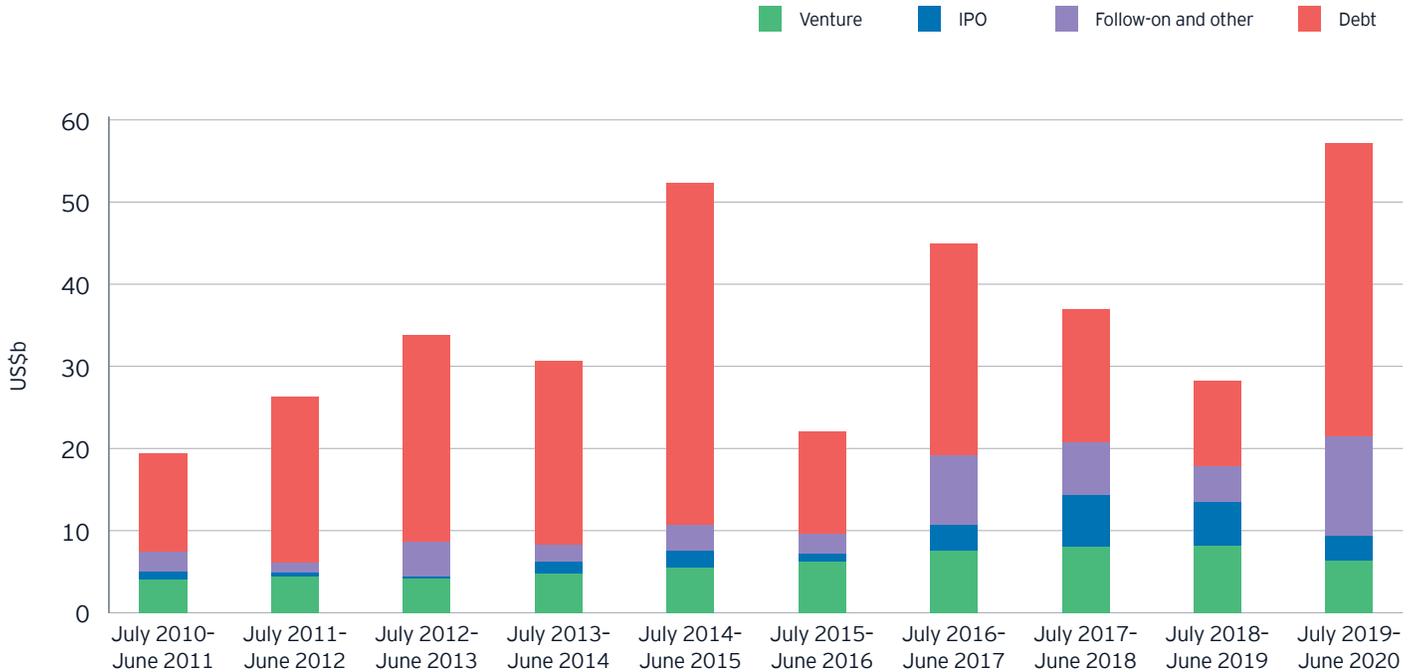
As we saw in the analysis of valuations, the non-imaging diagnostics segment is booming in 2020, with COVID-19-related diagnostics needed in bulk on the clinical front line. Yet COVID-19 could act as a growth driver for non-imaging diagnostics in the longer term as well. To take one example of the 2019 performance of non-imaging diagnostics, Exact Sciences' revenue surged 93% to US\$876 million as use of its Cologuard at-home colon cancer tests doubled to 1.7 million. This illustrates the growing demand both for precision medicine and for individuals to be able to obtain a diagnosis without attending a hospital or clinic. This demand will be amplified by the situation in 2020, with individuals now

having even stronger incentives to avoid in-person attendance at clinics where possible.

Whether non-imaging diagnostics, and the broader medtech sector, can sustain this revenue growth in the longer term depends on the sector's ability to keep innovating and bringing new products to the market. This, in turn, depends on medtech's underlying financing. Here, the impact of COVID-19 is evident in 2020.

Figure 6. Medtech funding surges, but cheap capital and debt financing are the main cause

Capital raised in the US and Europe by year



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

Numbers may appear to be inconsistent because of rounding. Private investments in public equity included in "follow-on and other."

Financing: major players load up on debt as startups face uncertainty

Medtech’s financing levels more than doubled to a record US\$57.1 billion in the 12-month period from July 2019 to June 2020, compared with the previous 12 months (see Figure 6). Over 40% of this dramatic growth was a result of US\$35.6 billion of public debt financing, fueled by historically low interest rates. In fact, a record 18 companies raised US\$500 million or more, with Thermo Fisher Scientific alone accounting for US\$9.2 billion of the total. As yet, it is unclear to what extent this rise in debt financing

represents either companies drawing into their credit reserves to allay financial concerns arising from the pandemic, or companies raising more financing to increase investment in innovation.

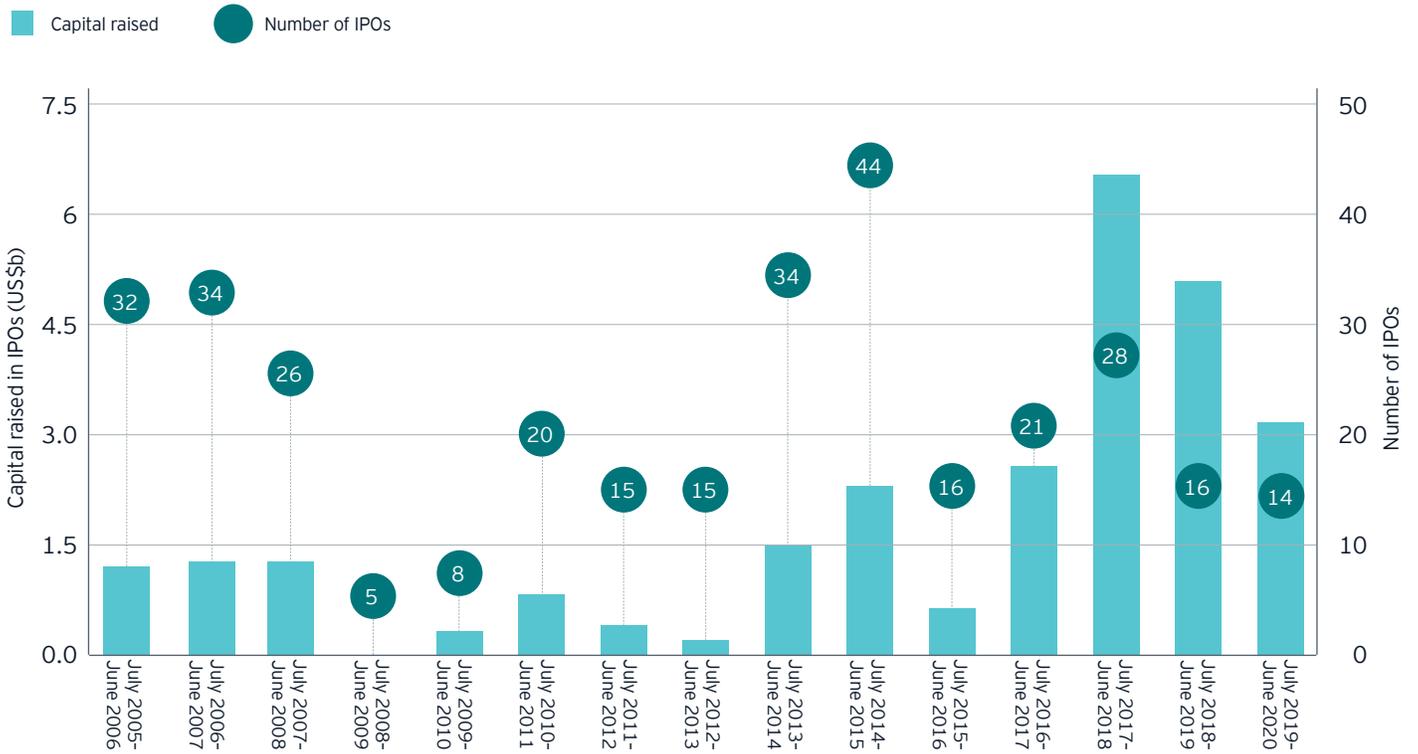
However, it is clear that both debt and follow-on fundraising (which constituted roughly another US\$11.8 billion - 23% of the period funding total) was driven by medtech’s bigger players, rather than the smaller companies that form a key component of the industry’s R&D engine. Overall “innovation capital” (money raised by the industry’s noncommercial leaders) slid to US\$18.4 billion, accounting for only 32% of total funding (down from the previous 10-year average of 47%).

The IPO and venture capital (VC) fundraising channels saw less activity than debt and follow-on financing over the same 12-month period, which presents a challenging landscape for early-stage companies reliant on these financing options. Josh Makower, MD, a general partner with venture capital firm NEA, told us that while “companies whose work can proceed without being impacted by the state of elective surgeries are seeing good valuations and good financings,” others “will experience a higher challenge in obtaining capital right now and may need to rely on insider’s capital to extend runway, or they may face down-rounds or valuation resets if they must raise externally.”



Figure 7. Medtech IPOs were down again

US and European medical technology IPOs by period



Source: EY, Capital IQ, BioCentury and Dow Jones VentureSource.



While the US\$3.2 billion total for IPOs was the third highest on record, just 3 deals constituted roughly 85% of that volume, and the number of deals (14) was the lowest in a decade (see Figure 7). The biggest IPO illustrates the trend toward virtual health: SmileDirectClub raised almost US\$1.4 billion through its September 2019 IPO. SmileDirectClub has developed a “teledentistry” model in which consumers can use an at-home kit to make an impression of their teeth and then receive custom aligners without going to an orthodontist. The COVID-19 pandemic is now accelerating the demand for these types of business models. Yet most of the IPO volume in the 12-month period considered here was concentrated in Q3 2019, before COVID-19 had an impact. IPO activity fell precipitously in the first two quarters of 2020.

In the meantime, after three straight years of record VC investment, the total for the most recent 12-month period fell by 22%, with Q2 2020 being particularly painful – presumably reflecting the impact of the pandemic. Moreover, early-stage companies secured a smaller proportion of the total in this period (43%) than in the previous 12-month period (52%) (see *Databook*), suggesting possible challenges in funding early innovation.

It’s notable that non-imaging diagnostics, once again, have been a major target for venture activity. The biggest US VC round saw Northern California-based Karius raise US\$165 million for its Karius Test blood testing technology platform, which combines genomics and AI to spot trace DNA marking the presence of infectious pathogens. The top VC round overall

went to UK-based CMR Surgical Limited, which makes the next-generation Versius surgical robotics system. Surgical robotics have been a standout in the therapeutic devices segment in recent years, with market leaders Medtronic and Johnson & Johnson both investing in multibillion-dollar acquisitions in this maturing technology space (see the guest perspective from Dr. Jean Nehme and Dr. Andre Chow, cofounders of Digital Surgery, which Medtronic acquired in 2020).

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... after three straight years of record VC investment, the total for the most recent 12-month period fell by 22% ...

M&A: will the pendulum swing back in 2021?

The disruptive impact of the COVID-19 outbreak is particularly evident in the industry's M&A performance, with M&A expenditures from July 2019 to June 2020 plunging 60% to US\$27.1 billion compared to the previous 12-month period (see Figure 8). An already-low total deal value was further reduced when Thermo Fisher Scientific was rebuffed on its proposed US\$12.5 billion acquisition of Qiagen in August 2020. Focused on molecular diagnostics, including in infectious disease, Qiagen saw its operating income jump 84% in the first six months of 2020 due to the impact of COVID-19, leaving its shareholders reluctant to accept Thermo Fisher Scientific's enhanced offer.

The next-biggest deal - Stryker's US\$5.4 billion proposed acquisition of orthopedic company Wright Medical - is under regulatory review in the US and the UK as of September 2020. However, the impact on M&A is not confined to the fall in such "megadeals" (those worth over US\$10 billion): the total value of non-megadeals has also dropped 41%, while the average deal value across the industry shrank to US\$167 million (from US\$463 million in the previous year).

The slowdown in M&A, IPOs and VC funding raises concerns that a major source of innovation will disproportionately impact startups and small companies that are reliant on this capital. To sustain the cycle of innovation, larger medtech companies may need to consider other approaches, such as partnerships, incubators and

more milestone payments (a strategy these companies frequently employed during the aftermath of the 2007 and 2008 financial crisis).

There are signs, however, that the big medtech players may instead be contemplating a surge of acquisitions in the near future. A buyer's market may be developing as smaller, and perhaps even midsize, companies question whether they can survive the economic uncertainty triggered by the COVID-19 pandemic. Meanwhile, as noted, large medtech companies have recapitalized through debt and follow-on offerings, and now have substantial M&A firepower. "The industry anticipates an accelerated growth cycle, with companies valued at US\$30 million to US\$40 million becoming targets," suggests John Babitt, EY Americas Strategy and Transactions Medtech

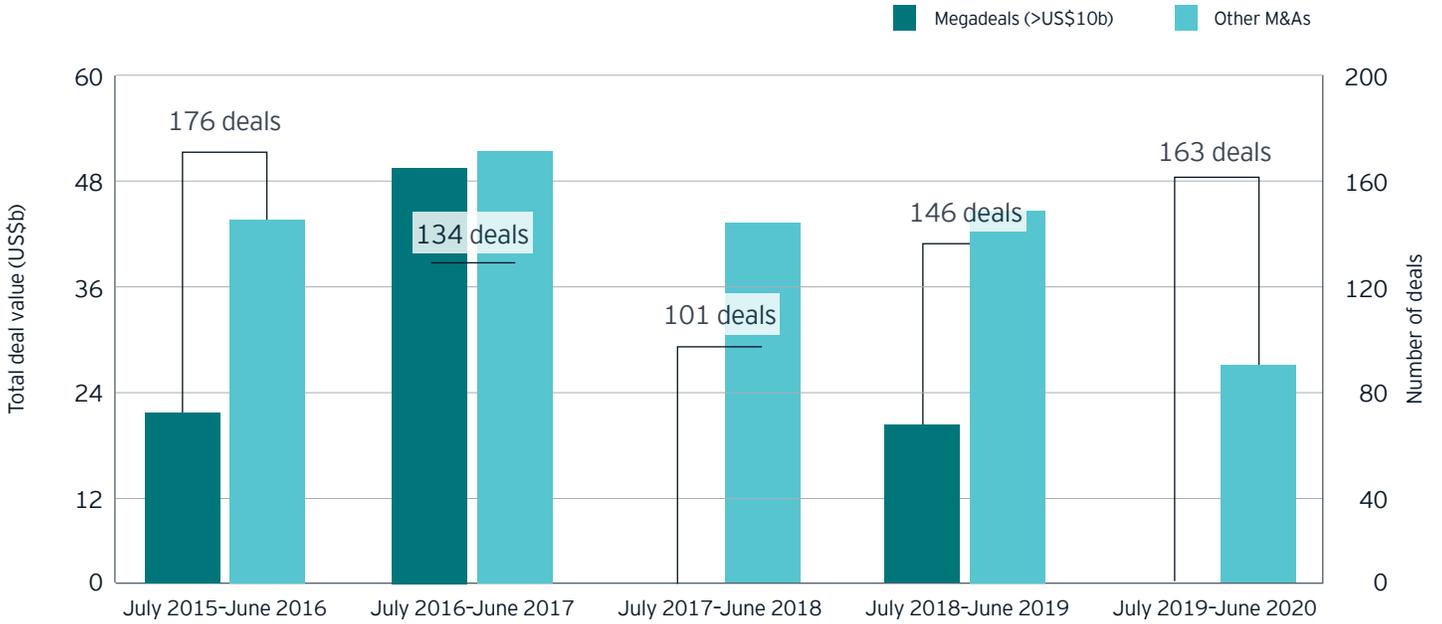
Leader; "if we as an industry get some sense of normalcy into the fall, the high level of available capital could trigger an M&A acceleration," he continued.

This is one of the areas to watch over the coming year in medtech. The industry has retained investor confidence as reflected in its valuations and shows early signs of a rebounding from the COVID-19-related revenue hit, with the non-imaging diagnostics segment in particular thriving. There are more mixed signals in the financing and M&A data, suggesting the current uncertainty about the future. Yet, as discussed throughout this report, there are also substantial reasons for medtech to be positive about the future - with COVID-19's long-term impact not constraining the industry, but potentially driving growth and transformation.



Figure 8. Total deal values decline in 2019-20

M&As in the US and Europe by year



Source: EY, Capital IQ, Thomson ONE.



Opportunities from the crisis: where medtech is heading in the Next and Beyond





We now turn our focus to the evolution medtech is undergoing in 2020. This evolution is not solely a result of the COVID-19 crisis; on the contrary, the underlying drivers for medtech's transformation have been increasingly evident in recent years, and have been explored in recent editions of this report. The rise of connected devices is drawing medtech into the internet of things and opening up new opportunities for data-driven improvements in clinical outcomes; growing cost constraints on health care systems; establishing the impetus for providers to assist medtech in reshaping its business models and ecosystem relationships; and seeing patient-consumers' increasing demands for a more customer-centered health care experience. These drivers of change were all recognized by the medtech industry prior to 2020.

However, COVID-19 has increased the urgency for medtech to respond to these drivers and to accelerate its transformation. The challenge of the COVID-19 pandemic has highlighted the room for improvement in medtech's business models, supply chain systems, regulatory relationships, and deployment of digital and data tools. The industry now has the chance to address these limitations and place itself in a better position to thrive in the next and the beyond.

First, we consider the impact the pandemic has had on business models, and how medtech can capitalize on this change.

Changing business models

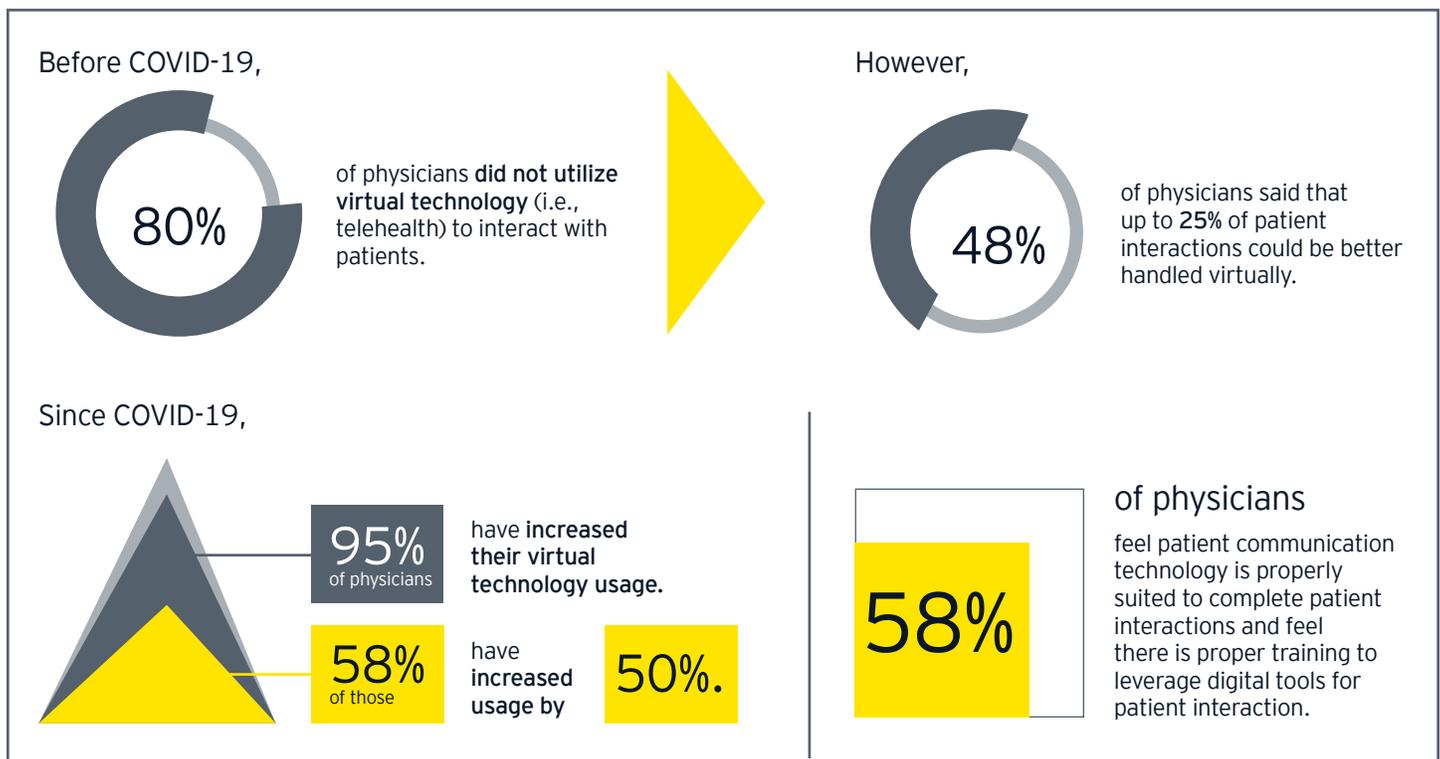
By the end of the 1950s, the technology for virtual health services already existed: two-way interactive video and voice contact, piloted by NASA to monitor astronauts' vital signs, was already allowing communication between the Norfolk State Hospital and the Nebraska Psychiatric Institute in Omaha, 112 miles away. And yet, six decades later, at the beginning of 2020, 80% of physicians in the US were not using virtual health in their patient interactions (see Figure 9).

And six months after that? Ninety-five percent of physicians had increased their use of virtual technology, with

58% of them increasing it by over 50%. "It was always going to happen in five years, but instead it happened in five months," one participant told the first EY/AdvaMed medtech CEO roundtable, on 4 August 2020 (see *Insights from the first EY/AdvaMed medtech CEO roundtable* below).

The lesson here is that technologies can exist for years before external events trigger the wholesale shift toward business models that can capitalize on those technologies. For virtual health, it was the COVID-19 pandemic that pulled the trigger. One of the leaders in virtual health, Teladoc Health, reported that in Q2 2020, its appointment volume had grown over 200% compared to Q2 2019.¹ Within a week of this

Figure 9. The rise of telehealth



Source: EY survey data.

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I think the shift to online commerce and remote video interactions will have a long-lasting impact that will change how we think about future opportunities.



Josh Makower, MD
General Partner, NEA

earnings call, Teladoc announced it would acquire digital health platform company Livongo for US\$18.5 billion in a potentially transformative deal for the remote care sector (see *The digital opportunity*). Suddenly, the movement toward virtualized, remote-operated business models for medical care is accelerating. “Companies with direct-to-consumer or digital business models, or those with necessary essential services or products, are gaining momentum

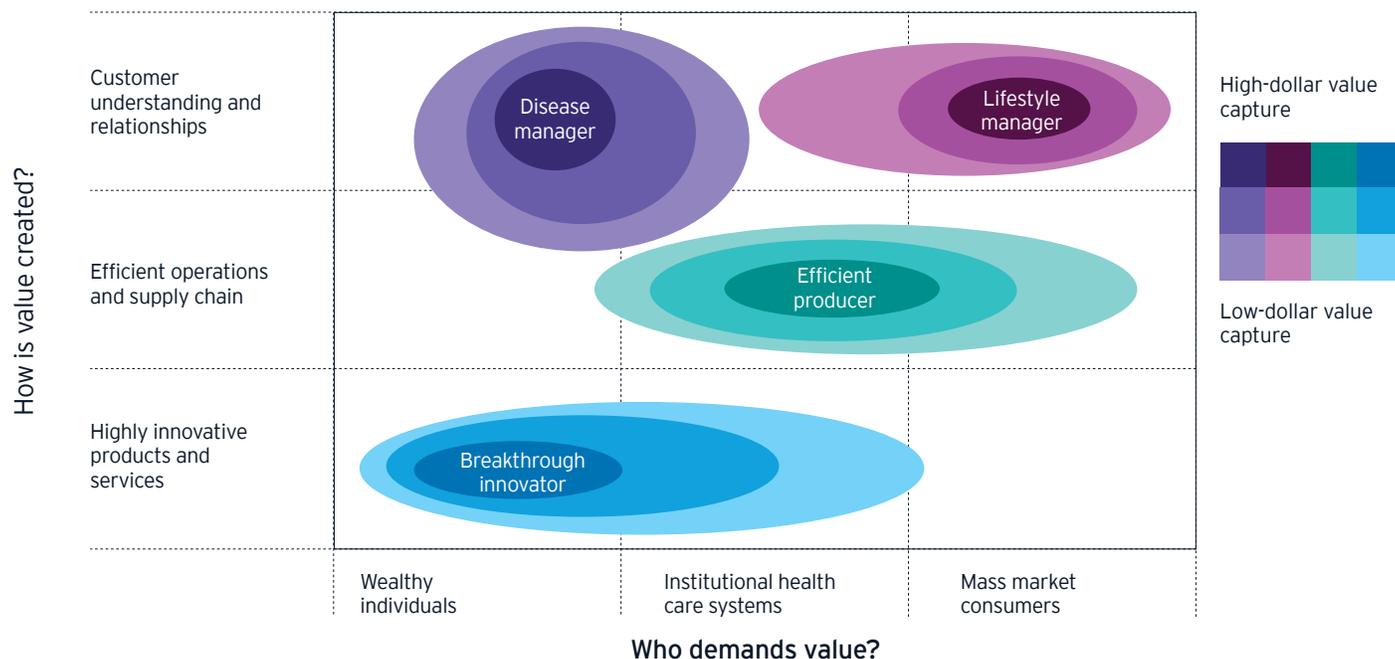
in this environment,” NEA’s Josh Makower told us. “I think the shift to online commerce and remote video interactions will have a long-lasting impact that will change how we think about future opportunities.”

We previously outlined the future business model approaches we believe medtech companies will need to adopt to futureproof operations against disruption and to enable effective

deployment of limited capital resources (see *Defining the four business models for the future*). The disease manager business model, as we describe it, is focused on remote care for chronic diseases. As we’ve seen in 2020, the need for this kind of care at a distance has suddenly become more relevant than ever before, with patients increasingly unwilling to seek care via bricks-and-mortar traditional channels. Particularly with the rise of diagnostics and the integration of diagnostics with remote care delivery (consider the way continuous glucose monitors are now “closing the loop” with smart insulin delivery devices to become complete diagnostic-therapeutic systems), medtech is already at the forefront of delivering this new remote care model.

Figure 10. Four business models for the future

As stakeholders respond to evolving customer demands, their total market value will shift in ways that depend on their chosen business models.



Source: EY, Brian D. Smith, *The Future of Pharma* (Gower Publishing Ltd, 2011).

¹ Teladoc Health's Financial Info: 2Q20 Earnings Release, 29 July 2020 (https://s21.q4cdn.com/672268105/files/doc_financials/2020/q2/EPR-Q2-2020-0729-pdf.pdf).

Lifestyle managers, too, can offer care at a distance. Here, once again, the disruption of 2020 has shown the urgency for remote care models. Worldwide, populations face the challenges of maintaining mental and physical health while being cut off from normal routines. In recognition of this, the FDA lowered barriers to bringing behavioral therapy devices to market in April 2020, with the aim of heading off a potential mental health crisis.² This could be the moment for lifestyle managers to prove their value.

Yet not all business model change is based on virtualization of care, and the business models that deliver remote care are not the only tools to be highlighted by the events of 2020. As new health challenges emerge, new breakthrough innovations are needed to address them: in 2020, medtech players have aimed not only to rapidly design, redesign or retrofit devices that can help with COVID-19 management, but also to bring forward innovative offerings that can address the crisis. For one recent example, consider ExThera Medical's Seraph 100 Microbind Affinity Blood Filter, an EU-approved device that received its FDA EUA in August

2020; a first-in-class tool for reducing pathogens in the bloodstream, even before identification of the pathogen.³

Finally, efficient producers, too, have never been as vital as in 2020, with health systems worldwide needing commodity equipment, from protective personal equipment (PPE), ventilators and diagnostics to many other hospital basics, at scale and at speed. Efficient producers with robust and agile systems for manufacturing and distribution have been at the forefront of medtech's efforts to mitigate the disruptions caused by the pandemic. Not least among these disruptions has been its impact on global supply chains.

Defining the four business models for the future

1. Breakthrough innovator: Developer/provider of best-in-class products and services that command high prices and are primarily paid for by traditional health insurance. Innovative technologies such as Abbott's MitraClip "toolbox" for structural heart repair, or Intuitive Surgical's da Vinci platform (and other cutting-edge robotic surgery platforms) illustrate the scope of this business model.

2. Disease manager: Developer/provider of products and solutions that manage chronic conditions in a more personalized way, with a focus on customer experience, convenience and maximum adherence. Companies such as Dexcom, which are building interoperable disease management systems for diabetes patients (combining tools such as infusion pumps, smart pens, continuous glucose monitoring systems and apps to offer the most convenient, effective all-around care), illustrate how this business model can best offer personalized chronic disease management.

3. Lifestyle manager: Developer/provider of products and services aimed at overall health and wellness maintenance and disease prevention, marketed directly to the consumer. Technologies such as the Apple Watch Series 4, which contains an integrated ECG monitor, and the ever-growing number of apps focused on aspects of health maintenance and wellness – from diet to exercise, blood-pressure monitoring, mindfulness and well-being – address this growing need.

4. Efficient producer: Developer/provider of lower-cost commodity products and services that offer the same outcomes as more expensive alternatives, with an emphasis on a high-volume, low-margin revenue model. In other sectors, companies such as Amazon and UPS have revolutionized distribution – medtech awaits this kind of transformation with regard to margin.

Each of these four business models has demonstrated its essential role in the medtech ecosystem during the COVID-19 crisis. Now, medtech companies need to be more proactive and focus on the business model that can secure value for them in the long term. As 2020 shows, the future can arrive more suddenly than expected.

² FDA, Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, April 2020. <https://www.fda.gov/media/136939/download>.

³ See ExThera website (<http://www.extheramedical.com/seraph-100>). The study supporting the device's potential efficacy in related to COVID-19 was published in August 2020: SW Olson, et al. Treatment for Severe Coronavirus Disease 2019 With the Seraph-100 Microbind Affinity Blood Filter. *Crit Care Explor.* August 2020; 2(8): e0180. doi: 10.1097/CCE.0000000000000180.

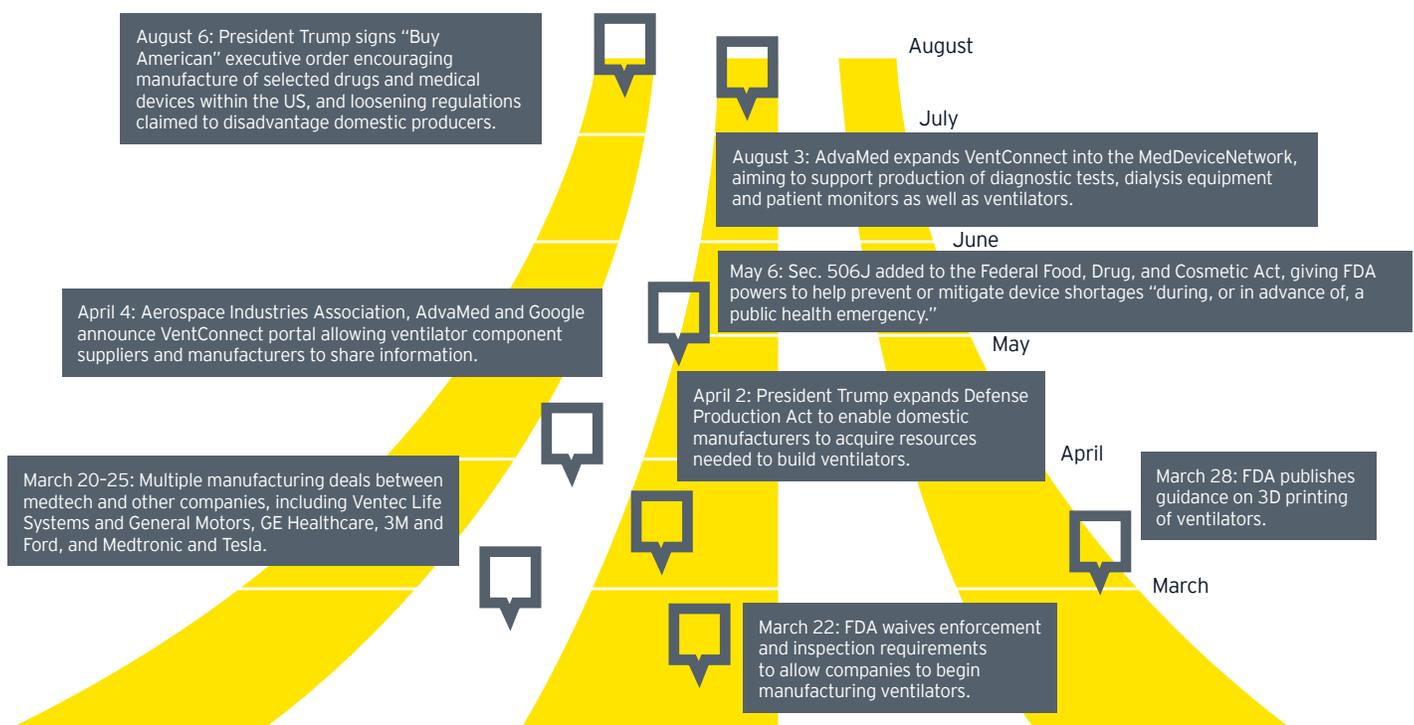
Supply chain transformation

President Trump's "Buy American" executive order of August 2020, pertaining to essential medicines, medical devices and their components, and PPE, was the latest in a succession of moves by the administration to try to secure the medical supply chain. On 14 August, the FDA for the first time posted a list of medical devices at risk of shortage or limited supply, under new powers granted to the agency to help relieve device shortages associated with a public health emergency (to be revoked when the COVID-19 emergency is over.)

This intervention from the federal government underscored the chaos that threatened supply chain operations as the COVID-19 pandemic spread in the early months of the year. Back in February 2020, concerns were focused on the risk to medtech supply chains with significant reliance on Chinese manufacturers. FDA Commissioner Stephen Hahn noted that the agency recognizes 63 manufacturers "which represent 72 facilities in China that produce essential medical devices."⁵ Even at this stage, a backlash against the globalization of supply chains, and a drive to "onshore" manufacturing was evident in political rhetoric.

Yet the medtech industry has mounted its own creative response to supply chain disruption, without seeking the localization of supply. One prime example is the VentConnect platform, launched by AdvaMed and its members in May 2020 and intended to link medtech firms with component suppliers to enable and accelerate access to components needed for production and distribution. In August, AdvaMed expanded the platform (now rebranded the MedDeviceNetwork) to cover devices beyond the immediate COVID-19 context, including "patient monitors, dialysis machines and diagnostic tests, among other equipment."⁶

Figure 11. Timeline of US supply chain policy developments since COVID-19 outbreak



Source: EY, Informa.

⁴ Nicholas Florko, "Trump orders government to buy certain drugs solely from U.S. factories, setting up major shakeup for industry." STAT News, 6 August 2020. <https://www.statnews.com/2020/08/06/trump-to-order-government-to-buy-certain-drugs-solely-from-u-s-factories-setting-up-major-shakeup-for-industry/>.
⁵ FDA, Coronavirus (COVID-19) Supply Chain Update. February 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>.
⁶ Sue Darcey, AdvaMed Expands VentConnect Platform To Bolster Medtech Supply Chain. Medtech Insight, 3 August 2020. <https://medtech.pharmaintelligence.informa.com/MT142521/AdvaMed-Expands-VentConnect-Platform-To-Bolster-Medtech-Supply-Chain>.

The expansion of this platform solution beyond the challenges of the pandemic underlines the fact that the supply chain issues for medtech didn't begin in 2020. Industry insiders have in the past noted the inefficiencies associated with supply intermediaries and inflexible legacy systems, in addition to the lack of transparency for regulators and companies alike. Concerns around supply chain visibility and efficiency were already at the forefront of industry discussions, with companies considering the wider use of analytics to address these issues, reduce costs and better meet their customers' changing demands. Along with supply-side changes caused by shifts in commercial models, these topics had become an important part of the conversation long before this year's pandemic disruption.

Moreover, nationalistic criticism of globalized operating models also preceded the pandemic, and these tensions look set to continue no matter how COVID-19 plays out from this point. Medtech companies are obliged to assume a disrupted global political environment for the foreseeable future.

The challenges of building transparency and resiliency into supply chain operations are now firmly front of mind for the industry following 2020's upheaval, and these issues were discussed in the second EY/AdvaMed medtech CEO roundtable. Participants noted that even aside from the political pressures (which have necessitated constant two-way discussion between companies' supply chain and government affairs units), the crisis has highlighted existing limitations of the supply chain model.

In particular, participants said that the tremendous ramping up of demand in 2020 has demonstrated to medtech companies that they are scaled for efficiency, not redundancy. They have depended on a relatively small and shared base of suppliers, often concentrated in low-cost geographies. With shutdowns restricting the ability of some of these suppliers to export (and with diversified suppliers being classified as nonessential by some governments, thus losing their special exemptions to continue operating during the crisis), medtech companies have been hit by shortages, which have impacted the areas of raw materials and low-tech basic items, from swabs and pipettes to O-rings and screws (by contrast, the roundtable agreed, major components have been much less problematic to source during the disruption). One medtech CEO noted that in the future, the industry will "have to figure out how we can do that better, maybe in a virtual environment" - perhaps this will entail using digital technology and data to track how much scale redundancy suppliers have and whether they can pivot toward greater production. In the longer term, the industry will need to accommodate the ongoing reality of travel restrictions between countries and even between US states, as our roundtable revealed: "a new wave of complications is coming to travel, and we need to redefine the [standard operating procedures]." The industry also may need to bring some manufacturing capacity back to the US or Europe, to safeguard the supply base.

In short, once the COVID-19 pandemic has been managed, supply chain challenges will remain. As business models change, new supply chain problems also will arise. Consider the rise of remote care, as discussed in the Changing business models section. If care moves toward an "anytime, anywhere" model, how can medtech companies shift their supply chains to accommodate this change?

Moreover, as medical devices become ever smarter and more reliant on software and data, this will increase the need for medtech companies to take a broader product life cycle approach to their devices. "As the manufacturer, once the device is placed in the hospital, I have little visibility into it," one participant told the 2020 EY trusted medical device ecosystem roundtable. Yet manufacturers retain ultimate responsibility over the continued security and "cyber hygiene" of these legacy products that remain in the market. As more and more medical devices connect to the internet of things, these issues will become ever more relevant, with supply chain management needing to extend beyond product launch into the post-market phase. Addressing these emerging issues will involve working closely with regulatory bodies to create a new paradigm for regulating devices. This is another area where progress has been made in 2020 as a result of the pressures of the COVID-19 crisis.



If care moves toward an "anytime, anywhere" model, how can medtech companies shift their supply chains to accommodate this change?



A revolution in regulation

Whatever the lasting commercial impact of the pandemic, we can see already that it has transformed regulatory norms. In the US, concern over product supply has not only led to increased policymaker involvement in the supply chain (see *Supply chain transformation*), but also significantly cut in the barriers to market entry, with the FDA authorizing over 250 emergency use authorizations (EUAs) since February 2020 (see Figure 12). These EUAs cover many products, including in vitro diagnostics and other tests, personal protective equipment and ventilators, and equipment that can be repurposed as ventilators.

The loosening of regulatory conventions goes beyond EUAs, with the beginning of the pandemic prompting the FDA to ease its policy controlling X-ray, ultrasound and MRI imaging systems and software; for example, in April 2020, while issuing guidance relaxing restrictions on fetal and maternal monitoring devices, allowing manufacturers to modify these devices so they can be used at home.⁷ This drop in regulatory stringency is not confined to the US, with Canada allowing the import of drugs and devices that aren't strictly compliant with its own regulatory norms during the crisis.⁸ Meanwhile, across the Atlantic, the EU has deferred the implementation of

the Medical Device Regulation - which will require high standards of quality and safety for medical devices being produced in or supplied into Europe - for a year.⁹

The crisis in this respect represents an opportunity for the medtech industry. Participants in our medtech CEO roundtable (see *Insights from the first EY/AdvaMed medtech CEO roundtable*) lauded the "extraordinary response" from FDA reviewers, "moving at warp speed" to help get new devices to market in 2020. It's not only new products that have been accelerated into the medtech space, but also new entrants. Multiple companies from outside the

⁷ Shawn M. Schmitt, "Guidance: FDA Will Look Other Way If Manufacturers Modify Imaging Systems To Fight COVID-19." Medtech Insight, 27 April 2020. <https://medtech.pharmaintelligence.informa.com/MT126652/Guidance-FDA-Will-Look-Other-Way-If-Manufacturers-Modify-Imaging-Systems-To-Fight-COVID19>.

FDA, "Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." April 2020. <https://medtech.pharmaintelligence.informa.com/-/media/supporting-documents/medtech-insight/2020/04/fda-imaging-systems-enforcement-policy-guidance.pdf?la=en&hash=43F02625F949FE7552D084FB149D915780917E73>.

FDA, "Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." April 2020. <https://medtech.pharmaintelligence.informa.com/-/media/supporting-documents/medtech-insight/2020/04/fda-fetal-monitoring-enforcement-policy-guidance.pdf?la=en&hash=87B57341D501BA1F8E9D75713A605F35C66F6D91>.

⁸ Vibha Sharma, "Canada Allows Exceptional Drug, Device Imports To Tackle COVID-19 Shortages." Medtech Insight, 8 April 2020. <https://medtech.pharmaintelligence.informa.com/MT126552/Canada-Allows-Exceptional-Drug-Device-Imports-To-Tackle-COVID19-Shortages>.

⁹ Maria Rachal, "EU regulators propose 1-year MDR delay," MedtechDive, March 2020.

sector came together with medtech companies to meet the demand for vital equipment, with General Motors teaming up with Ventec Life Systems to build ventilators, Ford Motor Co. announcing manufacturing partnerships with GE Healthcare and 3M, and Medtronic working closely with Tesla to increase its production capacity.

Collaboration within the sector has also been facilitated by the regulators' permissive attitude in 2020, with the U.S. Department of Justice and the Federal Trade Commission confirming that medical device suppliers can collaborate during the crisis without risking violation of antitrust laws, sharing capacity and expertise as needed.¹⁰

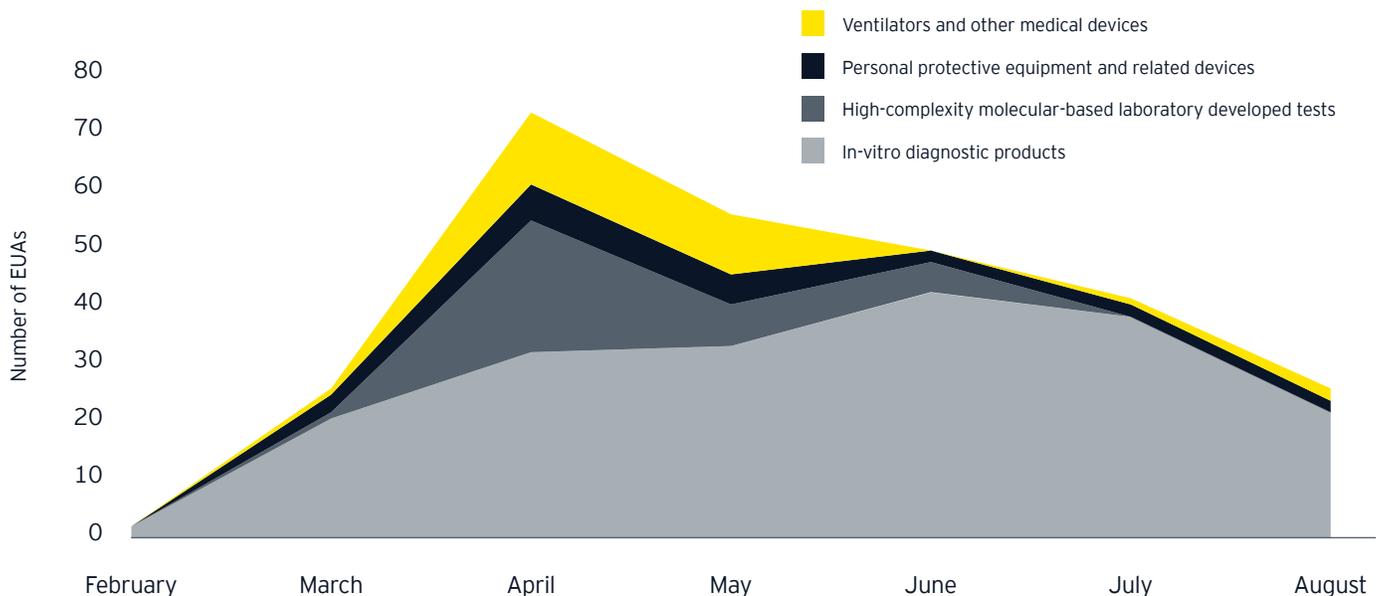
In short, the opportunities of this situation go beyond the chance to produce and sell more products relevant to COVID-19. More broadly, the crisis appears to have fostered an attitude of collaboration and cooperation within the medtech sector, and between the industry and its stakeholders. The receptive attitude of the FDA and other regulatory bodies offers great scope for the industry to shape the dialogue about how it is regulated in future.

Partnership is going to become an ever-more vital part of that conversation. Consider the FDA's proposed approach to managing AI, which would see the agency moving away from regulating individual products toward a broader and more continuous assessment of

companies as viable partners to bring software and analytics into the market. Digital and data transformation have received a shot in the arm in 2020 (see *The digital opportunity*). With the buy-in of regulators, medtech is well-placed to continue this transformation and usher in a new era of digital, data-driven smart devices that can potentially transform the industry.

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The crisis appears to have fostered an attitude of collaboration and cooperation within the medtech sector, and between the industry and its stakeholders.

Figure 12. Emergency use authorizations



Source: EY, FDA.

¹⁰ Elizabeth Orr, "DOJ: Medical Supply Firms Can Collaborate During COVID-19 Crisis." Medtech Insight, 8 April 2020. <https://medtech.pharmaintelligence.informa.com/MT126553/DOJ-Medical-Supply-Firms-Can-Collaborate-During-COVID19-Crisis>.

The digital opportunity

While the medtech industry has always been built on clinical data, the digital world evolving around us offers far broader, richer sources of data. From environmental data to lifestyle data and real-time data on biological processes captured inside and outside the body, we are living through a proliferation of data that has the potential to transform health care. Stakeholders acknowledge this. They also recognize that the challenge now is not a lack of data, but a lack of data integration: the data being generated is trapped in silos, and there are multiple challenges to joining it together.

In part, these challenges are technical, and the rapid progress of technology makes it likely that they will be overcome. Other challenges are regulatory. We have seen how fast

regulatory adaptation has happened during the COVID-19 crisis (see *A revolution in regulation*); now, we need to see that adaptation continue, to accommodate the use of data in ways that can transform health care.

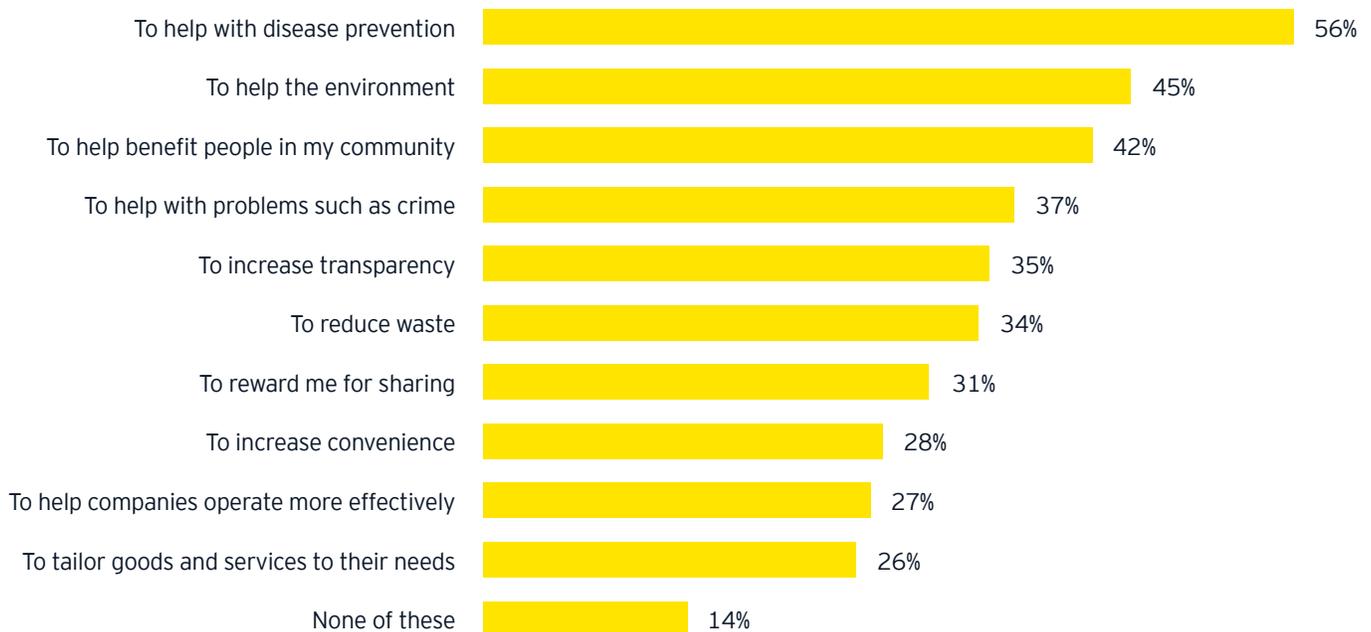
There is also the challenge of consumer willingness to share their data. Data privacy has presented an obstacle in the past, but the EY Future Consumer Index survey, performed in April 2020, suggests that 56% of consumers would make their personal data available if it helped to monitor and track an infection cluster, potentially opening an avenue for new business models.

Yet perhaps the biggest obstacle to data-driven transformation of the medtech business model has been the industry's own reluctance to embrace change. While medical devices increasingly incorporate software and connectivity,

many companies have hesitated to make significant investments into building the digital capabilities needed to access and use the ever-expanding wealth of real-world data.

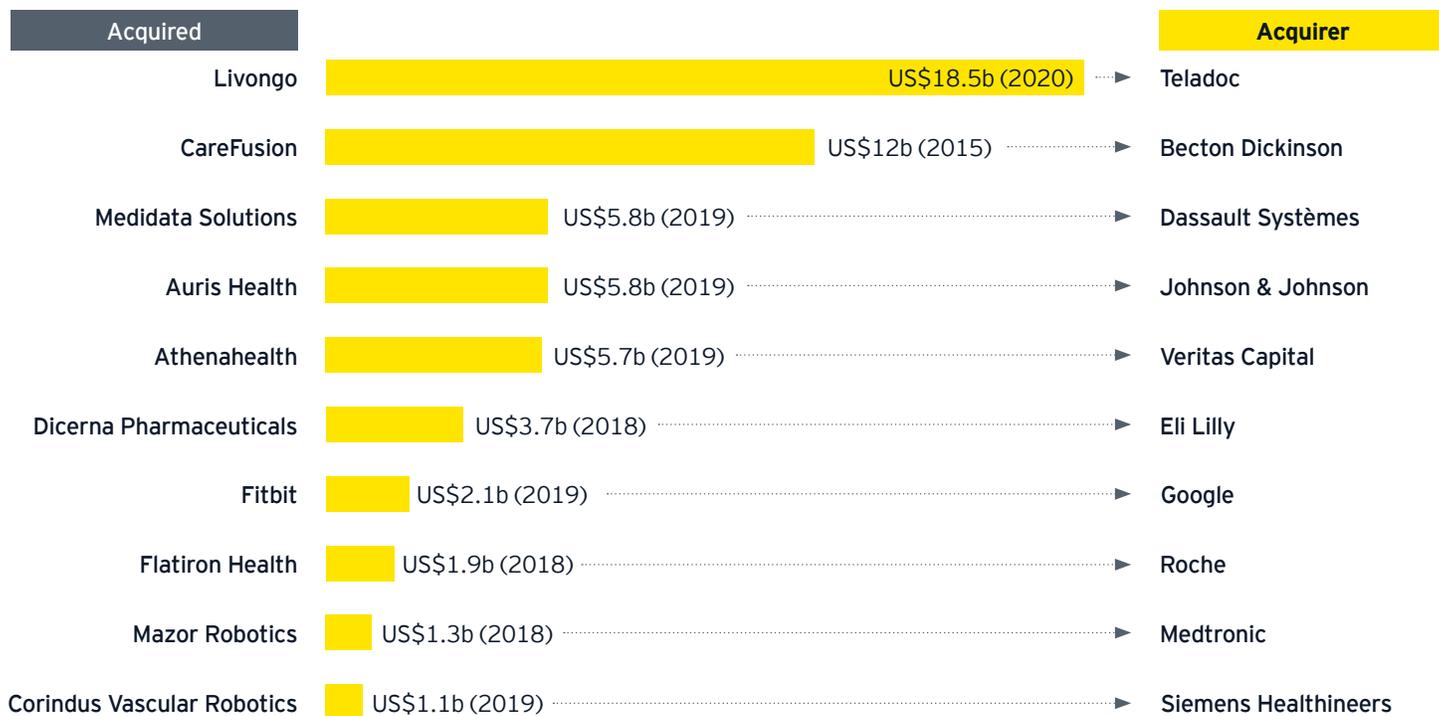
It may be that the events of 2020 will conclusively demonstrate to medtech and the broader life sciences industry that digital acceleration is needed. Digital technologies are key to enabling the move toward remote care models for chronic disease and for health maintenance, and as such have been the focus of rapidly rising demand during the pandemic. While medtech valuations have performed more strongly than most other life sciences sectors (see *Medtech valuations rise again in 2020*), digital health has been even more favored by investors, with the Rock Health Digital Health Public Index rising 65% between January 2019 and August 2020.

Figure 13. Why consumers will share data



Source: EY Future Consumer Index.

Figure 14. Recent digital health acquisitions



Source: EY, Rock Health Digital Health Public Company Index and company reports.



Indeed, the year 2020 witnessed the largest M&A investment yet made in the digital health space (announced in August, it fell outside the time period used in our M&A data in this report) when Teladoc Health announced that it will buy Livongo for US\$18.5 billion. The move prompted Forbes to write that an “unprecedented event in digital health history has taken place.”¹¹ The deal is a potentially transformative move, creating a health tech giant and a new high benchmark for the valuation of digital health.

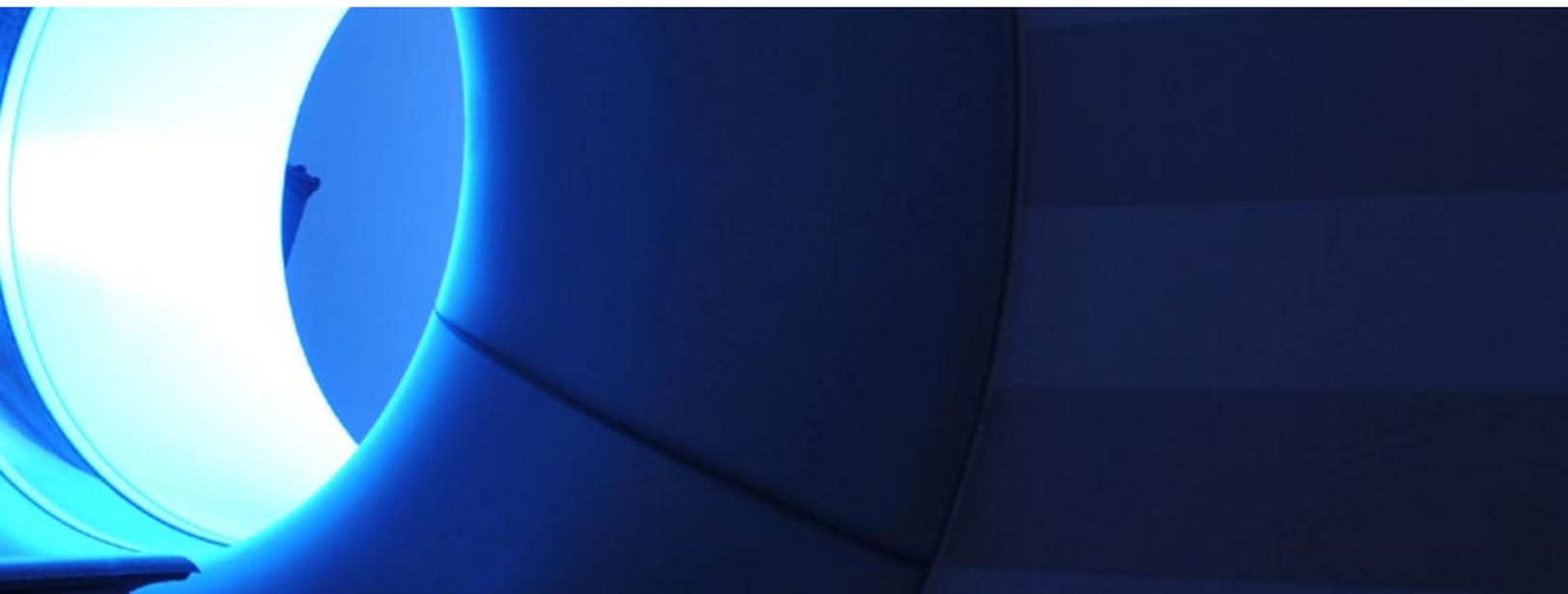
Livongo provides technologies to help people manage chronic conditions such as diabetes, and through this acquisition, they will be available across the 175 countries in which Teladoc Health is already active (instead of only in the US). It’s also notable that these two digital players have taken the initiative to create their new platform for themselves, rather than being united under a traditional medtech giant or Silicon Valley behemoth.

August 2020 also saw another indication that major medtech companies may be ready to place their own big bets on digital health capabilities, with Siemens Healthineers announcing its US\$16.4 billion deal to acquire Varian Medical. While coverage of this deal has focused primarily on Siemens’ bid to add radiation therapy expertise to its oncology solutions, Varian also offers a suite of relevant digital capabilities. As one BTIG analyst noted, Varian’s business in recent years “has shifted considerably” toward software, and “adding Varian’s capabilities and products will allow [Siemens] to address the issue of fragmented cancer care by enabling earlier diagnosis and precise, targeted therapies powered by artificial intelligence.”¹² The deal therefore offers further suggestions of a sharp acceleration of investment into digital capabilities for medtech. These digital capabilities will be key to unlocking the power of data to transform medtech and the broader health care ecosystem.

The final obstacle to embracing this transformation may lie within the culture of medtech companies themselves, which are used to viewing data as a proprietorial asset to be protected rather than a resource that can gain value from being shared. However, the COVID-19 crisis has allowed companies to work together without risking antitrust infringements (see *A revolution in regulation*); and as participants in our CEO roundtable told us, being a trusted partner has become more important than ever in the past year (see Insights from the first EY/AdvaMed medtech CEO roundtable). Greater collaboration – with competitors as well as customers – built on data can open future growth possibilities for medtech that will still be unfolding long after the COVID-19 crisis is in the rearview mirror.

¹¹ Chase Feiger, M.D. “Say Hello To The Largest Virtual Care Company: Telavongo, The \$38 Billion Merger Between Teladoc And Livongo.” Forbes. 5 August 2020.

¹² Marie Thibault, BTIG, cited in Omar Ford, “Siemens to Acquire Varian in One of the Largest Deals During the Pandemic.” *Medical Device and Diagnostic Industry*, 3 August 2020, <https://www.mddionline.com/business/siemens-acquire-varian-one-largest-deals-during-pandemic>.





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We've got technology that can change the world ... people need our tech more than ever.

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This is an opportunity to solidify that partnership we all talk about.

Insights from the first EY/AdvaMed medtech CEO roundtable

“None of us were trained to run companies from our dining room tables, but now we’ve been doing it for 21 weeks,” observed one of the participants at the first EY/AdvaMed medtech CEO roundtable, on 4 August 2020. As the senior leaders (many of whom represent members of AdvaMed’s Accel program for smaller medtech companies) attending the roundtable confirmed, the COVID-19 crisis has caused serious disruption to the industry - but also opened significant opportunities.

One pre-revenue-stage medtech company, for example, adapted successfully when the COVID-19 pandemic brought a halt to its pivotal clinical trial in March 2020. “We rolled with the situation optimistically, and were fortunate that the timing was good for our remote monitoring diagnostic,” reflected a representative from this company, who explained that by requesting a broader indication for its product and working with the FDA, it succeeded in filing a 510(k) application ahead of schedule. If approved as expected, the company will effectively be commercializing one year in advance of its expectations. Success stories like this have been enabled by ingenuity on the part of companies but also, it should be noted, by the flexibility of regulators.

However, the pandemic has of course brought significant challenges as well as opportunities. On the personnel side, companies have had to balance keeping employees safe while also continuing to recruit and to validate that employees are performing with company operations inevitably disrupted. On the financial security side, smaller medtech companies in general have had to do “what entrepreneurs do best: plan for uncertainty,” with the market sometimes standing still and at other times speeding out of control. The effort to survive and thrive during the ongoing uncertainty have shown, according to one participant, that “culture is everything ... Culture kept us together.”

If medtech’s strong culture can help bring it through the crisis, then potentially it can also help the industry’s customers, presently still reeling from the pandemic. Participants argued that medtech companies can best seize the opportunities of this pivotal moment by strengthening relationships with their ecosystem partners: “this is an opportunity to solidify that partnership we all talk about; this is the chance to make it real. We’ll be talking about 2020 for years. ‘What was your experience? How did they do by you?’”

Participants also affirmed that if 2020 offers medtech the chance to build its partnerships, the industry already has the technologies (such as AI and remote management tools) to address the current crisis: “we’ve got technology that can change the world ... people need our tech more than ever.” The pace at which this technology is being adopted has accelerated in 2020: “it was always going to happen in five years, but instead it happened in five months.”

Yet while participants estimated that the direct impact of COVID-19 will endure for the next three to five years, pivoting too far into the needs of the immediate crisis carries its own risks, with one participant warning that there is “a better chance than not you’re going to flame out” by following this approach. Instead, the participants agreed, medtech companies need to be “driving with one foot on each pedal, the gas and the brake” so that they maintain the strength of their core business model, while simultaneously seizing the opportunities of this moment for the industry.

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Companies that scramble back to how things used to be are going to be the losers.

Insights from the second EY/AdvaMed medtech CEO roundtable

On 26 August 2020, the EY and AdvaMed teams convened representatives from some of the medtech industry's leading players - but one consistent theme in their discussion was that the events of 2020 had already brought these companies together as never before. Medtech, which one participant described as "on the front lines from the absolute beginning" of the COVID-19 outbreak, mounted a joint response to the virus. They continued by noting that competitors who would usually "fight tooth and nail for contracts" came together in a "unified effort" to supply the PPE, ventilators and diagnostics the US and the wider world as the pandemic spread.

Pandemic pressure has also brought the industry closer to its stakeholders, participants agreed, with one adding that a shift in attitudes is evident on the customer side: if, for example, IT staff in hospitals prior to COVID-19 "weren't confrontational exactly, now there is real receptivity; the speed is so different." Another participant called out the "remarkable" evolution of the industry's relationship with the FDA in recent years, emphasizing the regulator's role in enabling the industry's response to the COVID-19 pandemic.

Yet while the industry's representatives asserted their justifiable pride in their companies, their employees and

the collective effort they have made alongside their stakeholders to battle the effects of COVID-19, they also emphasized the scale of the challenges remaining. The wake of the pandemic will bring new obstacles, from the increased financial burden on hospitals and health care systems now obliged to "clean and sterilize like never before," to the cumulative health impact on patients deterred from attending elective, but nevertheless urgent, surgeries by the aggressive public health messaging urging those with chronic diseases to avoid hospitals and clinics.

Digital technologies offer remote care options that can help "to massively accelerate the utilization of medicine and our interaction with customers," and participants again noted the rapidity with which the industry has adopted digital approaches in 2020. While the level of digital adoption achieved during the peak months of the crisis may not be sustained, participants agreed that there will be no mass rollback: "patient interaction with health care systems is going to change, too; that's going to stay, and it's going to be a more efficient system long term." Companies have indeed become more efficient through the use of virtual operations. Whereas a year ago, "inviting a customer to a virtual demo would have been insulting," now companies are doing just this every day, one participant pointed out.

However, unanswered questions remain about just how fundamentally the industry's business models will change in the longer term. The temptation will be to try to restore the status quo ante as soon as possible, but this could be a big error. As one participant put it, the "conventional way of thinking is a big obstacle for us as an industry." Or, as another asserted more baldly, "post-COVID-19, companies that scramble back to how things used to be are going to be the losers."

This is because customer interactions and customer expectations have also shifted as a result of the crisis and the ways health care has adapted to it: "the days of going in and expecting customers to give us a couple of hours are over," this participant argued. Short, focused, often virtual conversations may increasingly become the norm, allowing clinicians to focus more on patients rather than spending time with medtech representatives. The companies that grasp these necessary shifts to standard operating procedures and focus on becoming their customers' trusted partners can gain significant advantages in trust and access in the future.



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Companies have indeed become more efficient through the use of virtual operations.



Scott Whitaker

President and CEO
AdvaMed

Mobilizing medtech to combat COVID-19 and protect public health

The full impact of the COVID-19 pandemic on patients and the health care system has yet to unfold, but from the vantage point of the medical technology industry, the effort to alleviate that impact has been clear and consistent. It's been centered on speed, innovation and resilience in the name of saving lives. From the earliest days of the pandemic, AdvaMed member companies have poured every resource into combating the coronavirus and delivering exceptional care. As a result, patients and providers are better equipped than ever to fight back.

Production of personal protective equipment (PPE) is topping 100% capacity. One AdvaMed member company aims to quadruple global output of N95 respirator masks to 2 billion per year by December 2020, and triple production for the US market to more than 95 million per month.

Ventilator production has been just as impressive. Manufacturing power in the US has increased more than tenfold, with 10,000 ventilators coming off the line each week (compared to 700 per week before the pandemic).

The trend continues with the growth of diagnostic testing capabilities. In May, diagnostics innovators were shipping around 600,000 molecular tests per day, and by mid-September leading IVD companies were shipping 1.5 million tests per day. In all, since March, diagnostics innovators have shipped more than 200 million COVID-19 tests – molecular, NGS, serology/antibody and antigen – to the hospitals, health clinics and community testing sites that need them. And we expect the ramp up of point-of-care antigen tests to continue, anticipating more than 100 million antigen tests, per month, to be shipped nationwide by the end of fall 2020.

These numbers speak for themselves. Medtech mobilized with historic speed. We are so proud of this industry, and we're grateful at AdvaMed to have played a role in helping our industry to save and improve lives throughout this pandemic.

As AdvaMed members were busy producing PPE, we at AdvaMed worked to open global supply chains, eliminate tariffs and lift export limits, so that product could reach its destination as quickly and efficiently as possible.

As AdvaMed members were ramping up ventilator production, AdvaMed, along with Google and the Aerospace Industry Association and other partners, launched a crucial online platform - VentConnect - to link ventilator manufacturers with component suppliers in partnerships to help scale the creation and distribution of the devices. We later expanded the platform - now known as MedDeviceNetwork - to include other critical medtech.

Then, as diagnostic companies raced to develop diagnostic tests, AdvaMed and AdvaMedDx stood up a comprehensive, national COVID-19 Diagnostic Supply Registry to support state and federal efforts to better understand the state of test manufacturing.

From production drives to policy measures

Throughout the crisis, we have continued to drive policy measures in support of the broader medical technology community: most importantly, securing economic relief for companies struggling under the disruption of so-called elective procedures and other care not related to COVID-19. The Coronavirus Aid, Relief, and Economic Security Act (also known as the CARES Act) included federal funding for small and midsize medical technology companies and federal grants for providers to cover expenses and lost revenue. With that aid secured, we pivoted to the source of the problem: in collaboration with other leading health care associations, we released "Re-entry Guidance for Health Care Facilities and Medical Device Representatives" to help hospitals and other health care centers return to surgery safely and responsibly.

All of this work was accomplished hand in glove with Congress and the Trump administration. We worked closely with the Department of Health and Human Services (HHS), Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS), among other relevant agencies, to support flexible policies for pandemic response and to encourage the transitional and long-term continuation of those policies. This will enable us to improve patient access to medical technology even after the current crisis has passed.

Specifically, HHS has maintained the public health emergency status, which removes major regulatory and access barriers and expedites the manufacture and distribution of medical technologies. FDA has worked tirelessly to review and issue emergency use authorizations for diagnostic tests, ventilators, PPE, infusion pumps, remote and wearable monitoring devices, and more. CMS has issued temporary waivers and notices of enforcement discretion that have been essential to expanding telehealth and outpatient services along with other aspects of COVID-19 response and patient care.

These are just a few examples among hundreds. Along with our member companies, we continue to assess how the pandemic has driven changes in health care policy and health care delivery at a pace that would have been hard to imagine even six months ago. How can we keep that pace up? How can we spur it along even further? Each year, we look to the *EY Pulse of the industry* report to help shed light on the developments and trends that are shaping the medical technology field and advancing patient care. That insight has never been more important; we're in a strong position to harness our unique circumstances and drive new, transformative business and health care models that center on innovative medical technologies. As I'm writing this, we still don't have a clear idea of when this pandemic will end or when we can all return to normal - or even what normal might look like on the other side. But the passion and dedication I have seen from the medtech industry over the past several months makes me confident we will get there together and emerge stronger than ever.

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We are so proud of this industry, and we're grateful at AdvaMed to have played a role in helping our industry to save and improve lives throughout this pandemic.



Dr. Andre Chow

Vice President and General Manager,
Digital Surgery
Medtronic



Dr. Jean Nehme

Vice President of Business Development &
Strategic Partnerships, Digital Surgery
Medtronic

Mapping the art of surgery, on a global scale

Surgery is seen by many as an art. Yet we look at it as an algorithmic, step-by-step process.

That perspective – plus our aspiration to take surgical training to the next level and reduce surgical variability – puts us at the center of the next big frontier in surgery. That is, the application of data and analytics in one of the most cost-intensive areas of a hospital: the operating room (OR).

Before we go any further, it's important to understand why we do what we do. And why it's important to patients, clinicians, hospitals and health care as a whole. Only then can we fully appreciate the role data and analytics can and must play in the inevitable, exciting future of surgery. And the incredible value it can bring.

Focused on solving big problems

We're grounded by our fundamental belief that every patient everywhere deserves access to quality surgical care.

Sadly, this is not the case today.

Studies show that as many as 5 billion people lack access to basic surgical treatment – mostly in underdeveloped countries.¹ Even in highly developed countries like the United States or our home, the United Kingdom, surgical care varies greatly.²⁻³

There's broad recognition of this reality across all health care stakeholders, from medical societies and clinicians to payors and patients. Indeed, we've all either asked or been asked: who is the best surgeon for my case?

The thinking behind this question is that a surgeon with the most experience is the best choice. That may be generally true. But that kind of experience can take 20 or more years to develop, and even then we must still contend with the inherent variability of surgery.

We wondered: is it possible to harness surgeons' collective experience and expertise, and use it to accelerate and optimize surgical training and potentially reduce variability?

The answer is yes.

You cannot improve what you cannot measure

Surgical training methods tend to be very siloed and incredibly variable. Surgeons can learn how to do the same operation a different way every day, even within the same hospital. There were also no tools allowing a surgeon to review their performance, like an elite athlete would review a game tape.

Realizing you cannot improve what you cannot measure, we first aimed to create a standardized way to share knowledge among different surgeons, by codifying the surgical process.

In doing so, we had moved from the pure training space into the surgical analytics space. We had built a 4D map structure around surgical data, codifying the steps of the surgical procedure into three spatial dimensions, plus time. This map offered an instructional algorithm for training surgeons.

This robust library of surgical training simulations and surgical videos lives in the Touch Surgery™ mobile app, an academically accredited mobile training platform for surgery.

The Touch Surgery™ app may accelerate surgical proficiency.⁴

It's also helping in our new reality with COVID-19, as many hospital systems restructure operations. There are great advantages in having mobile-based tools that can support surgeons on procedures in a simple, straightforward way.

Training computers and shaping the future of surgery

With our surgical map rapidly gaining traction – today the Touch Surgery™ app is used by more than 300,000 surgeons – we were compelled to take things to the next level. To further our work to reduce surgical variability.

We began to use our surgical map to train computers, and suddenly we were on the cutting edge in surgical robotics. And the question became: what do we train the computer to do?

We came back to our focus – to create digital solutions that can solve problems that contribute to surgical variability – and the answers became clear.

In all of this, we cannot lose sight of the importance of simplicity. After all, the true potential of any technology is only fully realized when it is easy to use.

With that principle in mind, we set out to solve another problem for surgeons: making it easier to record, store, share and analyze surgical videos.

We took a cumbersome process and essentially made it effortless. A smart computer for the OR, the DS1 records surgical videos from an endoscope and stores them on the cloud, providing surgeons and hospitals secure access on mobile phones or computers.

What's novel and critically important is that the DS1 uses artificial intelligence to automatically anonymize any footage that could potentially include protected health information.

Add to that ability to generate analytics from the case – made possible by our Touch Surgery™ Enterprise software – and you have a powerful tool at your fingertips.

The robot is just the beginning

Now that we're part of the Surgical Robotics operating unit at Medtronic, we're incredibly excited to integrate data and analytics into our robotic-assisted surgery platform in development.

The robot provides an interface between surgeons and patients, with software that can augment the actions and decisions that a surgeon takes during an operation. While the opportunities seem limitless within robotics, it's important to note that data and analytics has applications in laparoscopic surgery today. And Medtronic is a leader in that space.

Now, at the intersection of surgical data, artificial intelligence, visualization and robotics, we're blazing new trails for this next big frontier in surgery, working to develop a robust pipeline of data and analytics solutions that will integrate with our robotic-assisted surgery platform and be available for use in laparoscopic surgery, too.

Ultimately, our vision is that data-based surgery can reduce variability and produce positive outcomes, predictably – for more patients around the world.

The bigger picture

If we can properly track a patient through their entire surgical journey from diagnosis to discharge – with data – we'll understand all the levers we can pull to improve outcomes and efficiency.

That will be one of the big keys to value-based models. And it has applications far beyond the OR. Indeed, we believe data and analytics has the potential to optimize the patient care continuum across all areas of care and care settings.

That's one of the many reasons we're incredibly excited to be part of Medtronic, to partner with teams across the business and have an even greater impact on health care globally.

Here's another big one: trust.

As with any technology that is integrated into patient care – whether used to treat the patient or not – there is a sacred trust that must be earned, nurtured and protected. We consider it both a great privilege and responsibility, and we take it seriously.

Medtronic doesn't just share that perspective; it's codified into the organizational DNA, through its Mission. And, we'd argue, that's why it's the world's leading medical technology, services and solutions company; because we have great people that make great products for a great purpose – to alleviate pain, restore health and extend life – and never lose sight of that.

Now, when you add pioneering data and analytics solutions and capabilities to a medical technology portfolio built over 60 years, the possibilities seem even greater. And we couldn't be more excited about that.

¹ Meara JG, Greenberg SLM. The Lancet Commission on Global Surgery Global surgery 2030: evidence and solutions for achieving health, welfare and economic development. *Surg.* 2015;157(5):834-835. doi: 10.1016/j.surg.2015.02.009.

² Birkmeyer JD, Finks JF, O'Reilly A, et al. Surgical skill and complication rates after bariatric surgery. *N Engl J Med.* 2013;369(15):1434-1442. doi: 10.1056/NEJMsa1300625.

³ Ibrahim AM, Ghaferi AA, Thumma JR, Dimick JB. Variation in outcomes at bariatric surgery centers of excellence. *JAMA Surg.* 2017;152(7):629-636. doi: 10.1001/jamasurg.2017.0542.

⁴ Swathikan Chidambaram, Simon Erridge, Daniel Leff, Sanjay Purkayastha. A randomized controlled trial of skills transfer: from touch surgery to laparoscopic cholecystectomy. *J Surg. Res.* 2019;234:217-223. doi: 10.1016/j.jss.2018.09.042.





Mark Benson

Vice President, Medical Devices
Supply Chain

Johnson & Johnson

Resiliency in times of crisis

At Johnson & Johnson, we have demonstrated resilience in maintaining business continuity throughout the global COVID-19 pandemic. Past challenges, such as Hurricane Maria in 2017, have taught us about the kinds of teamwork, capabilities and resource infrastructure needed to anticipate, mitigate and overcome potential major disruptions to our medical devices supply chain. There have been significant challenges in 2020, such as the high volatility in supply and demand planning due to fluctuations in elective surgeries. However, by sticking with proven, clearly defined sales and operations planning and financial processes, we have managed to keep our programs on track: around 85% of our new product innovations, for example, have seen no delays of any kind. We continued to meet dynamic customer and patient needs with high-quality products and services, while safeguarding the health and safety of our employees.

Throughout the crisis, we've stayed true to our Credo, which places the highest emphasis on protecting our people. Our efforts to protect our workforce went beyond validating that they had PPE and maintaining exemplary safety standards in our facilities, to offering complimentary telehealth and access to mental well-being training and webinars, among many other measures. In Juarez, Mexico, for example, we rolled out an additional private health insurance plan to our employees.

We have also been able to assist in the wider societal effort to combat the pandemic. Amid early concern about potential ventilator shortages, one company approached us with the IP and design for a product that splits airflow, allowing a ventilator to provide air to two or more patients at a time. Through collaboration with Prisma Health and Jabil, we were able to leverage the 3D manufacturing technology, which moved us from concept to launch in about 10 days. It was incredible to see what we were able to deliver.

Innovating the supply chain

Johnson & Johnson is in a unique position, with our businesses diversified across pharmaceuticals and consumer health as well as medical devices. Thus, our supply chain strategy was coordinated across the enterprise, enabling us to meet the challenges we faced this year. As one aspect of this strategy, we repurposed a project team to focus on maintaining business continuity and establishing the reliability of our supplier base.

We recognize that the near future will bring further macroeconomic and geopolitical pressures, and we may, for example, need to include more stockpiling or more local-sourcing (or dual-sourcing) elements in our supply chain planning in order to meet local governments' needs. Fortunately, by learning the lessons of 2020, we are also managing to accelerate our supply chain agenda in certain key areas.

We see significant opportunities in data and digital technologies, and the past year has allowed us to speed up the advance in these fields. For example, our salesforce did an incredible job at connecting with hospitals and supporting them, which has brought us closer to customer data around procedures and surgeries. This has really helped us strengthen our partnerships with hospitals, understand what they need and what is happening in the market, and improve our demand planning.

We've also accelerated our touchless supply chain concept, which focuses on understanding which procedures are scheduled and verifying that we send in the appropriate products for the specific procedure and the specific patient. With orthopedic surgery, for example, you need to send in a huge range of instruments. By identifying exactly what is needed, we can slim down that inventory, improve efficiency and speed up surgery.

Our touchless supply chain concept involves working out how to apply technology and digital enablement across the supply chain. We're accelerating investment in these areas, because doing the right thing for the customer in the long term means getting our supply chain operations right.

Future opportunities to evolve the business model

Ultimately, we need to keep our focus on the unmet needs and the transformational innovation that can really improve outcomes. We need to identify the newer technologies that can truly make a difference. But to get the maximum value, we don't just need the technologies; we also need to pursue supply chain innovation and business model innovation, and put all of these pieces together.

The robotics and digital surgery space is a perfect example. We've invested heavily in that space, but it isn't just a question of putting the right equipment out there. You have to build a strong and credible support infrastructure around the equipment. Take our VELYS Digital Surgery system, which will be a platform of connected technologies intended to elevate the orthopedic surgery experience. Yes, the robotic-assisted solution is important, but the intelligent system will include technology that spans the entire care continuum and relies on data and learning to inform operative decisions before, during and after surgery. Therefore, we have an opportunity to offer an enhanced customer and patient solution, linking it back to the supply chain, with the data and the predictive analytics that help plan each step of the surgical approach. If you can join these pieces together, it becomes almost a new business model, offering a wide breadth of possibilities to innovate how you support the doctors and the patients in the surgeries.

There are many elements to bring together, but we have shown in the past year that our core processes are strong enough to meet these challenges. By continuing to enable collaboration across the enterprise, aligning on our approach to investments and trade-offs, mobilizing the organization to "fail forward" and maintaining our focus on new market opportunities, we are confident we can continue to deliver for our customers long after the disruptions of 2020 are in the past.



Nicholas Galakatos

Global Head of Life Sciences
Blackstone

Funding life-saving medtech innovation

At Blackstone Life Sciences (Blackstone), we remain committed to helping bring novel medical devices and therapies to patients in need of new innovations and treatments. The fundamental problem that we're trying to solve in the life sciences is there are many more products in late-stage development than there is capital available to fund them.

The late-stage development of a product is the most expensive phase of development, with average costs ranging from US\$100 million to over US\$500 million. Private capital is playing a critical role by helping advance and develop products and medicines that otherwise may not have been adequately funded.

Partnering to drive innovation in chronic disease treatments

There is a high demand for new therapies and products in areas such as oncology and cardiovascular disease, two of the leading causes of death in the United States and in the world. With innovation continuing at a rapid pace, and the cost of product development growing, there are many more innovative products in need of funding than there is available capital.

New innovations such as genomics, gene therapies, RNA interference (RNAi) therapeutics and big data will impact this investment landscape. For example, companies such as Anylam and Novartis are pioneering new, innovative medicines like inclisiran, an innovative, twice-a-year, subcutaneously injected RNAi therapeutic. If approved, inclisiran is expected to help patients lower LDL cholesterol, which is a major risk factor for cardiovascular disease, the single biggest global cause of mortality.

More broadly, however, the US and global population is aging, so that megatrend will have an increasing impact on our world, the medical technology industry and the overall investment landscape. As people continue to take a more active role in their care, as well as the care of loved ones, medical technologies that enable simplicity and greater ease of use – while providing better outcomes for patients – will be compelling areas of development.

Our partnership with Medtronic (announced in June 2020), for example, was conceived to enable the development of important diabetes products that otherwise may not have been funded. The strategic imperatives of this collaboration reflect Blackstone's previous experience with the many pharmaceutical and biotechnology companies with whom we partnered during the past decade. We expect that this strategic partnership model will flourish in medtech, and our pioneering deal with Medtronic will be replicated to bring more important products to the patients who need them.

The rise of remote health care during the COVID-19 pandemic, and the opportunities for medtech

The COVID-19 pandemic has reshaped many long-term considerations in health care, including where care is provided, who is providing it and what role medical technology plays. Better implantable devices that last longer and require fewer follow-up visits will be increasingly important, as will diagnostics and monitoring technologies that provide greater accuracy and real-time data for patients and caregivers.

Patients are also participating more in managing their health care through an increasing number of distributed platforms. Telemedicine and online platforms are gaining momentum as many individuals prefer the ease and privacy of these modalities.

Point-of-care and low-cost home diagnostics are enabling the trend toward remote delivery of care, as patients can generate their own high-quality diagnostic data (ranging from blood pressure readings to saliva tests) without visiting a physical office. Greater patient fluency with data, including patient-generated statistics (ranging from data generated by medical devices to genetic data captured via increasingly widespread genetic testing), is also an important factor. Patients continue to take an active role in monitoring their health minute by minute through implantable and wearable devices. This data should result in better outcomes for patients and greater understanding of the pathophysiology of human disease.

Of course, we continue to see consumer habits redefining health care practices: the expectation is that medical technology should increasingly integrate seamlessly with mobile devices to provide faster detection, better-quality data and improved long-term outcomes. We see an expanded role for medical technology in all aspects of the trends accelerated by the COVID-19 pandemic.

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Private capital is playing a critical role by helping advance and develop products and medicines that otherwise may not have been adequately funded.



Aloha McBride

EY Global Health Leader

Accelerating the hyperconnected smart health system by seamlessly integrating physical and virtual care

The future of health is changing rapidly as health systems move beyond digital, beyond connected, to embracing an intelligent, smart health ecosystem.

EY teams see that technology-enabled innovation is accelerating and is giving rise to the care models of tomorrow – many of which are imaginable today. Technologies that enable, automate and engage consumers differently make possible a suite of new health solutions around well-being, remote care, smart homes and communities. Health care is shifting to bring care to the patient, rather than the patient to care, and this applies whether the person is at home, in the hospital or anywhere in between.

Interconnecting people, the environment and infrastructure as a unified intelligent, data optimized system of care is the point where health becomes smart. This opens up a realm of possibilities as health heads into the space where the virtual and the physical worlds converge. Moreover, as integrated care platforms incorporate social determinant, sensor and wearable data along with patient health information into algorithms, a personalized, smart care experience is possible. This is an important shift, because in the wider environment the world is fast becoming smart – smart cities, cars, utilities and homes leverage the internet of things, data and intelligent connected systems to enable economic, social and environmental sustainability.

Smarter health systems create extensive and integrated ecosystems that support improvements in consumer and workforce experiences, better care outcomes and greater access to health care services. Health systems can increase productivity and efficiency, provide better care to more people and eventually proactively manage population health.

As we discuss in our newly released research paper, across the globe, COVID-19 has exposed health systems' reliance on in-person care delivery. The pandemic has driven the health industry to the tipping point of digital transformation. In meeting an immediate need due to COVID-19 by rapidly standing up digital services, the health industry has in fact created the foundations of a digital and smart system. The lessons learned from the COVID-19 pandemic make the transition to smart a more urgent priority than it may have been, even just a short time ago.

One silver lining of the pandemic is that around the world, health systems have taken a significant step toward delivering a more integrated, seamless and smarter health care experience. It has challenged preconceived notions of how health care needs to be delivered and has eliminated existing barriers to digital health adoption. Health systems and physicians have learned how to successfully deliver remote care, and they intend to do so in the future as an integral part of their service mix. Consumers have seen firsthand how health technologies can simplify, enhance and personalize their care experiences, and they will increasingly demand such care in the future.

The medtech industry has a significant role to play as health care becomes further decentralized and virtual care consolidates as a core service in a digital-first delivery model.

- ▶ Smart, pervasive health systems arise through a distributed network of hyperconnected interoperable devices and technologies – wearables, mobile monitoring, human activity recognition and non-contact monitoring of chronic health conditions are but a few areas of strength.

- ▶ Telehealth and telemedicine, triage tools and symptom checkers are key to the rearrangement of the production function of health care. Self-management of disease, a dynamic connected ecosystem for safer medication management, and nudging consumer and physician behavior change all address some of the root causes of low consumer engagement, adherence to treatment and workflow challenges.
- ▶ AI and natural language processing analytics will support the sheer volume and complexity of heterogeneous health data that is central to the new integrated data environment.

It is abundantly clear that the future of health is smart and that advances in smart technology, smart algorithms and smarter care models will shape the way that care is delivered and experienced. This new frontier enables us to deliver the right insights to the right people at the right time. And this leads to smarter, better informed and more cost-effective care for providers and consumers.

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It is abundantly clear that the future of health is smart and that advances in smart technology, smart algorithms and smarter care models will shape the way that care is delivered and experienced.

Databook





Financial performance

Medical technology at a glance

(US\$b, data for pure-play companies except where indicated)

Public company data	2019	2018	Change	% change
Revenues	\$429.8	\$404.3	\$25.5	6%
▸ Conglomerates	\$167.6	\$165.9	\$1.6	1%
▸ Pure-play companies	\$262.2	\$238.4	\$23.9	10%
▸ Commercial leaders	\$243.5	\$220.8	\$22.7	10%
▸ Noncommercial leaders	\$18.7	\$17.6	\$1.2	7%
R&D expense	\$21.2	\$19.0	\$2.2	12%
Net income	\$28.5	\$20.5	\$8.0	39%
Market capitalization	\$1,399.4	\$1,045.2	\$354.2	34%
Number of employees	912,300	838,900	73,400	9%
Number of public companies	440	441	(1)	-0.2%

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

Numbers may appear to be inconsistent due to rounding.

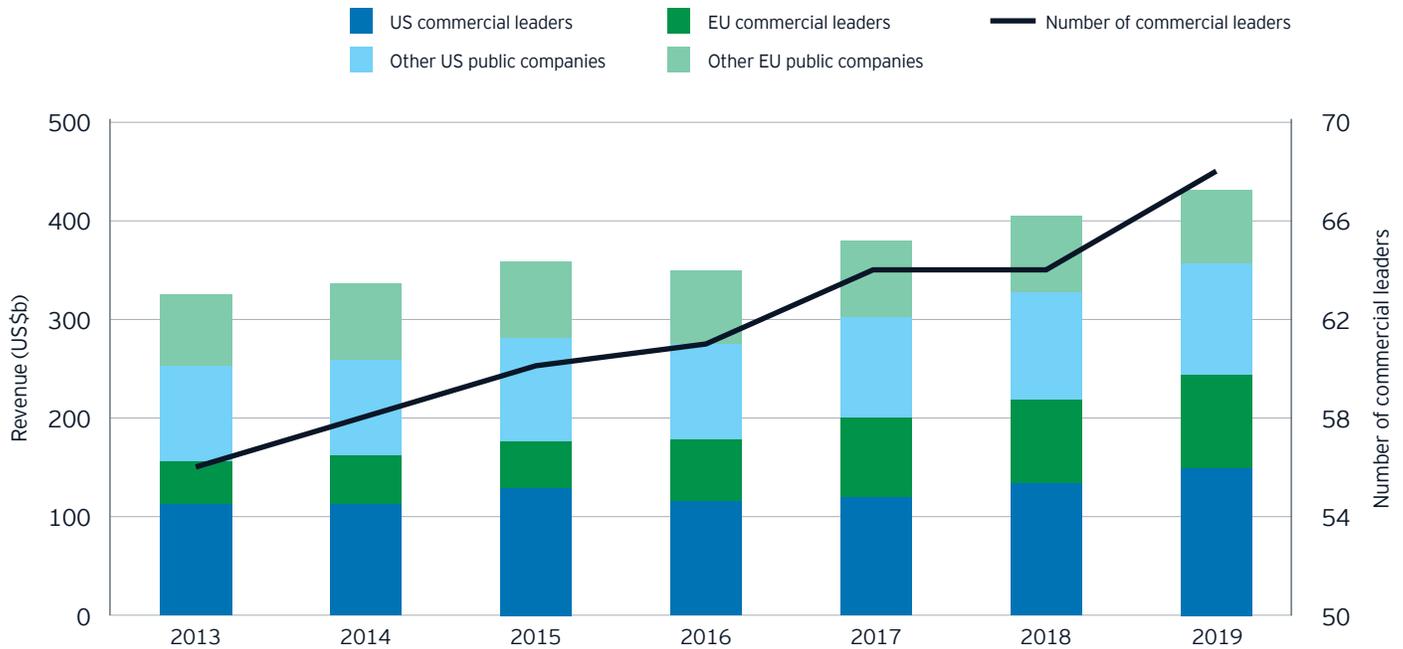
Data shown for US and European public companies.

Market capitalization data is shown for 31 December 2019 and 31 December 2018.

- Overall industry revenue growth slightly dropped to 6.3% in 2019 from 6.7% in 2018. Across all pure-play companies, revenues were up 10.0% (vs. 9.1% the previous year).
- Conglomerates' revenue growth dropped from 3.3% to 1.0% between 2018 and 2019. This was largely the result of Novartis spinning out its Alcon division, and the largest conglomerate (and third-largest player overall), Johnson & Johnson's Medical Devices & Diagnostics business, experiencing a 3.8% decrease in sales to US\$26.0 billion.
- Noncommercial leaders saw 6.6% growth, up from 3.7% the previous year, but only 65% of these companies overall grew their top line.
- As in previous years, commercial leaders were at the forefront, with revenue growth at 10.3% (up marginally from 9.6% the prior year). In all, 91% of commercial leaders grew their top lines in 2019 – 10 of them by more than 15%.
- Across the industry, cumulative bottom lines grew even bigger in 2019 compared to 2018 (39% vs. 28%). US\$5.9 billion of this US\$8 billion increase in net income came from just three companies (Boston Scientific, Zimmer Biomet and Bio-Rad) – and was mostly driven by accounting charges, credits and other adjustments (similar to 2018). In all, 61% of commercial leaders and 47% of noncommercial leaders saw improved profits.
- The 11.5% growth in R&D surpassed 8.1% the previous year, with 59% of companies increasing R&D investment (including 73% of commercial leaders).
- The industry increased its employee headcount by 8.7%, after a 6.5% drop the previous year, with 76% of noncommercial leaders and 85% of commercial leaders adding or maintaining employee numbers.

Commercial leaders welcomed five new additions

US and EU medtech public company revenues



Source: EY and Capital IQ.

Commercial leaders are companies with revenues \geq US\$500m.

- ▶ US public medtech companies accounted for 62% of the industry's total size, with revenues rising 8.1% (their fourth consecutive year of growth) to US\$266.3 billion, in spite of a cumulative 1.6% foreign exchange rates negative impact across the 10 largest pure-plays.
- ▶ European public companies recorded a 3.6% revenue rise, to US\$163.5 billion.
- ▶ Overall, pure-play commercial leaders continue to account for a majority (56%) of total industry revenue. The cumulative revenues for the commercial leaders grew 56% between 2013 and 2019, compared to 12% growth for all other companies.
- ▶ There were 68 commercial leaders in 2019, with five additions since 2018, including:
 - ▶ Envista Holdings: Dental spinout from Danaher, with revenues of US\$2.8 billion
 - ▶ Alcon: US\$7.5 billion-revenue ophthalmic spinout from Novartis
 - ▶ SmileDirectClub: Staged medtech's largest IPO in 2019 and commands US\$750 million in revenues
 - ▶ Penumbra: Neurovascular devices player that crossed the commercial leader threshold with 23% organic growth, bringing its annual revenues to US\$547 million.
 - ▶ Natus Medical: Disappeared from the group as its revenues fell below US\$500 million
- ▶ Exact Sciences: Grew its revenues 93% (to US\$876 million), largely as a result of doubling the use of its Pfizer-partnered Cologuard at-home colon cancer tests to 1.7 million

Dexcom and ResMed joined the list of biggest market movers

Top 10 changes in pure-play market capitalizations, H2 2015-H1 2020 (US\$b)

Company	Market cap as of 30 June 2020	Market cap as of 1 July 2015	Market cap change	CAGR
Thermo Fisher Scientific	143.1	52.1	91.0	22%
Intuitive Surgical	66.4	17.9	48.5	30%
Becton Dickinson and Company	70.8	30.0	40.8	19%
Stryker	67.6	36.4	31.3	13%
Dexcom	37.4	6.3	31.1	43%
Edwards Lifesciences	42.8	15.4	27.4	23%
Boston Scientific	50.0	23.9	26.2	16%
Illumina	54.4	31.8	22.6	11%
IDEXX Laboratories	28.0	5.9	22.1	37%
ResMed	27.8	7.8	20.0	29%

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

CAGR = compound annual growth rate.

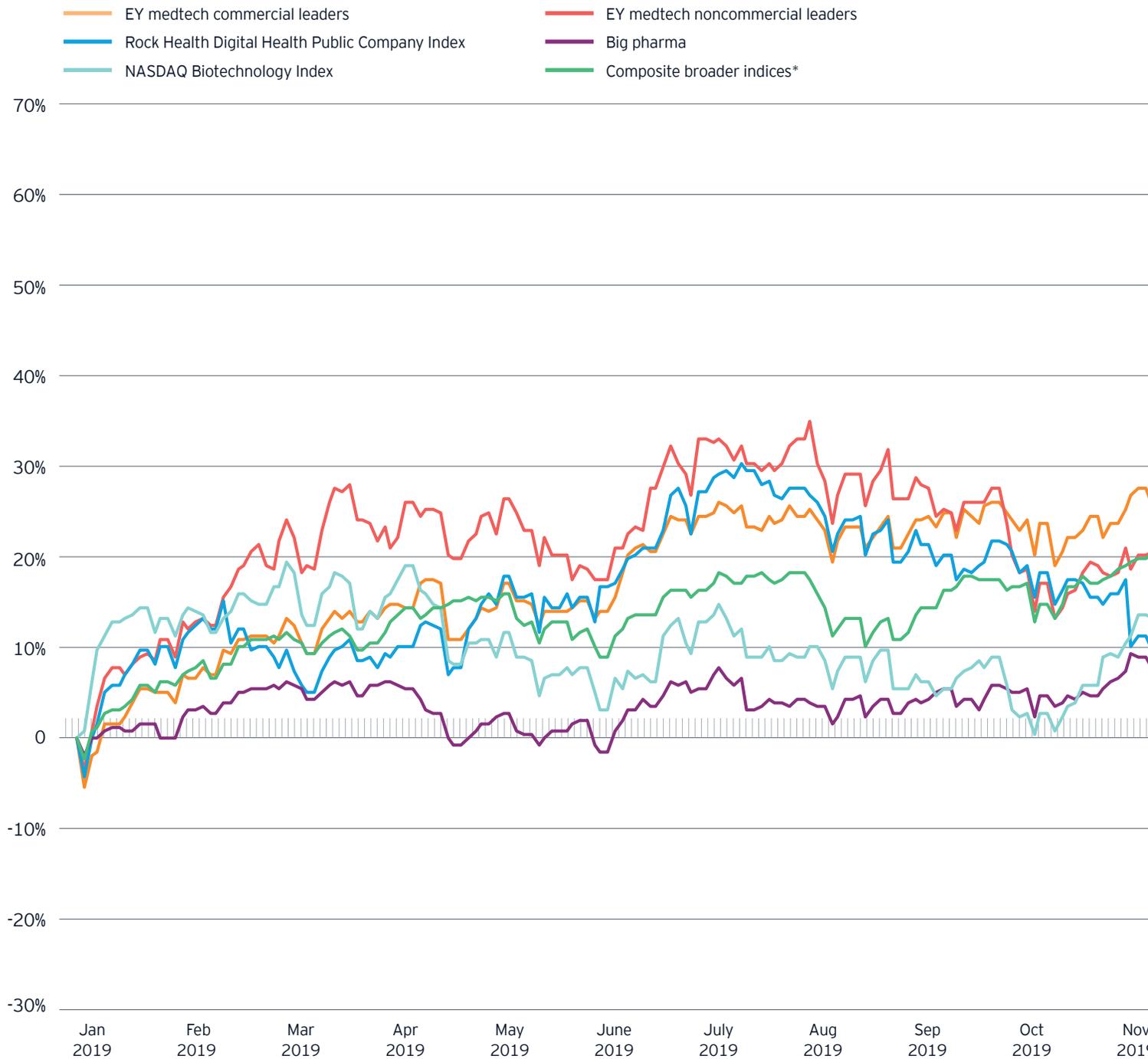
- ▶ Thermo Fisher Scientific saw the largest five-year increase in its public valuation, driven largely by a series of acquisitions (including Patheon in 2017 and FEI in 2016) to bolster its strong organic growth; however, its planned acquisition of Qiagen, announced in March 2020, fell through this year. Becton Dickinson (which acquired C.R. Bard in 2017) is the only other company among the biggest market-cap movers to have boosted its valuation primarily through M&A.
- ▶ Stryker has largely grown through smaller acquisitions and organic means; its proposed US\$5.4 billion acquisition of fellow orthopedic company, Wright Medical (announced in November 2019, but still awaiting regulatory approval) will be its largest deal in at least the past decade.
- ▶ Companies joining the list of biggest movers include ResMed, a San Diego-based provider of cloud-connectable devices treating respiratory conditions, including sleep apnea and chronic obstructive pulmonary disease, and

Dexcom, which has seen its market cap hit US\$37.4 billion. Dexcom's G6 continuous glucose monitoring system has driven its stock sevenfold higher in the roughly two years since its launch.

- ▶ IDEXX Laboratories, which offers a broad range of animal health diagnostic and information technology-based products and services, also joins the biggest movers. IDEXX is one of many diagnostics firms soaring in value: Quidel, for example, has seen its stock rise 331% with the FDA issuing an EUA for its Lyra SARS-CoV-2 Assay rapid point-of-care test two days after the World Health Organization officially declared COVID-19 a pandemic.
- ▶ In all, diagnostic company valuations have risen 116% between January 2019 and August 2020, far outperforming the other segments of the medtech industry: research and other equipment valuations rose by 67%, therapeutic devices by 40% and imaging by 13%.

Medtech outperformed the broader indices

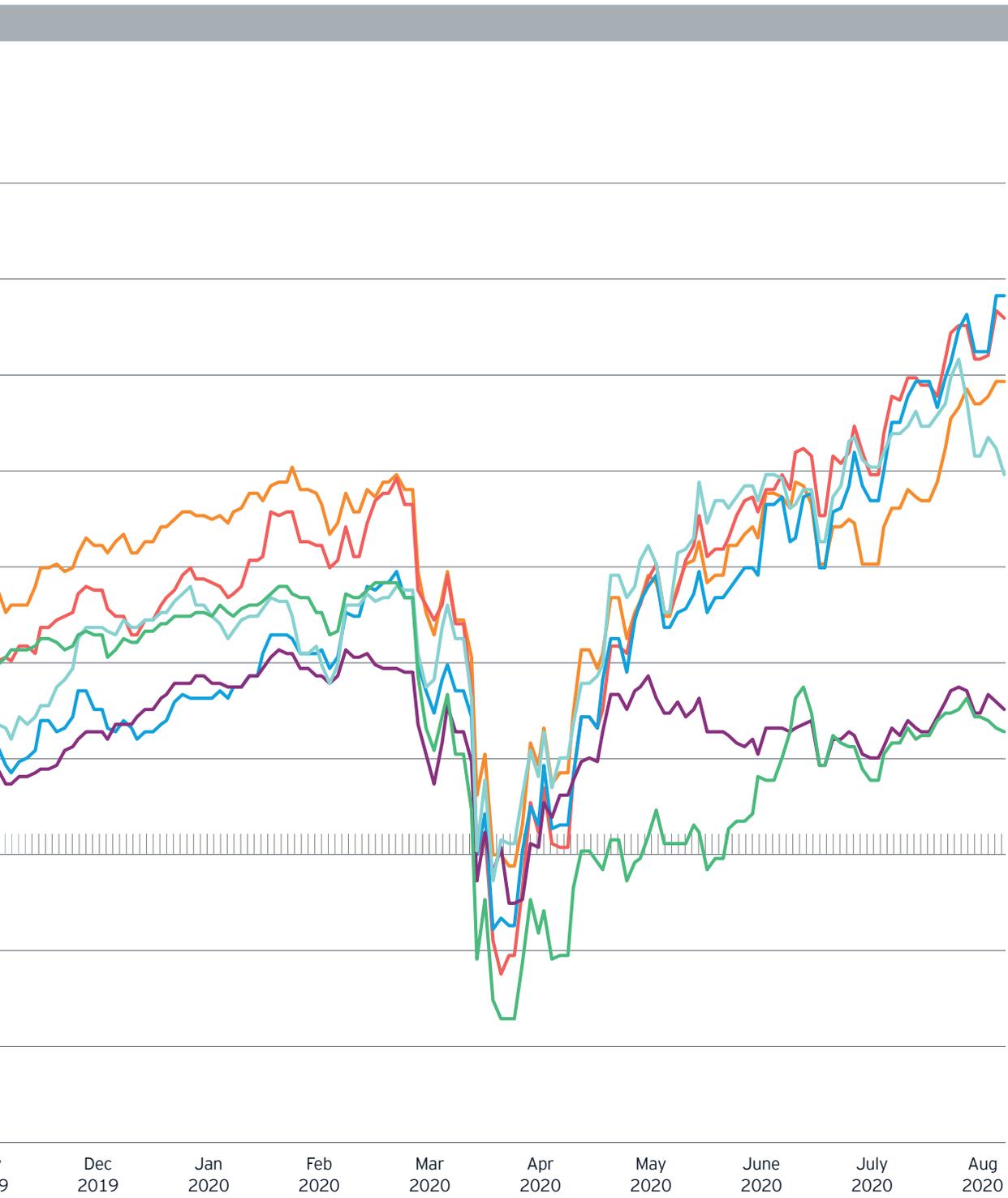
US and European medtech market capitalization relative to leading indices



Source: EY and Capital IQ.

Charts include companies that were active on 22 March 2020.

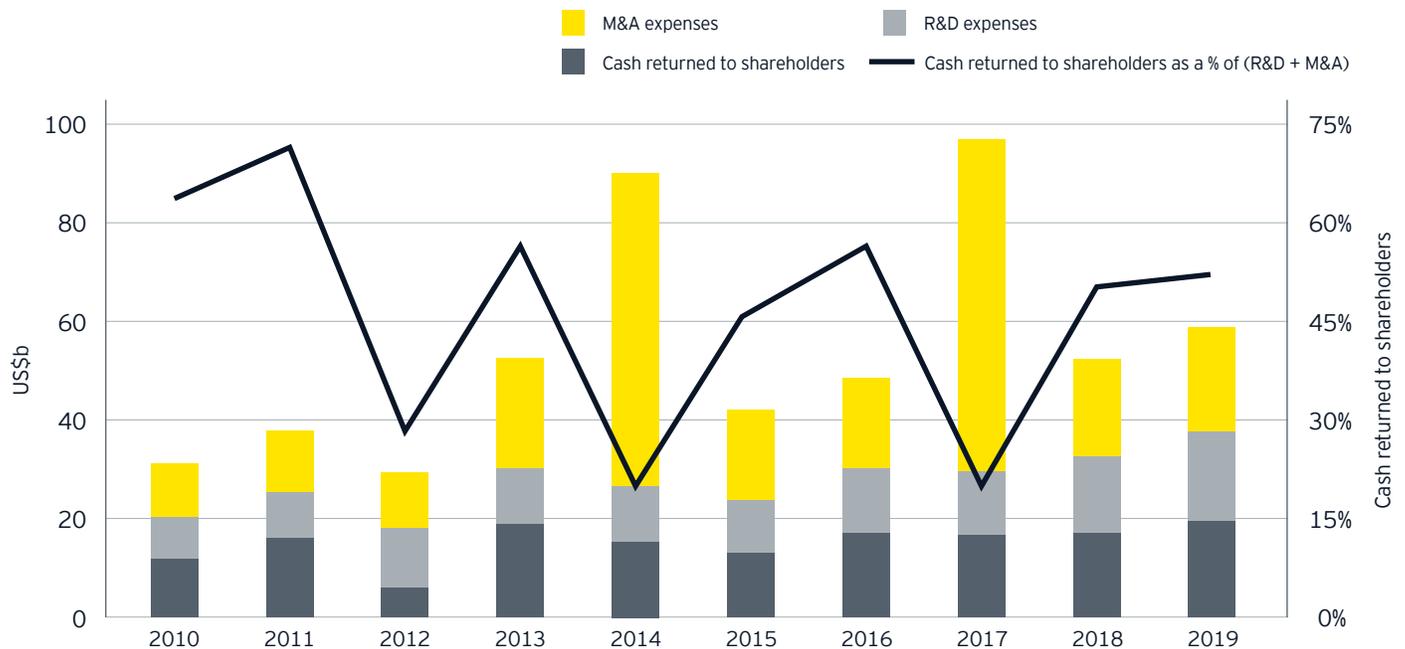
*Composite broader indices refers to the daily average of leading US and European indices: Russell 3000, Dow Jones Industrial Average, NYSE, S&P 500, CAC -40, DAX and FTSE 100.





Capital allocation

Cash returned to shareholders rises once again

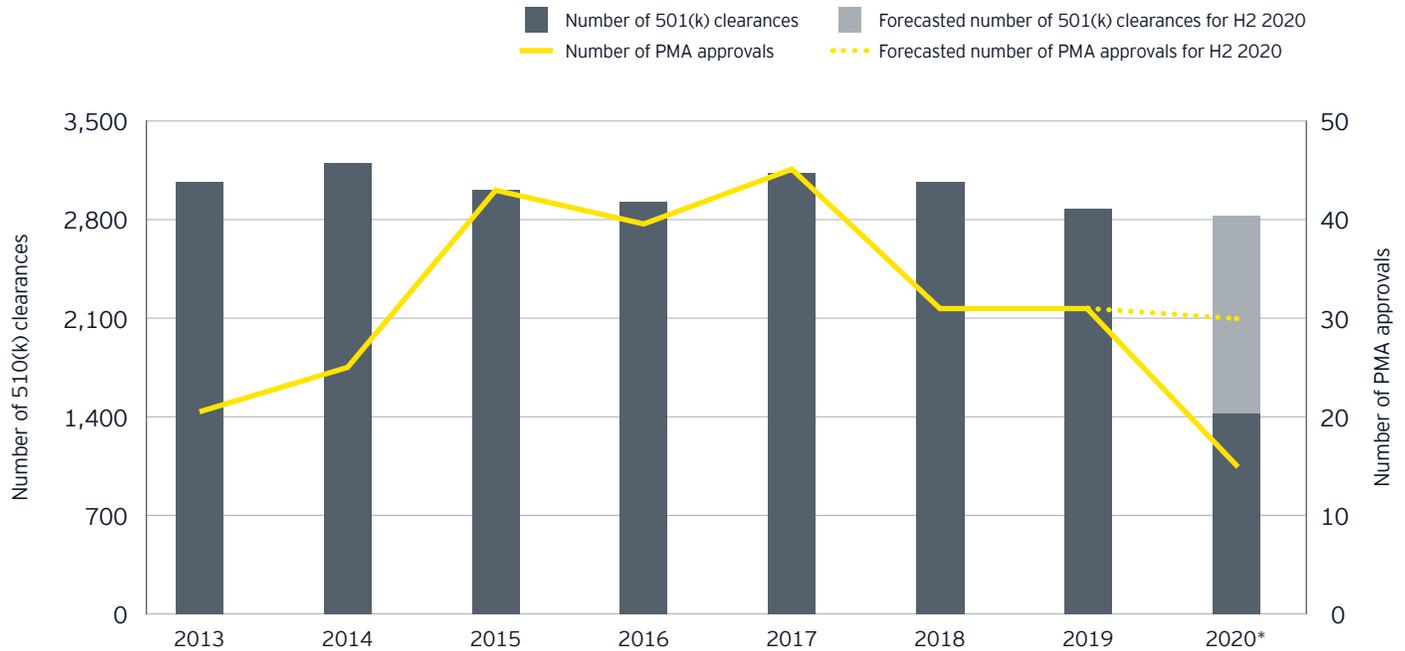


Source: EY, Capital IQ and company financial statement data.

- ▶ While R&D spending rose to a 10-year high of US\$17.8 billion (compared to the previous 10-year average of US\$11.4 billion) in 2019, commercial leaders increased the percentage of their cash returned to stakeholders for the second year in a row.
- ▶ Stock buybacks and dividends equaled 51% of the total invested in growth activities (i.e., for every US\$2 spent on R&D or M&A, more than US\$1 was returned to shareholders) over the period. Though the US\$19.6 billion going back to shareholders was a record, it was roughly in line with the previous 10-year average of 48%.
- ▶ Of the 10 largest medtechs, 8 offered stock buybacks or paid dividends. Market leader Medtronic returned US\$4.2 billion, compared to US\$2.4 billion invested in R&D, with second-ranked Thermo Fisher Scientific returning US\$1.8 billion (and spending US\$1.0 billion on R&D). However, 6 of the other top 10 companies did spend more on R&D than they returned to shareholders.

New device approvals

U.S. Food and Drug Administration medical device approvals



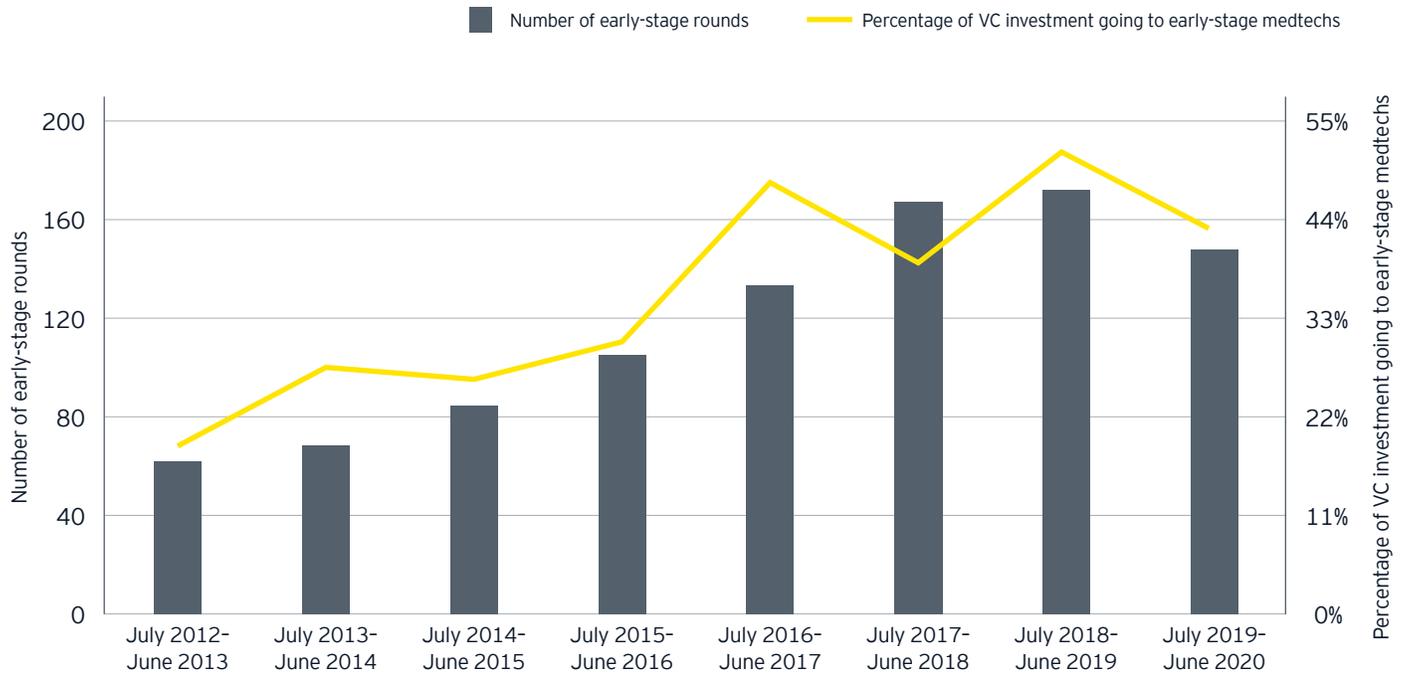
*Data through June 2020 for 510 (k) clearances and approvals.

Source: EY, Dow Jones VentureSource and Capital IQ.

- ▶ At the end of the first half of 2020, the industry was on course to achieve approximately the same number of pre-market approvals and 510(k) clearances as in 2019.
- ▶ Both pre-market approvals and 510(k) figures have shown only slight (negative) change between 2018 and 2020, suggesting a stable level of innovation and new product launches within the industry.
- ▶ If the industry maintains this rate in 2020, this will indicate that the FDA’s reviewing processes have not been negatively affected by the pandemic (concerns were raised about whether stretched regulatory capacity could cause delays this year).
- ▶ It should also be noted that the figures do not take account of the large number of emergency use authorizations issued by the regulator in 2020 to address urgent COVID-19-related needs (see Figure 12 in the report and accompanying discussion).

COVID-19 negatively impacted early-stage VC funding

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



Source: EY, Dow Jones VentureSource and Capital IQ.

Early-stage rounds are seed-, first- and second-round VC investments.

- ▶ The US\$6.6 billion raised in VC financing was the lowest since 2015 and 2016, following three consecutive years of record VC investment. A slowdown in VC funding was evident in Q2 2020 - as of now, it remains to be seen if this is a transient impact of COVID-19 or a more durable downturn resulting from the pandemic.
- ▶ Just 43% of all VC dollars (US\$2.9 billion) went toward early-stage companies, down from US\$4.4 billion (52% of the total) the previous year.

Digital platform and diagnostic companies were among top venture targets

Top US and European venture rounds, July 2019-June 2020

Company	Region	Product type (disease)	Gross raised (US\$m)	Quarter	Round type
CMR Surgical	United Kingdom	Therapeutic devices (non-disease-specific)	240	Q3 2019	Late stage
Karius	US - Northern California	Non-imaging diagnostics	165	Q1 2020	Early stage
Freenome	US - Northern California	Non-imaging diagnostics	160	Q3 2019	Early stage
INSIGHTEC	Israel	Therapeutic devices (multiple)	150	Q1 2020	Late stage
Element Science	US - Northern California	Therapeutic devices (cardiovascular/vascular)	146	Q1 2020	Late stage
Outset Medical	US - Northern California	Therapeutic devices (renal)	125	Q1 2020	Late stage
Vayyar Imaging	Israel	Therapeutic devices (ophthalmic)	109	Q4 2019	Late stage
RefleXion Medical	US - Northern California	Therapeutic devices (oncology)	100	Q2 2020	Late stage
GenapSys	US - Northern California	Research and other equipment	90	Q4 2019	Late stage
Laboratory for Advanced Medicine	US - Southern California	Non-imaging diagnostics	86	Q4 2019	Early stage
Sonendo	US - Southern California	Therapeutic devices (dental)	85	Q1 2020	Late stage
Imperative Care	US - Northern California	Therapeutic devices (neurology)	85	Q4 2019	Late stage
Rodenstock	Germany	Therapeutic devices (ophthalmic)	84	Q2 2020	Early stage
Pulmonx	US - Northern California	Therapeutic devices (respiratory)	83	Q2 2020	Late stage
Zap Surgical Systems	US - Northern California	Therapeutic devices (oncology)	81	Q1 2020	Early stage
Impulse Dynamics	US - New Jersey	Therapeutic devices (cardiovascular/vascular)	80	Q4 2019	Late stage

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

- ▶ CMR Surgical, which won a CE mark for its Versius surgical robotic system in March 2020, achieved European medtech's largest-ever private financing round, and the largest of the July 2019 to June 2020 period overall. The investment attention on CMR Surgical follows the significant M&A activity in the surgical robotic space last year.
- ▶ Non-imaging diagnostic companies were also prominent among the biggest funding rounds. Karius, which uses AI and genomics to identify traces of infectious pathogen DNA in blood samples, raised US\$165 million. Vision Fund 2, Japanese conglomerate Softbank's second technology-focused VC megafund, was the leading backer.
- ▶ Freenome, also combining blood testing and machine learning (in this case, with the aim of early cancer detection), recorded the third-largest round, with backers including Google Ventures, Verily Life Science and oncology pharma leader Roche. Laboratory for Advanced Medicine, another AI/blood-test company targeting early cancer detection, was also among the top 10 funding rounds.
- ▶ The emphasis on new digital platforms and diagnostics saw therapeutic devices taking a back seat. Nevertheless, Israel's Insightec generated US\$150 million for its ultrasound system for treating Parkinson's disease essential tremor, and Element Science's cardioverter defibrillator technology was also prominent, with Google again investing.



The top three IPOs accounted for 85% of all funding

US and European IPOs, July 2019–June 2020

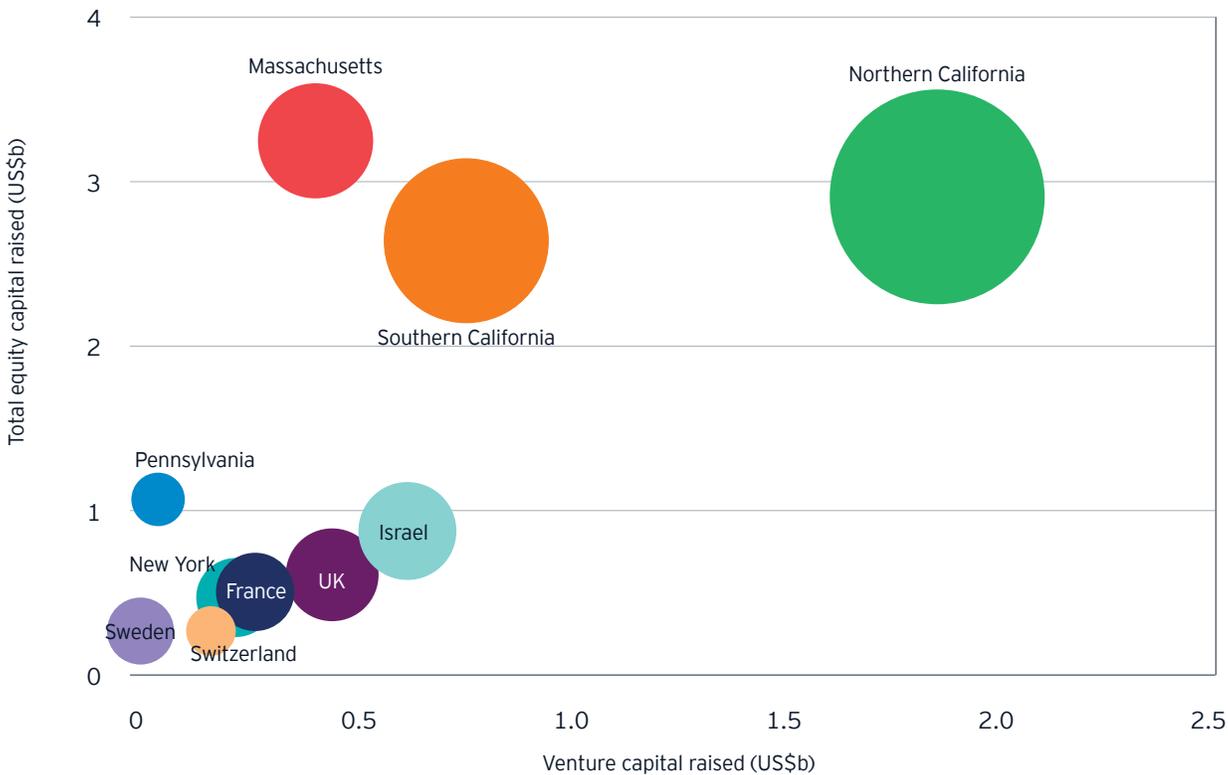
Company	Ticker	Region	Product type (disease)	Gross raised (US\$m)	Quarter
SmileDirectClub	SDC	US - Tennessee	Therapeutic devices (dental)	1,346	Q3 2019
Envista Holdings	NVST	US - Southern California	Therapeutic devices (dental)	677	Q3 2019
GVS	GVS	Italy	Therapeutic devices (respiratory)	642	Q2 2020
Inari Medical	NARI	US - Southern California	Therapeutic devices (cardiovascular/vascular)	179	Q2 2020
InMode	INMD	Israel	Therapeutic devices (aesthetics)	77	Q3 2019
Castle Biosciences	CSTL	US - Texas	Non-imaging diagnostics	74	Q3 2019
Exagen	XGN	US - Southern California	Non-imaging diagnostics	58	Q3 2019
TELA Bio	TELA	US - Pennsylvania	Therapeutic devices (wound care)	52	Q4 2019
Optomed	OPTOMED	Finland	Imaging	35	Q4 2019
Inspecs Group	SPEC	United Kingdom	Therapeutic devices (ophthalmic)	29	Q1 2020
Imricor Medical Systems	IMR	US - Minnesota	Therapeutic devices (cardiovascular/vascular)	8	Q3 2019
Qlife Holding AB	QLIFE	Sweden	Non-imaging diagnostics	5	Q1 2020
Monivent AB	MONI	Sweden	Therapeutic devices (respiratory)	2	Q1 2020
Carbiotix AB	CRBX	Sweden	Non-imaging diagnostics	1	Q4 2019

Source: EY, BMO Capital Markets and Capital IQ.

- ▶ The total of 14 IPOs between July 2019 and June 2020 was the lowest in any 12-month period since the 2009 to 2010 period; the cumulative total raised, US\$3.2 billion, was lower than the previous two years' totals, but still well above any other year since before the financial crisis.
- ▶ The 14 IPOs were equally divided between the US and Europe. However, the seven US IPOs generated US\$2.4 billion, compared to US\$792 million for the seven European offers.
- ▶ The two largest IPOs were executed by dental companies, SmileDirectClub and Envista Holdings. SmileDirectClub, which generated 42% of the year's IPO total itself, is focused on disrupting the traditional dental industry with its teledentistry offering, while Envista is a Danaher spinout that already holds a significant share in the implants, orthodontics and digital imaging markets.
- ▶ Alongside GVS, which manufactures biohazard masks and filter components for ventilators and has thrived during the pandemic, the dental companies accounted for US\$2.7 billion of the IPO total. Only two IPOs were executed in Q2 2020, with GVS' maneuver so far an exception in the market.
- ▶ Yet again, non-imaging diagnostic companies were prominent in this area of the market, with four going public. Among these were Castle Biosciences, which manufactures the DecisionDx test for personalized genomic information in an oncology (melanoma) setting.

California was once again the epicenter of medtech funding

Capital raised by leading US and European regions excluding debt, July 2019–June 2020



Size of each circle shows relative number of financings per region.

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

- ▶ The US remains dominant within venture funding, generating 71% of the total VC fundraising. This compares to a US share of 88% (US\$50.4 billion) in total non-debt medtech financing, with the US providing 94% of the debt financing, 85% of the follow-on financing and 75% of the IPO dollars.
- ▶ Europe contributed US\$6.8 billion in total toward medtech financing in the past year. Israeli medtech companies generated an impressive overall US\$622 million in VC financing, while UK-based companies brought in US\$456 million in VC and US\$639 million in total.
- ▶ Within the US, California dominated in terms of both equity capital raised (US\$5.7 billion), and VC raised (US\$2.6 billion). Northern California accounted for US\$3.0 billion of the equity and was also the leading source of VC financing, with US\$1.8 billion raised; Southern California, generating US\$755 million, was the second-largest VC financing source.
- ▶ Massachusetts-based medtech companies raised the biggest equity total (US\$3.3 billion), but only the fifth-largest VC total (US\$416 million).

Stryker was active in the market for transactions

Select US and European M&As, July 2019-June 2020

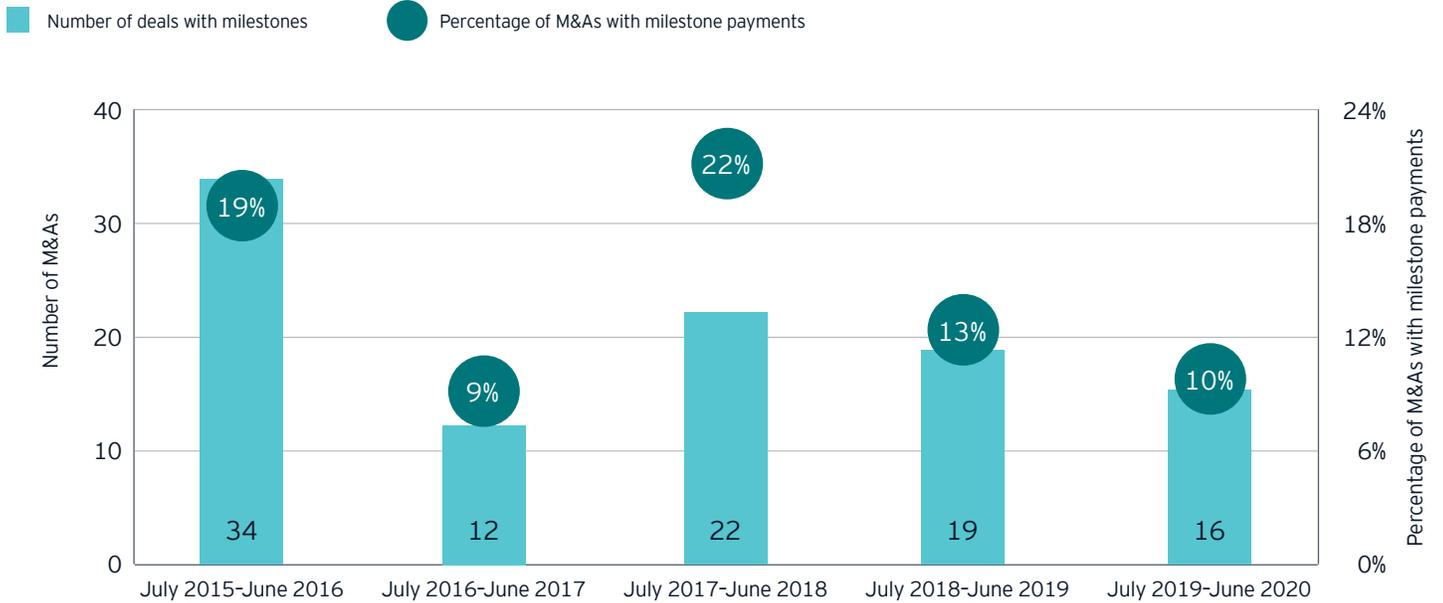
Acquiring company	Location	Acquired company	Location	Value (US\$m)	Buyer's deal driver
Stryker	US - Michigan	Wright Medical Group	Netherlands	5,400	Build scale (orthopedic)
Exact Sciences	US - Wisconsin	Genomic Health	US - California	2,800	Build scale (non-imaging diagnostics)
Baring Private Equity Asia	Hong Kong	Lumenis	Israel	1,200	Diversification (aesthetics)
Agilent Technologies	US - California	BioTek Instruments	US - Vermont	1,170	Build scale (research and other equipment)
Siemens Medical Solutions USA	US - Pennsylvania	Corindus Vascular Robotics	US - Massachusetts	1,100	Diversification (robotics)
AMETEK	US - Pennsylvania	Roper Technologies (Gatan division)	US - California	925	Build scale (research and other equipment)
Cantel Medical	US - New Jersey	Hu-Friedy	US - Illinois	775	Build scale (dental)
Sartorius	Germany	Danaher (FortéBio and SoloHill businesses)	US - District of Columbia	750	Build scale (research and other equipment)
Recipharm Holdings	UK	Consort Medical	UK	652	Build scale (respiratory)
Altaris Capital Partners	US - New York	3M (Kindeva Drug Delivery)	US - Minnesota	650	Diversification (drug delivery)
Zambon	Italy	Breath Therapeutics	Germany	559	Build scale (respiratory)
Laborie Medical Technologies	Canada	Clinical Innovations	US - Utah	525	Build scale (women's health)
Stryker	US - Michigan	Mobius Imaging/ GYS Tech	US - Massachusetts	500	Build scale (imaging/robotics)
Glaukos	US - California	Avedro	US - Massachusetts	500	Build scale (ophthalmic)
Lantheus Holdings	US - Massachusetts	Progenics Pharmaceuticals	US - New York	500	Diversification (biopharma)

Source: EY, Capital IQ and Thomson ONE.

- ▶ While the total number of announced M&As over US\$10 million jumped 12% in the July 2019 to June 2020 period compared to the previous 12 months (163 deals vs. 146), every other indicator slid significantly, with the total value of M&A activity dropping from US\$67.6 billion to US\$27.1 billion, and average deal size down 49% from US\$463 million to US\$167 million.
- ▶ The total could slump further if the Stryker acquisition of Wright Medical fails to close; the deal was announced in November 2019, but as of late August 2020 it remains pending and faces regulatory issues in the UK (where concerns linger about the fact that the deal will give Stryker 90% of the total ankle replacement prostheses market).
- ▶ Stryker was the most active among the top medtech companies, with three acquisitions (two among the year's highest-value deals). The Wright deal will place Stryker among the market leaders in implants for the treatment of bone fractures as well as joint replacements. Meanwhile, its acquisition of Mobius Imaging and its sister company, GYS Tech, doubles down on the early US\$1.68 billion bet Stryker put on the robotic surgical market when it acquired Mako Surgical in 2013.
- ▶ By contrast, many traditional acquirers, such as Abbott, Becton Dickinson, GE and Johnson & Johnson, made no significant M&A deals, and Medtronic made a single acquisition for US\$30 million (AV Medical). This reflects the fact that the traditional, therapeutic device market presently seems less dynamic than other medtech segments.
- ▶ Non-imaging diagnostics plays were, again, at the forefront in the M&A space. Exact Sciences' acquisition of Genomic Health (which closed in November 2019) will allow it to combine its colorectal cancer testing with Genomic Health's Oncotype DX gene expression tests, adding scope and scale, with the combined company operating in 90 countries.
- ▶ The value of M&A also fell sharply in the second half of the year compared to the first half, suggesting a negative impact from the COVID-19 pandemic, which is partly disguised in the full-year figures. In the second half of 2019, medtech closed 69 M&A deals worth US\$22.2 billion. In the first half of 2020, the number of deals was down slightly at 65, but the value of the deals fell precipitously, to US\$5.1 billion.
- ▶ Nevertheless, the first week of August 2020 saw two megadeals announced, perhaps signaling a reversal of this trend. Teladoc Health acquired Livongo (see *The digital opportunity* for more discussion), while Siemens Healthineers moved deeper into oncology by taking out radiotherapy hardware and software developer Varian Medical Systems for US\$16.4 billion. This raises the prospect that the industry may now be ready to deploy some of its debt-financed firepower in more aggressive M&A deals.
- ▶ Siemens' 2019 acquisition of Corindus Vascular Robotics' minimally invasive platform for vascular therapeutics is also notable, with robotic systems among the few areas of therapeutic devices still perceived as representing major market opportunities (witness also Stryker's deal with Mobius and CMR Surgical's financing performance in the top venture rounds).

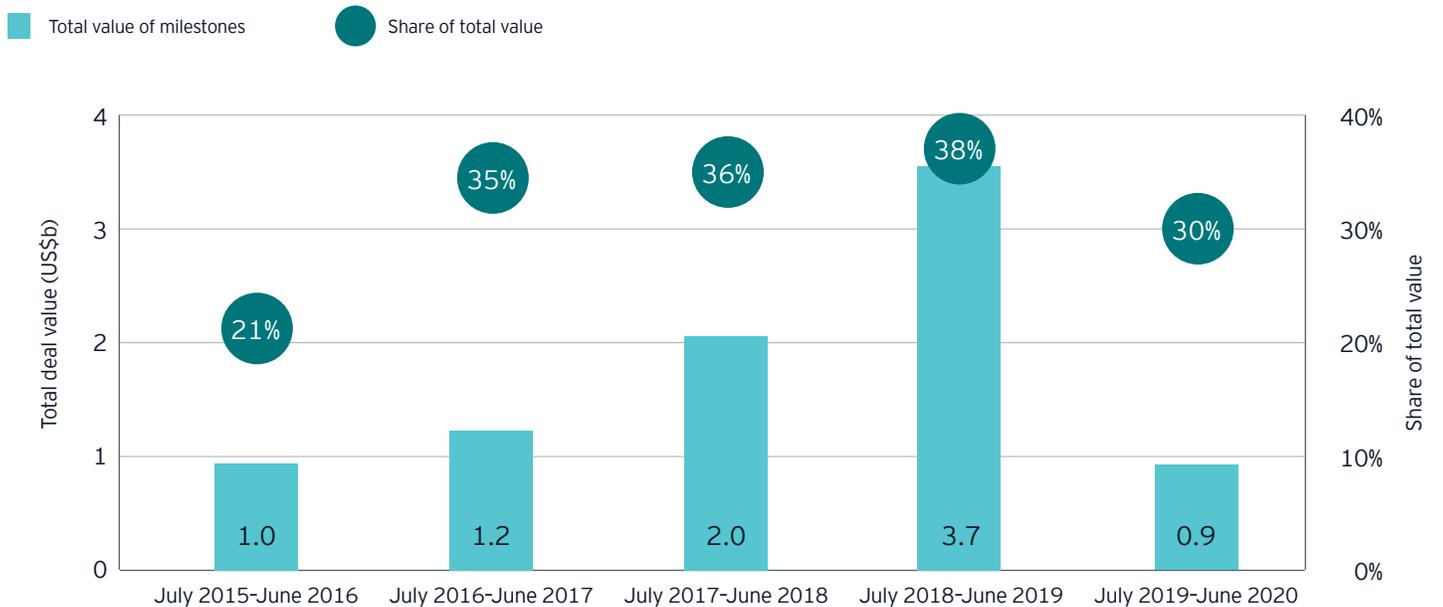
The use of milestone payments slightly decreased

Milestone payments in US and European medtech M&As



Source: EY, Capital IQ and Thomson ONE.

Milestone share in US and European medtech M&As



Source: EY, Capital IQ and Thomson ONE.

- ▶ Just 10% of M&A deals (16 in total) involved milestone payments, down from 13% in the previous 12 months and 22% the year before that. The total value of deals with milestones dropped to US\$910 million, down 75% compared to the previous year.
- ▶ Only the Stryker and Mobius Imaging deal (with an upfront US\$370 million supplemented by US\$130 million in milestones), and Atricure's acquisition of SentrelHEART (US\$40 million upfront and US\$260 million in milestones) witnessed milestone agreements worth over US\$100 million.





Scope of this report

Defining medical technology

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

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

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

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

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

Conglomerate companies

United States

- ▶ 3M: Health Care
- ▶ Abbott: Diagnostics and Medical Devices
- ▶ Agilent Technologies: Life Sciences & Applied Markets and Diagnostics & Genomics
- ▶ Baxter: Renal Care, Medication Delivery, Advanced Surgery and Acute Therapies
- ▶ Corning: Life Sciences
- ▶ Danaher: Life Sciences and Diagnostics
- ▶ General Electric: GE Healthcare
- ▶ IDEXX: Health & Science
- ▶ Johnson & Johnson: Medical Devices & Diagnostics

Europe

- ▶ Agfa-Gevaert: Agfa HealthCare
- ▶ Allergan: Medical Devices
- ▶ Zeiss: Carl Zeiss Meditec
- ▶ DSM: Medical
- ▶ Dräger: Medical
- ▶ Eckert & Ziegler: Medizintechnik
- ▶ Fresenius: Medical Devices
- ▶ GN Store Nord: ReSound
- ▶ Halma: Medical
- ▶ Jenoptik: Medical Technology
- ▶ Merck KGaA: MilliporeSigma
- ▶ Royal Philips: Philips Healthcare
- ▶ Lumibird Group: Quantel Medical
- ▶ Roche: Roche Diagnostics
- ▶ Sanofi: Genzyme Biosurgery
- ▶ Semperit: Sempermed
- ▶ Smiths Group: Smiths Medical

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Project leadership

James Evans, EY Global Health Sciences & Wellness Senior Analyst, served as managing editor responsible for content development, including the co-creation of the report's articles and data analysis.

Ehren Meditz, Ernst & Young LLP Senior Editor-Writer, coauthored the main article, "A new decade, new disruption – and a new dawn? Where medtech stands in the Now."

Jason Hillenbach, EY Global Health Sciences & Wellness Knowledge Leader, led the analysis of industry trends, developed the data book and provided project management over the entire report.

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How EY's Global Life Sciences Sector can help your business

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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