As data personalizes medtech, how will you serve tomorrow's consumer?

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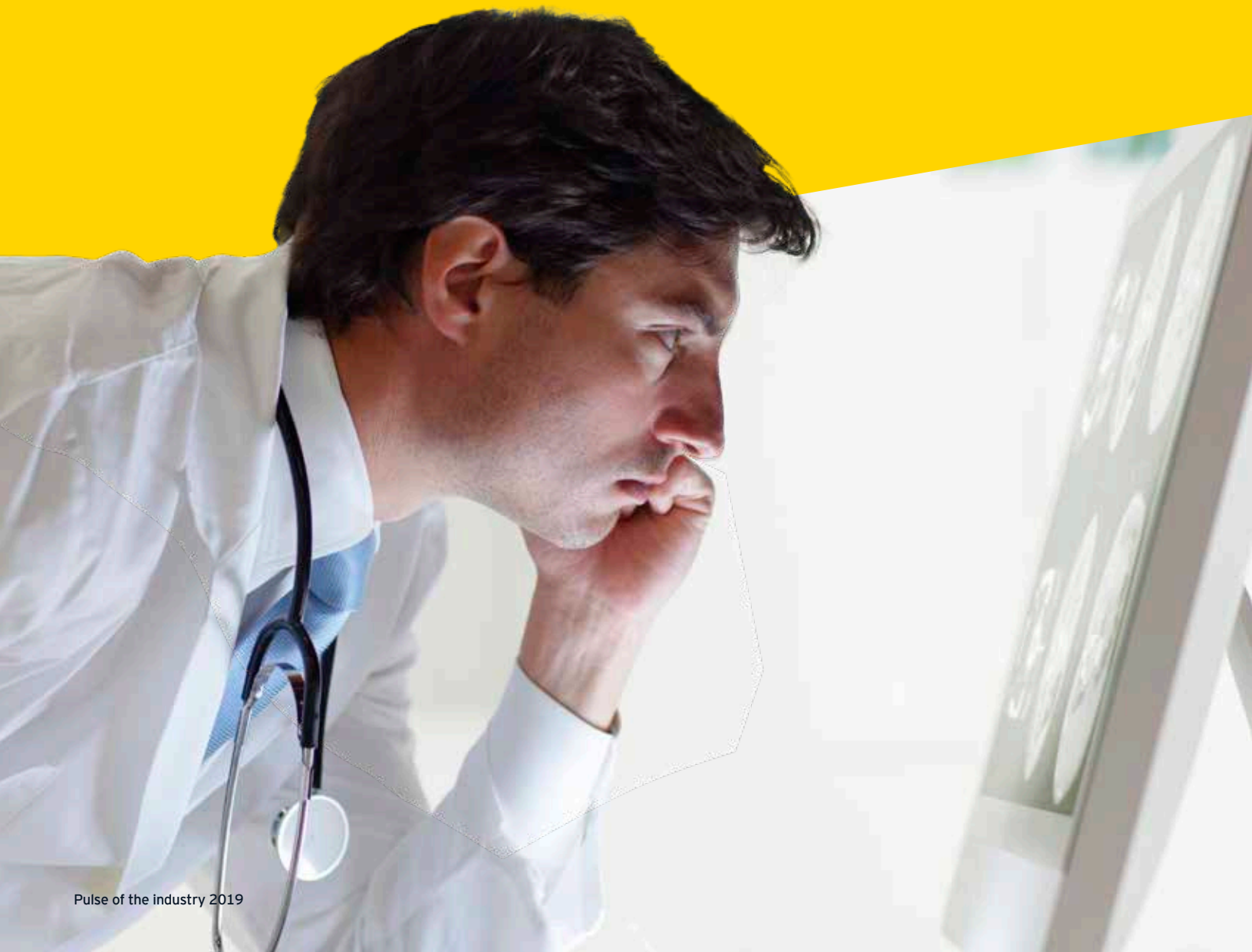

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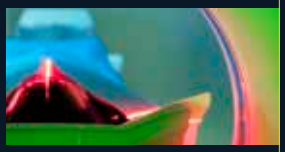

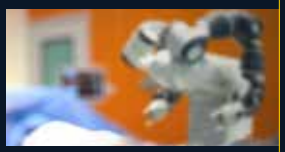

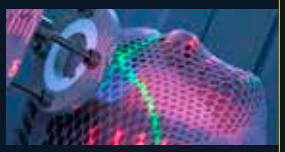

Key findings

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Metrics suggest the **medical technology industry is strong,** but warning signs remain.

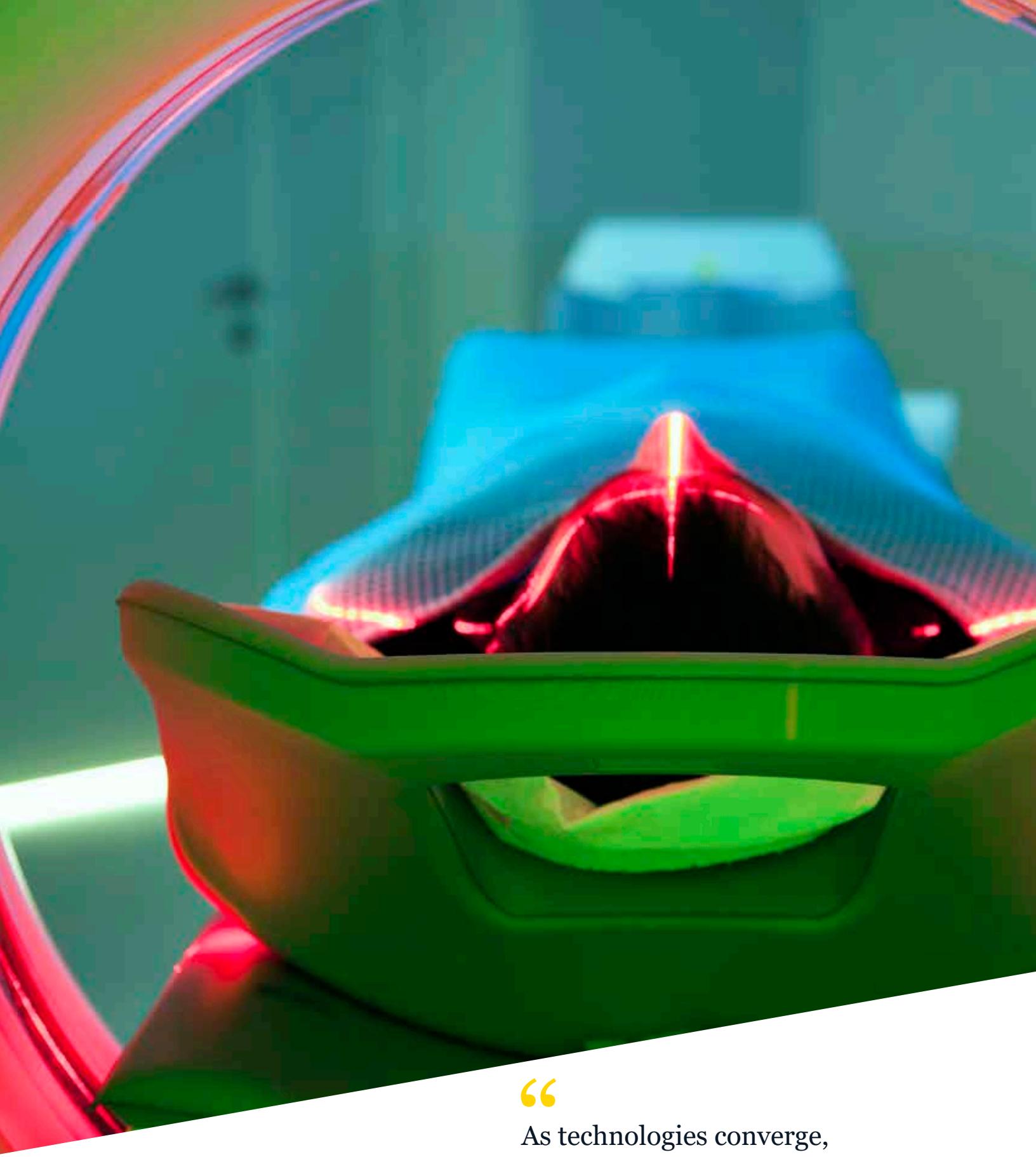
- **Revenue grew 7% year over year,** but the annual growth rate has yet to rebound to pre-2008 levels.
- **Robust R&D spending demonstrates a commitment to innovation,** but capital allocation trends suggest there is still more focus on near-term growth via share repurchases.

Healthy IPO and venture financing totals were a positive, but a two-year decline in total financing may signal the public market's declining appetite for medtech. The **total value of M&A increased more than 50%,** but average deal values fell as buyers outside the sector became increasingly prominent. Robotic surgery, diagnostics and artificial intelligence (AI) provide signposts to how medtechs will create value in the future.

- **The robotic surgery market** attracted major M&A interest as **buyers invested more than US$6 billion on new platforms.**
- **Non-imaging diagnostics companies outpaced the broader industry in both revenue growth** and share of early-stage venture financing, underscoring the technology's importance for personalized medtech innovation.
- **AI remains a top area of innovation**, with at least **33 algorithms winning US regulatory approval** since the beginning of 2018.

But for long-term success in a data-driven future, **medtech must address some key challenges.**

- With health data breaches on the rise, medtechs must develop secure data ecosystems in which **connected devices can easily exchange and use data.**
- As care shifts from traditional settings, medtechs needs t**o develop faster, more flexible and multidirectional supply chains** that meet the real needs of its customers.
- As new entrants play a more important role in care delivery, medtechs must **invest in data-driven, value-based care approaches.**
- To thrive in the shifting health care environment, medtechs need **to adapt their business models,** first determining **who is the customer they are best-placed to serve and what data are required to drive maximum value.**



“As technologies converge, medtech can be at the center of a revolution in health care.

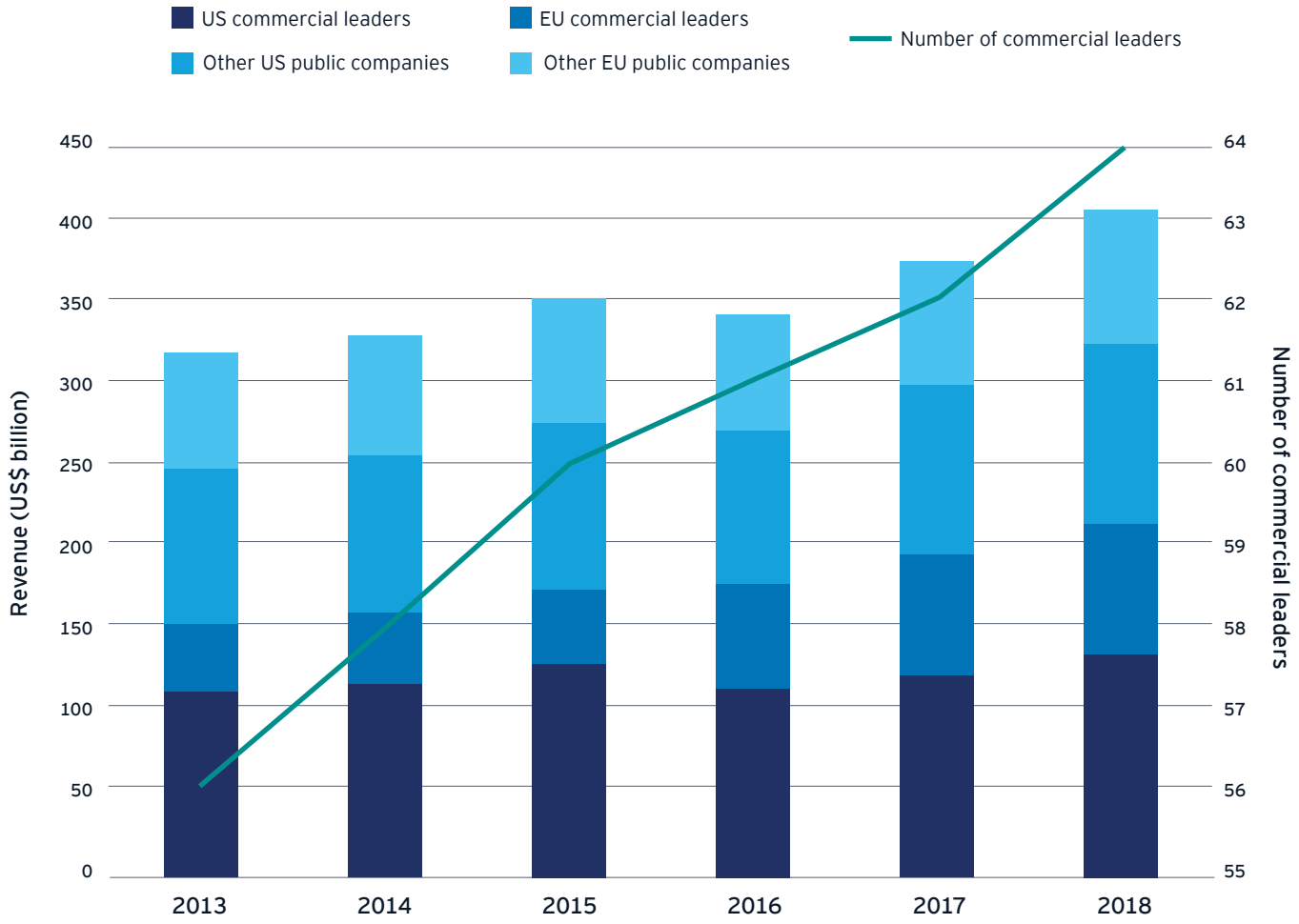
Medtech in 2019

Medtech is not in crisis in 2019, but neither is it ready for a future where care is decentralized, and platform participation is directly linked to value creation. In the future, that value will be driven by the personalized, patient-centered care models that empowered patient-consumers demand. Delivering this will require medtech to work outside the comfort zones of its traditional business models. It will need devices to work interoperably and securely, connecting together to capture and analyze data in real time, and deliver, via agile, data-driven supply chains, better interventions and care management. Achieving this transformation can finally bring the better outcomes needed both by patients and, in an increasingly value-based payment environment, by the industry itself.

But medtech isn't there yet. Nevertheless, the industry continues to grow: in 2018 its collective revenues increased by 7% to US$407.2 billion, medtech's third consecutive year of growth, and its highest revenue total ever (see Figure 1). Net income also increased, mainly due to tax benefits to major companies.

And valuations are also robust: medtech's cumulative public valuation rose 38% between 1 January 2018 and 31 July 2019, far outpacing the broader life sciences industry (see *"Databook"*). Investors still see medtech as less vulnerable than pharma to the headwinds of political controversies about product pricing. Perhaps investors also recognize that medical devices' intimate, ongoing relationship

Figure 1: US and European medtech public company revenues



Source: EY and Capital IQ.
Commercial leaders are companies with revenues greater than US$500 million.
Other companies include figures for conglomerates.

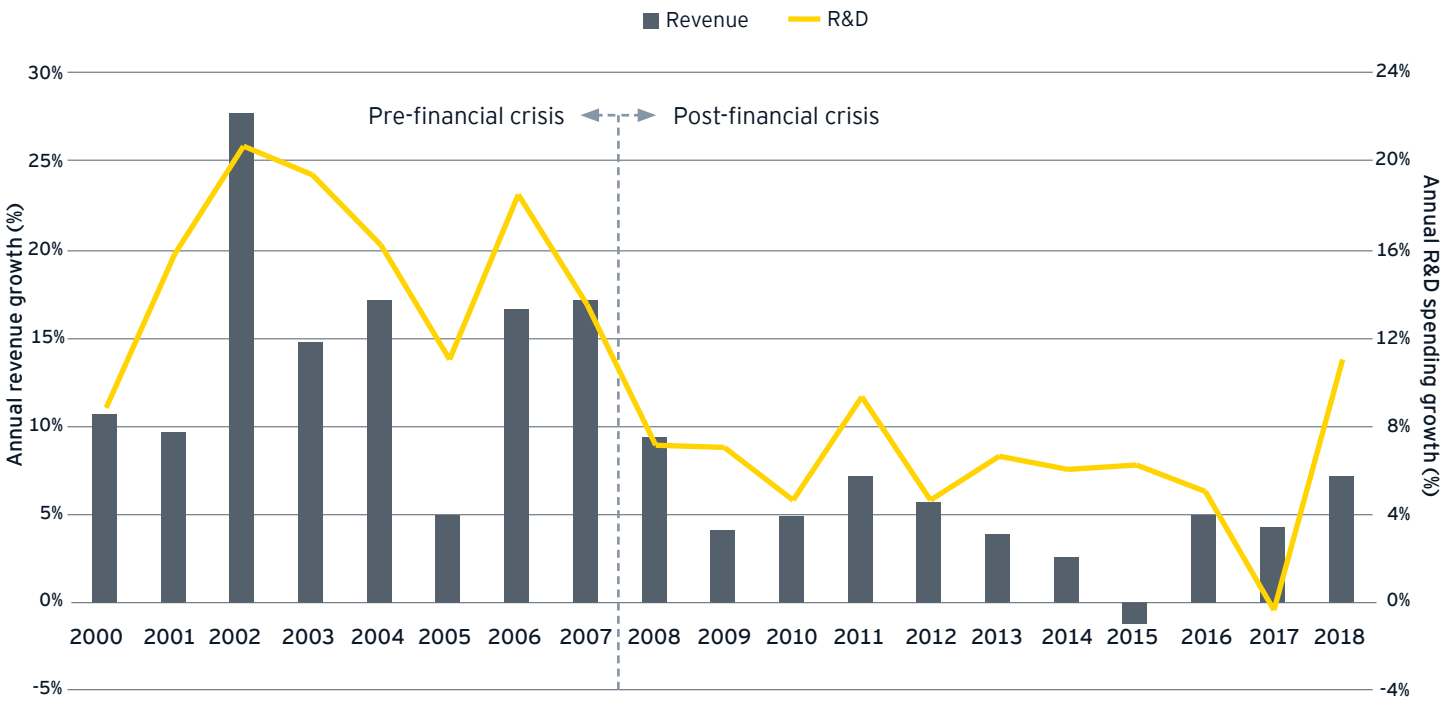
with patients offers medtech a potential basis to build the kind of personalized health model that has proved difficult for biopharma so far.

Investors are right that medtech has huge potential for the future of health. As technologies converge, medtech can be at the center of a revolution in health care. But is the industry investing enough in its own future? Here the numbers are less promising. Though R&D spending increased 11% this year, a glance at the longer-term picture shows that growth in both R&D spending and company revenues has yet to regain the levels the industry recorded prior to the financial crash of 2007 (see Figure 2). While the 11% R&D rebound in 2018 is a promising sign after a particularly disappointing 2017 for research investment, it is too soon to determine whether this is the beginning of a sustained re-investment in R&D or merely an outlier.

One thing is clear: the industry overall is still allocating more of its capital to share buybacks and investor dividends than it is to R&D spending (see Figure 3). The proportion of cash returned to shareholders increased in 2018, exceeding R&D spending, and reaching roughly half the value the industry invested in all growth activities (whether research or M&A-based). With medtech's future dependent on innovation, this strategy may please shareholders in the short term but has long-term potential downside.

These figures need to be to be interpreted with care; not all company investment into research will show up as direct R&D spend, with the industry

Figure 2. Medtech's public company performance pre- and post-financial crisis



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

oftentimes working through more informal and creative partnerships with companies offering skills in, for example, digital and data technologies.

Nevertheless, the industry's willingness to return cash to shareholders still seems symptomatic of uncertainty about how to invest for growth. There are few billion-dollar opportunities in traditional medtech innovation in 2019; as Wende Hutton of Canaan Partners observes, "US$500 million–US$1 billion revenue opportunities are few and far between" in medtech, and the investment opportunity presented by the sector "pales in comparison to biopharma."

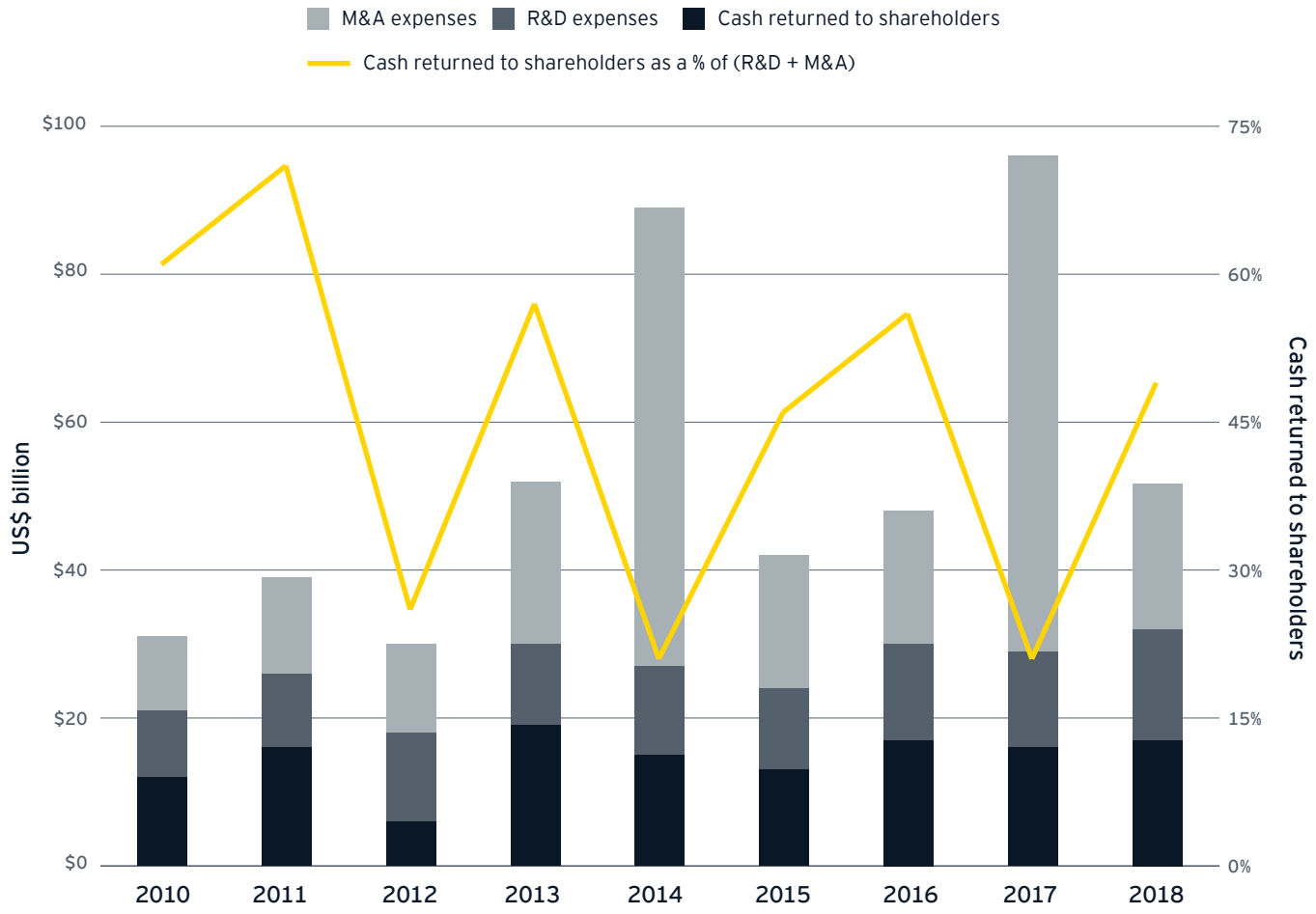
There are still opportunities in medtech. Witness Abbott's significant breakthrough with MitraClip, its mitral valve repair device that has driven up revenues for the company's structural heart franchise and initiated a surge in acquisitions and investments in this space. But advances of this scale in traditional device areas are limited.

In addition, such innovation green fields don't remain green for very long due to intense competition. This has recently been well demonstrated by robotic surgery platforms, where Intuitive has validated the concept and medtech's bigger players are now acquiring technologies that make them serious competitors (see *"Robotic surgery: an emerging battleground"*).

With clarity on the next big device innovation lacking, medtech companies are cautious about acquisitions, especially given the strong valuations for target companies. M&A spending increased in the 12 months ending 30 June 2019, but most of the difference comes from a small number of megadeals (absent last year — see Figure 4). Strip these out, and the total value of M&A is similar, albeit spread over a much larger number of deals. That means deals are getting smaller, with medtechs prioritizing tuck-ins and portfolio optimization, rather than bold or transformative deals.

The caution around unproven new technologies continues to hurt the start-up companies that provide the traditional fuel for medtech innovation. In the current M&A climate, many must win reimbursement before they can make an exit. And though venture capital continues to flow into medtech, overall industry financing levels

Figure 3. Cash returned to shareholders rises



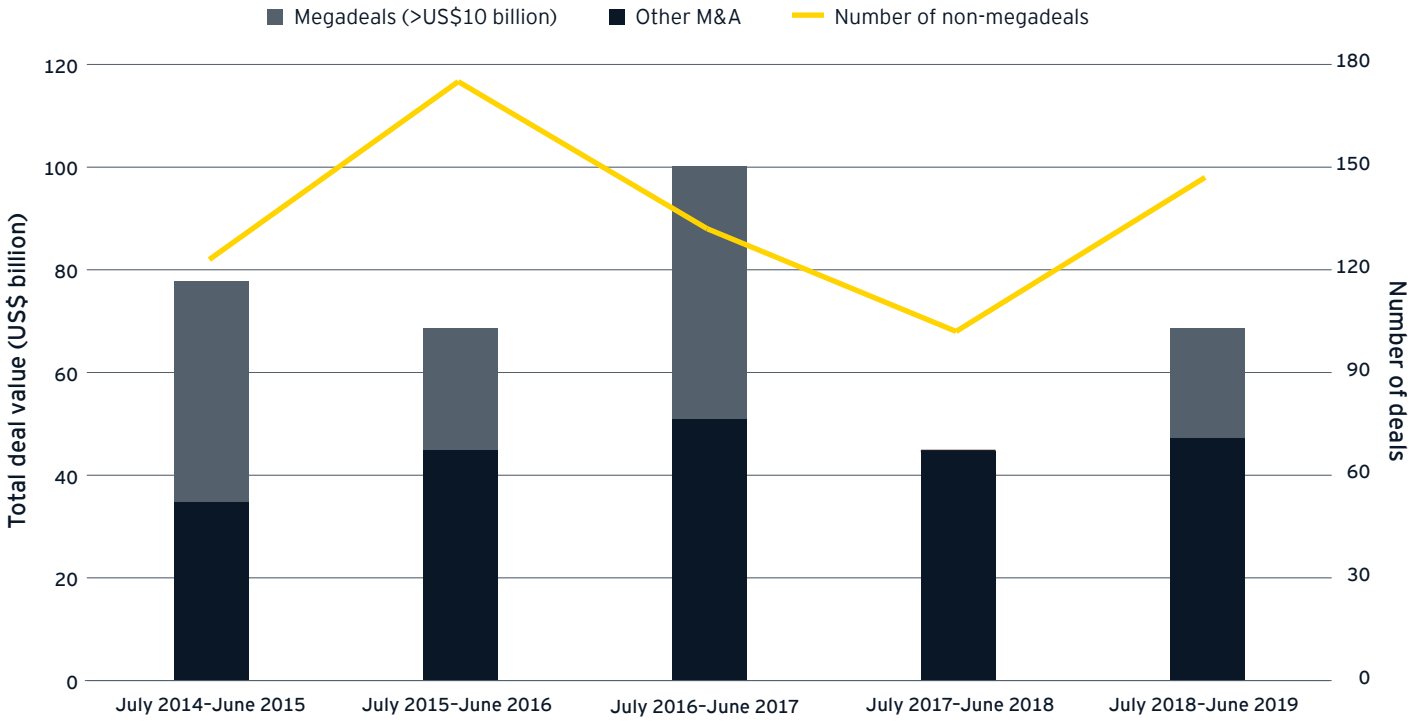
Source: EY, Capital IQ, company financial statement data.

declined for the second year running in 2018 (see "Data appendix"). This slight contraction in raised capital mirrors the drop in new approvals reaching the market this year via the U.S. Food & Drug Administration's PMA and 510(k) approval pathways (Figure 5).

In the meantime, stakeholders who traditionally represent the industry's primary customers are struggling. With payers cutting reimbursement to providers, hospital networks spend cautiously and resent the industry's ongoing efforts to upsell rather than deliver value. In short, medtech's stakeholders don't see the industry as a true partner that offers ongoing collaboration. As Chelsey Berstler, Vice President of Supply Chain at UnitedHealthcare Global, observes, "there is a long history between providers and industry supply partners of, sometimes, bad-faith negotiating, price gouging and generally not acting as partners. We are working to change that."

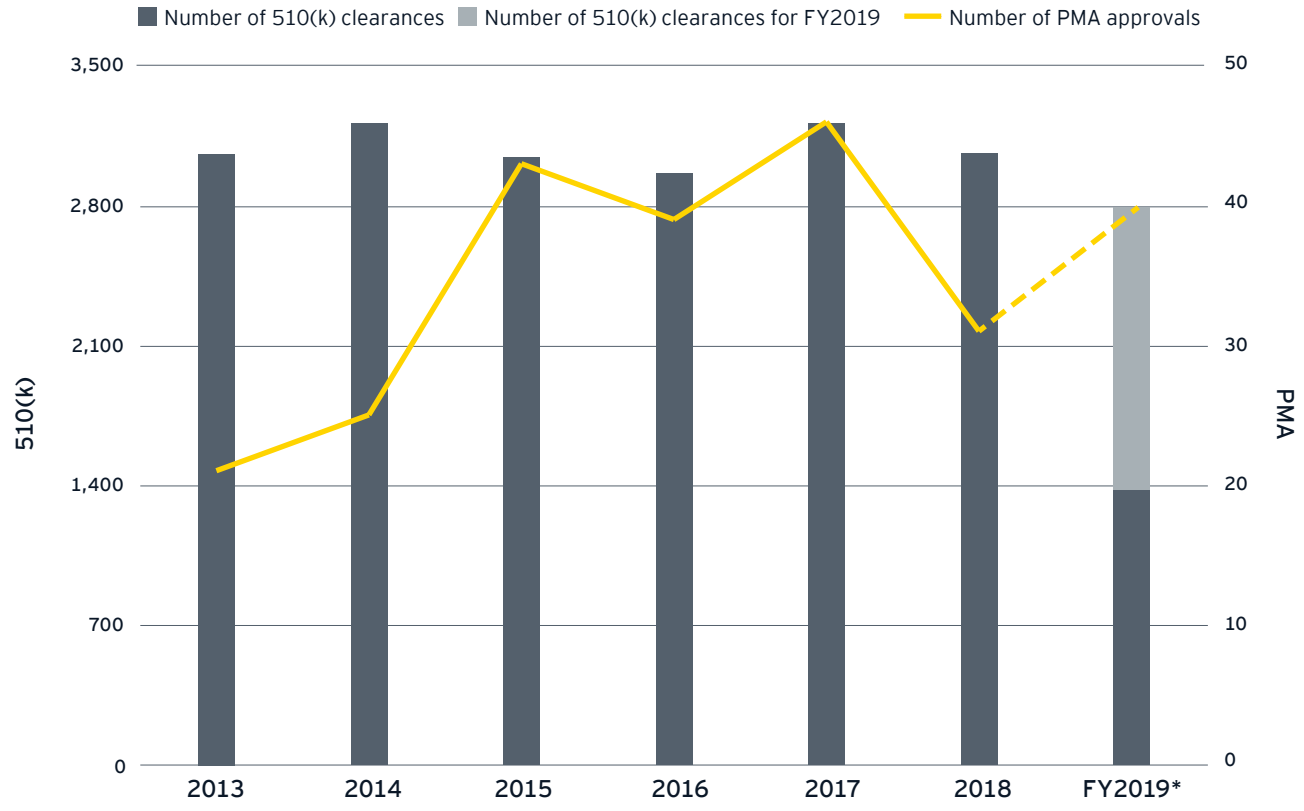
As for the ultimate end-users, medtech has yet to make the move toward regarding patient-consumers as its real customers: its efforts are still focused on provider systems. Yet medtech is beginning to acquire the tools and capabilities that will allow it to enter a data-driven, personalized new era. As Kevin Lobo, Chairman and Chief Executive Officer, Stryker, says in his guest perspective, "we are at the beginning of a digital transformation of health care. Data-driven medical devices will be at the forefront of that transformation," working to deliver "whole person care" to patient-consumers (see *"The journey so far for medtech – and the road ahead"*). Already, and despite the generally conservative activity of the medtech industry in the past year, we can see some indications of that transformation beginning to take place.

Figure 4. M&As in the US and Europe by year



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

Figure 5. U.S. Food & Drug Administration medical device approvals



Source: FDA website.
*Half year 2019 data (through 30 June) is extrapolated through 31 December.

What's next? Signposts to the future

Beyond the headline numbers for the industry in 2019, closer analysis reveals the emergence of important trends that signal the industry's direction toward a more personalized, data-driven future. Among these important trends:

- Medtechs continue to optimize their portfolios in ways that lay the groundwork for future growth strategies
- Non-imaging diagnostics continue to grow in commercial importance, signalling the growing emphasis on data-driven, personalized and proactive care
- Digital-based, data-driven technologies continue to win validation from regulators and investors alike
- Progressive providers and payers show a readiness to move toward a more data-driven approach to care

Smart portfolio strategies for future growth

The cautious M&A climate is a negative for overall industry growth, but medtech's strategic approach to optimizing company portfolios is a good first step to prepare for future growth. Specialization is a necessary step to ensure future success as innovation and personalization push medtech to invest more in data-driven approaches. In an environment where capital is scarce and development timelines are long and expensive, companies need to use their capital wisely to win. EY analysis suggests that life sciences companies with a narrower and deeper therapeutic focus outperform those with more dispersed portfolios, across a range of financial metrics (see the *2019 EY M&A Firepower* report).

With divestments and tuck-in deals prominent (see Figure 6), major medtechs continue to build areas of therapeutic strength and identify the right target markets. Instead of a steady stream of acquisitions, companies want to invest more in deals that potentially deliver bigger rewards.

Take Johnson & Johnson's Auris buy-out — the deal will not deliver significant immediate revenue no immediate revenue returns, but Johnson & Johnson is focused on the long-term opportunity of a genuinely innovative technology, as signaled by its series of investments and partnerships in this space since 2015 (see sidebar, "Robotic surgery: an emerging battleground"). A structured acquisition deal (with significant milestone payments; a trend increasingly prominent across the industry in the past year — see "Databook"), sets the investment on a long-term footing.

While companies arguably need to be doing more to invest in the right new technologies and innovations, these trends at least suggest medtechs are trying to identify the best areas and to invest with a longer-term strategic mindset. These are the approaches that medtech needs if it's going to be able to develop the real innovations that can change the market.

Non-imaging diagnostics point the way ahead to personalization

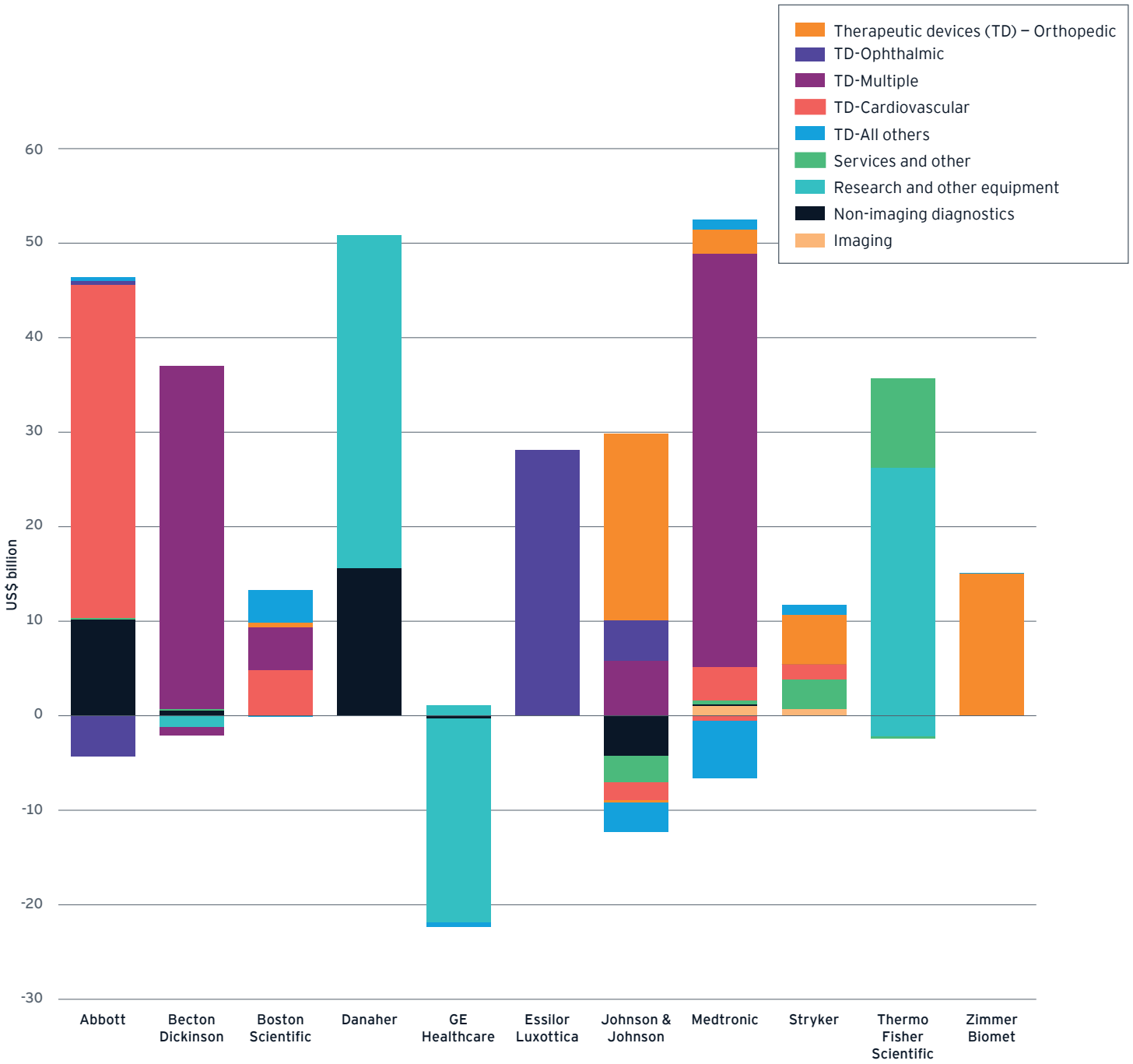
In a data-driven health care environment, medtech products will not have intrinsic value; their value will be commensurate with the data they generate. Data will ultimately become the most valuable product. That stage isn't here yet, but one sign that it's coming is the way that diagnostics continue to grow in importance. Diagnostics are the pathway offering medtechs direct access to the patient — and the field is booming.

Non-imaging diagnostics hit 11% revenue growth over the past year, while the traditional mainstay of the industry, therapeutic devices, grew only 8%. (See Figure 7.) Moreover, non-imaging diagnostics companies recorded some of the highest annual growth seen in the entire industry. For instance, Exact Sciences, a cancer diagnostics firm, led the way with 71% (+US$188 million) organic growth. These strong revenue figures were reflected in the high interest in diagnostics startups shown by VC investors — diagnostic start-ups, such as Thrive Earlier Detection and Click Diagnostics, were among the biggest funding rounds over the previous 12-month period.

Genomics form a major subset of the non-imaging diagnostics field and represent perhaps the single most critical data source for allowing personalized medicine to become a reality. In 2019, the advance of genomics toward mass-market availability continued, thanks in part to the activities of Illumina. The company announced it had reached an agreement to acquire Pacific Biosciences for US$1.2 billion in November 2018, allowing it to integrate Pacific's short-read DNA sequencing platform with its own market-leading long-read capabilities.

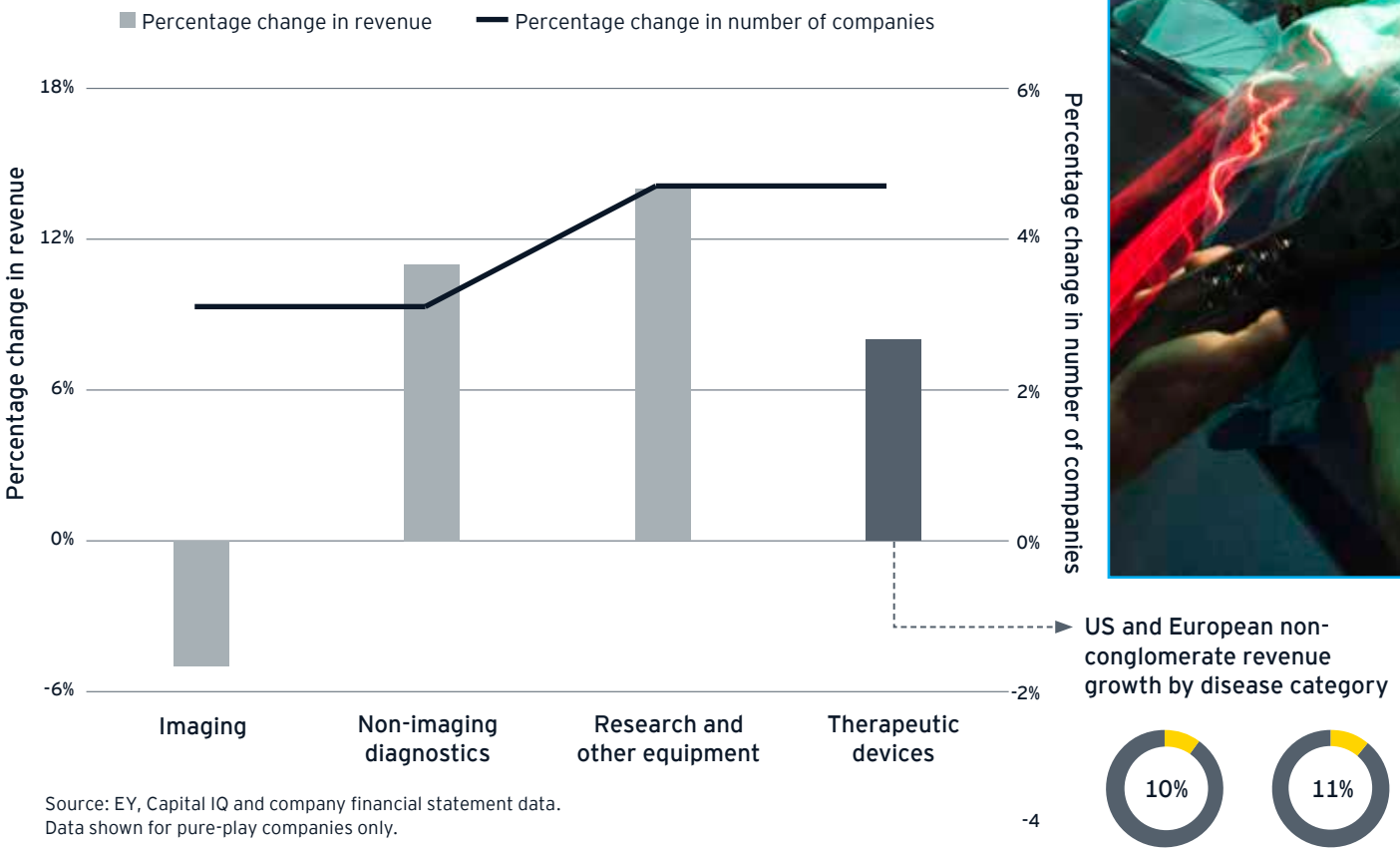
Illumina's dominant position in the market comes with an agenda to push access to genomic analysis into the mainstream and democratize another

Figure 6. Portfolio optimization continues to drive medtech M&As



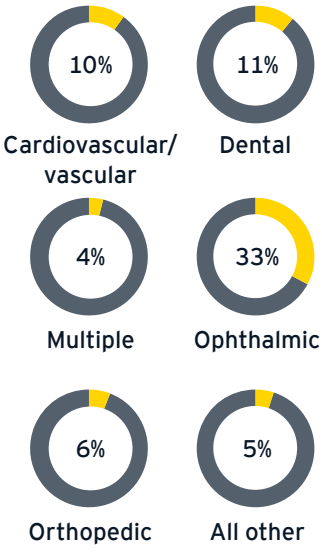
Source: EY, Capital IQ and Thomson ONE.

Figure 7. Non-imaging diagnostics records 11% revenue growth in 2019



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

US and European non-conglomerate revenue growth by disease category



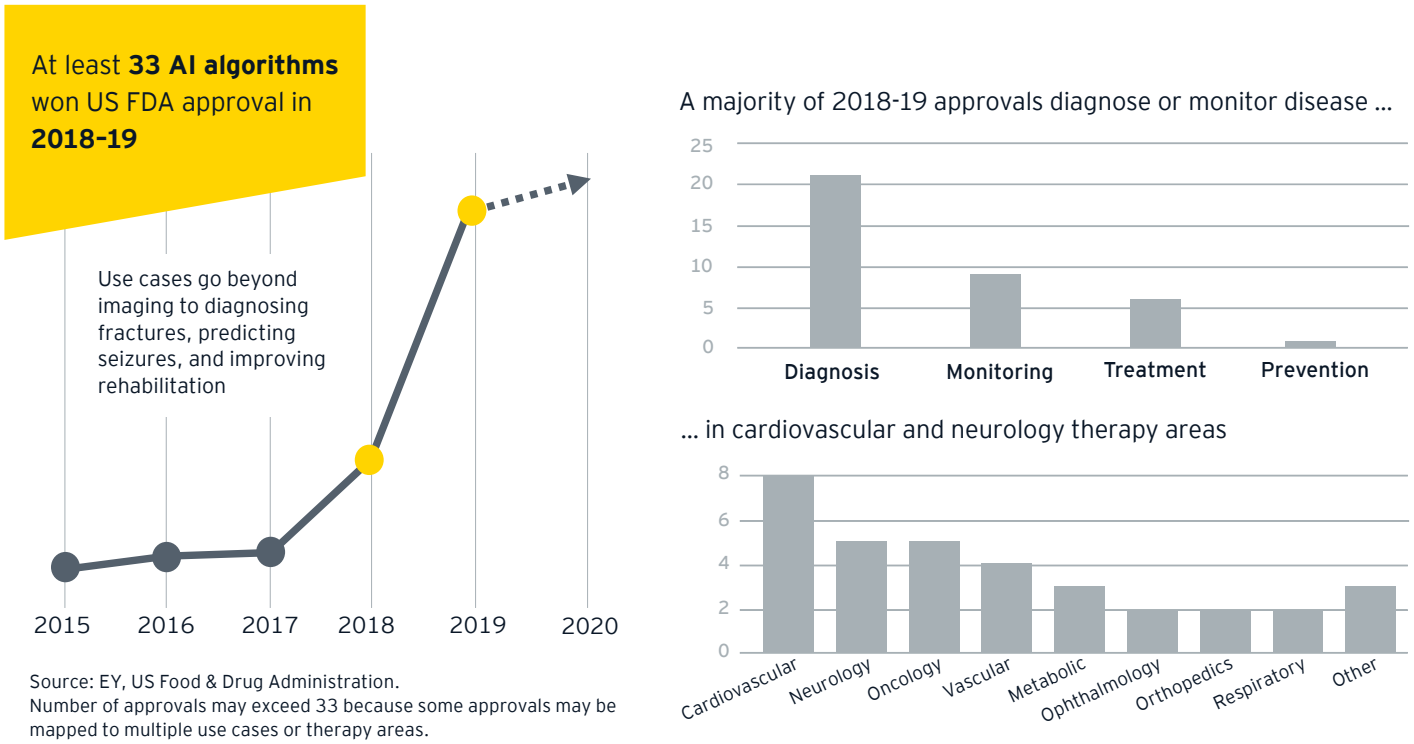
data stream. Susan Tousi, Senior VP, Product Development (see her guest perspective, "*The end of data for data's sake is now: driving the digital transformation of biology through the establishment of the internet of genomics*"), notes that Illumina is now generating more than 100 petabytes of data each year, and is focused on the need to "address cost and accessibility of genomic technology, but also to protect and standardize genomic data as a means to turn it into actionable and meaningful biological insights as quickly and as accurately as possible."

AI, augmented reality and type 2 diabetes are proving the value of digital health technologies

While diagnostics represent a push toward personalized care, the real breakthroughs in personalization require medtech companies to get better at capturing and using data. In many therapeutic areas, digital technologies that make the delivery of health care more efficient or make interventions more personalized and precise are essential to the strategy. However, the EY digital deals database (which uses a broad definition of digital health covering health applications of social media, data analytics supported by machine learning or AI, mobile/web services or platforms, telemedicine, wearables, IoT, cloud storage and digital patient data), indicates that medtech companies are still investing in piecemeal strategies when it comes to digital. The high valuations for digital health companies, which outperform the medtech sector overall, may be one reason for the hesitation. Another may be lack of clarity around which technologies will ultimately be market-leading.

But while medtech companies hesitate to sign new deals, a string of new approvals continue to validate the possibilities of digital health technologies. In October 2018, the FDA approved the first augmented reality system for pre-operative surgical planning, the OpenSight AR system built through collaboration between Novarad and Microsoft HoloLens.

Figure 8. More than 30 AI algorithms have won FDA approval 2018-19



Source: EY, US Food & Drug Administration.
Number of approvals may exceed 33 because some approvals may be mapped to multiple use cases or therapy areas.

The agency also approved a steady stream of AI algorithms over the past 12-month period (see Figure 8).

AI is transforming the imaging sector, but the potential for the technology is not just upgrading existing equipment, but potentially transforming the entire business model. As Abdul Hamid Halabi, NVIDIA Global Lead for Healthcare & AI, observes, AI is not only "making these instruments smarter, faster and more reliable, but it is also making them more portable and mobile" (see his guest perspective, "*The AI opportunity in health care*"). By pushing medtech rapidly in this direction, AI is a significant driver of decentralized care that can be delivered anywhere and anytime.

Diabetes is still the therapeutic area that sets the pace for the digital health market. In the last year, we've seen the continued rapid expansion of Dexcom, which has disrupted the traditional diabetes device market with its continuous glucose monitor (CGM) portfolio. Dexcom's edge in the market is not based on superior therapeutic device hardware, but on the data analysis potential of its CGM.

During this same timeframe, the Tandem t:slim X2 device Dexcom's CGM connects to won the first FDA recognition as an interoperable insulin pump in February 2019. The market success of Dexcom and Tandem's interoperable system illustrates Wende Hutton's point that "companies that are at the forefront of interoperability are starting to take market share away from companies that are wedded to a proprietary, siloed approach." It isn't devices alone but interoperable, patient-centered networks of devices and data analytics that can improve care and convenience and capture market share.

Progressive providers and payers demand more of medtech

The pieces are coming together but medtech is not moving fast enough to embrace the business models that can accommodate these technological innovations. In fact, other companies in the health ecosystem seem to be moving faster to rethink the business model. Consider Mercy, which has pursued the ideal of a bedless hospital

based on remote monitoring, predictive analytics and integrated clinician teams. Through its Virtual Care Center, it has a facility dedicated entirely to care outside of its own walls.

Other leading providers and payers are working to integrate data, with systems such as Johns Hopkins and Common Spirit Health seeking to build an architecture that can aggregate data above the EHR level. As discussed in the EY report, *New Horizons 2019,* building a viable long-term model for health care data may need companies to embrace an open data architecture that can incorporate core elements such as EHRs without being constrained by these systems. Payers also continue to try to reinvent the business model, with UnitedHealthcare, for example, pursuing value-based approaches and acquiring PatientsLikeMe is a signal of its intention to invest in patient-focused research.

To result in significantly better health outcomes for patient-consumers, individual data-driven innovations must be linked together via a common infrastructure. To create this infrastructure, companies need to invest in a secure, interoperable digital infrastructure that allows data to be shared appropriately. Separately, stakeholders will have to move away from transactional relationships to partnerships that emphasize supplying the right customers with the right products and services.

The achievement of this interoperable, open ecosystem based on partnership will be the long-term basis for medtech to achieve future value. Already, we can identify some of the key elements that need to be established for success, including building greater stakeholder trust in the security of connected devices, and building a more agile and data-enabled supply chain (see *"A cybersecure ecosystem for data exchange" and "Securing the supply chain"*). At a larger scale, medtech faces the challenge of constructing new business models, better adapted to the explosion of available data and the emphasis on better, more personalized outcomes (see *"Securing value"*).

Looking beyond: the connected medtech ecosystem

As the health care ecosystem becomes more connected, the advances in diagnostics, genomics, AI and other emergent data technologies will reinforce each other, driving an exponential acceleration toward personalized care. We can identify challenges that medtech must overcome to realize this vision. Ultimately, this acceleration toward personalized care points toward the realization of an anytime, anywhere care paradigm that will transform medtech in ways that cannot yet be fully anticipated.

Medtech is already creating connected devices. What it can't create is a connected ecosystem to plug these devices into. That's because building a working, linked-up ecosystem isn't a task for the industry to undertake alone — it needs to be a collaborative effort between industry, regulators, providers, payers and patient-consumers together. Put simply, if medtech can't strengthen its connections with the other stakeholders, it can't extract real value from its connected devices.

Two major roadblocks exist to industry forging closer collaborative links with other stakeholders. First, the technical challenge: the lack of interoperability between the data-management systems used across the existing ecosystem means that data remain locked in silos. Without a common digital backbone, there's no mechanism to allow data to flow seamlessly between stakeholders.

Second, there is no incentive for other stakeholders to work together on developing that digital infrastructure if they don't feel that medtech companies are aligned with their values. There are few precedents for stakeholders collaborating at the scale needed.

Overcoming stakeholder skepticism about medtech as a trusted partner will be a broad, ongoing challenge that requires more participatory relationships with partners across the value chain. This may involve medtech embracing value-based payment as part of a closer collaboration. As John Liddicoat, EVP and President, Medtronic Americas Region, says "In the journey toward delivering better patient outcomes, improving access, and lowering overall costs of care, collaborations in risk-based contracting, operational alignment, and data transparency are foundational requirements," which brings data analytics capabilities to clinicians to help them identify higher-risk patients, and does this as part of an "end-to-end offering in an at-risk business model" (see his guest perspective, *"Collaborations fueling the future of health care"*).

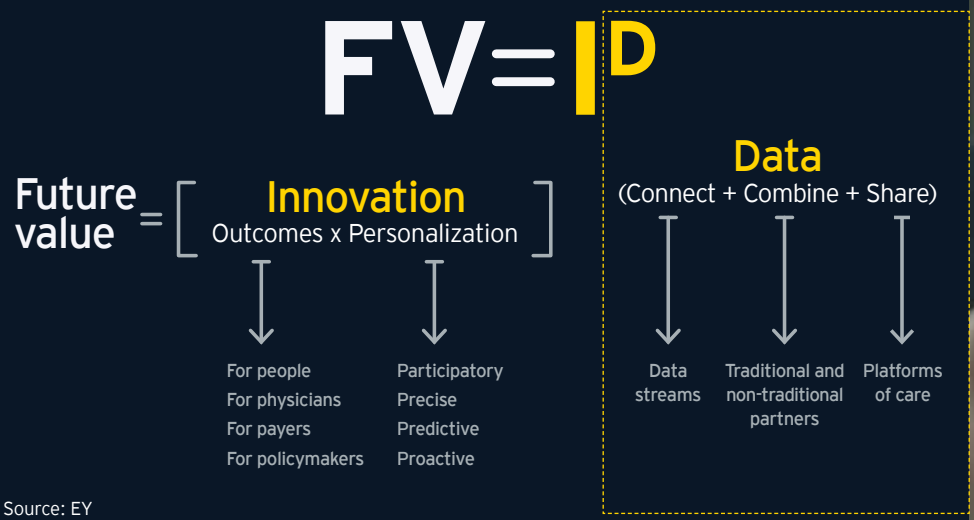
Some medtech innovators are already planning for a highly connected, data-driven future — consider Illumina's goal, as outlined by Susan Tousi "to

connect our smart sequencers to the internet, to each other, and to our partners' applications," with the intent to integrate "rich data streams, open up new analytical possibilities and usher in the era of digitized biology." At a broader scale, the technical and logistical demands of building a digital backbone that can be accepted and used across the ecosystem represent a longer-term challenge that may demand expertise with data systems that lie outside the industry's current capabilities.

Nevertheless, medtechs can begin to address both these issues at a local scale, by building devices that capture and share data securely, working closely to understand their real customers' needs and using data to better deliver value to those customers. The onus is on the industry to take the first steps toward constructing the connected ecosystem. The potential rewards are significant for the companies that seize this opportunity but to do so they will need to rethink the business model in fundamental ways. As Mark Boxer, Executive Vice President and Global Chief Information Officer, Cigna, says, "health care now, and in the future, requires a different orientation, different investments and different skill sets" (see his guest perspective, "*How data is fueling a new approach to whole person health*"). The companies that can realize these new and different capabilities will be those poised to dominate the era of data-driven, personalized medtech.

> "Put simply, if medtech can't strengthen its connections with the other stakeholders, it can't extract real value from its connected devices.

Figure 9. The equation for capturing future value



Source: EY

> The rising investment in the sector will continue to boost both awareness of the technology and the numbers of surgeons trained on robotic surgery platforms.

Robotic surgery: an emerging battleground

Since launching its first robotic surgery platform in 2000, Intuitive Surgical has maintained its leadership position in this sector. However, the increasing level of activity in recent years from both established and emerging players may soon change the market dynamics. Companies such as Stryker, Smith & Nephew, Zimmer Biomet and Globus Medical have all made acquisitions (and/or signed collaborations) to acquire or enhance robotic surgical platforms. In August 2019, Siemens Healthineers also placed a big bet on the sector, paying US$1.1 billion for Corindus Vascular Robotics' minimally invasive surgery (MIS) platform for coronary, peripheral and neurovascular operations.

But perhaps the most significant sign that robotic and digital surgery is assuming a major role in medtech companies' growth strategies comes from the dealmaking activities of two leading global medtechs: Medtronic and Johnson & Johnson. In its biggest buy since Covidien, Medtronic acquired Mazor Robotics in December 2018, paying US$1.7 billion for Mazor's orthopedic robotic guidance system and quickly integrating its own Stealth software to launch an upgraded version of the platform. In June 2019, Medtronic also formally announced its partnership with Karl Storz, focused on further integrating the endoscope manufacturer's 3D vision systems into Medtronic's new robotic platform for MIS.

Johnson & Johnson initiated its own digital surgery efforts in 2015 through its joint venture, Verb Surgical, with Verily Life Sciences. Verb plans to launch its digital MIS platform in

2020. After acquiring Orthotaxy for its orthopedic-surgery digital prototype in 2018, Johnson & Johnson spent US$3.4 billion in February 2019 to acquire Auris Health. The deal gives Johnson & Johnson access both to Auris' digital endoscopy platform Monarch, and to its CEO and founder Fred Moll, the co-founder of several robotics companies including Intuitive Surgical.

Despite growing confidence from medtech acquirers about the promise of the technology, health care stakeholders continue to debate robotic surgery's benefits relative to its costs. Nevertheless, while high capital acquisition and maintenance costs still represent a barrier to adoption, hospitals now have several arguments to justify the investment: robotic platforms can reduce surgical procedure complexity, increase precision and reproducibility, reduce time in the operating room, improve outcomes for patients, accelerate recovery, cut re-admission and re-operation rates and help providers enhance their own brand and gain competitive advantage.

The rising investment in the sector will continue to boost both awareness of the technology and the numbers of surgeons trained on robotic surgery platforms. Meantime, the intensifying competition will bring down the costs associated with robotic surgery, opening the market to medium-to-small hospitals in developed countries, and big hospitals in the emerging markets. Notably, Intuitive brought its more affordable da Vinci X range system to the market in 2017 and Smith & Nephew is planning to bring the ANTHEM Total Knee System to emerging markets by 2020.

Figure 10. Robotic surgery - top players

Company	Products in market or pipeline	Initial/latest approval and launch status	Area of intervention
Intuitive surgical	Da Vinci System (S, Si, Xi, X, SP, Ion lung biopsy system)	▸ 2000 / 2019	Minimally invasive surgeries (for several indications)
Stryker	Mako surgical robotic line	▸ 2005 / 2017	Partial knee, total hip, total knee replacement
Medtronic	Mazor X robotic guidance systems	▸ 2011 / 2019	Spine and brain surgery
	Mazor X Stealth Edition robotic guidance platform	▸ Pipeline	Minimally invasive surgeries (expected)
Smith & Nephew	NAVIO (PFS, Surgical)	▸ 2012 / 2017	Partial and total knee replacement
	NAVIO 7.0	▸ Pipeline	Upgrade of earlier versions; will bring the ANTHEM Total Knee System for Emerging Markets onto Navio (expected approval in H2 2019, launch in 2020)
Zimmer Biomet	ROSA robotic surgery platform	▸ 2012 / 2019	Single surgical platform for neurosurgical, spinal and knee pathologies
Globus Medical	ExcelsiusGPS robotic guidance and navigation system	▸ 2017	Minimally invasive and open orthopedic and neurosurgical procedures
TransEnterix	Senhance robotic surgery system	▸ 2017	Minimally invasive surgeries (laparoscopic surgeries)
CMR surgical	Versius Surgical Robotic System	▸ 2019: expected approval and launch	Minimally invasive surgeries
Johnson & Johnson	Monarch platform	▸ 2018	Lung biopsy (for diagnosing) and treatment of cancerous tumors
	Digital surgery platform	▸ Pipeline: expected approval and launch in 2020	Minimally invasive surgeries and orthopedic procedures
Siemens Healthineers	CorPath vascular robotic system	▸ 2012 / 2016	Percutaneous coronary and peripheral vascular interventions
	CorPath GRX (second generation vascular robotic platform)	▸ 2016 / 2019	Percutaneous coronary, peripheral vascular, and neurovascular interventions (PCI, PVI, NVI)

Source: EY, company reports.

Notes:
1. The information in the table is as of September 2019.
2. Only the top companies have been considered (the list is not exhaustive).
3. Approval and launch years are the first approval and launch years in any geography.
4. Surgical systems launched by a company before its acquisition have been captured under the acquirer.
5. Only robotic surgery specific M&A and partnerships have been considered.

While these developments make surgical platforms more accessible, smaller next-generation robots with enhanced vision systems, imaging and haptic feedback capabilities will further expand the range of possible procedures and open new indications, including MIS for lower-complexity surgeries. Intuitive has again led the way, with its Ion lung biopsy system expanding the platform to cover lung cancer diagnosis; Auris' Monarch platform is also expected to launch in this indication by 2020.

As the market becomes increasingly crowded with players and platforms, companies will need to invest in the right strategy to differentiate their solutions. Critically, they will need to invest in developing platforms that can link with the emerging, connected digital ecosystem, gathering data and leveraging it to drive better outcomes. Winning strategies will need to take advantage of future opportunities. These include: developing deep learning algorithms to complement surgical expertise to help with real-time decision-making during complex surgeries; seamlessly integrating and improving the end-to-end process (pre-, intra-, and post-surgery); and collecting data that can help establish outcomes-driven payment models. Ultimately, while the surgical robotic platforms represent a key new technology for medtech companies, their interoperability with connected operating rooms of the future will be equally important for their long-term prospects.

Company	Key M&A/partnerships/collaborations
Intuitive surgical	▸ 2019: acquired Schölly Fiberoptic's robotic endoscope business
Stryker	▸ 2013: acquired surgical robotic company Mako Surgical for US$1.65 billion ▸ 2018: acquired Invuity, an advanced photonics and surgical lighting company, for $190m
Medtronic	▸ 2018: acquired Mazor Robotics, maker robotic guidance systems for US$1.6 billion; later combined Mazor's products with Medtronic's Stealth software to create the Mazor X Stealth platform
	▸ 2019: partnership with Karl Storz to incorporate 3D vision systems and visualization components into surgical robotic pipeline
Smith & Nephew	▸ 2015: acquired Blue Belt technologies for US$275 million for its robotic surgical system
	▸ 2019: acquired Brainlab's orthopedic joint reconstruction business; installed Brainlab's hip software onto its in-development NAVIO 7.0 software ▸ 2019: acquired Atracsys and its optical tracking camera technology
Zimmer Biomet	▸ 2016: acquired Medtech SA (Rosa Surgical robot) for US$132 million ▸ 2018: collaboration with Apple to study patient experience with joint replacement surgery
Globus Medical	▸ 2014: acquired Excelsius Surgical for its ExcelsiusGPS system ▸ 2017: acquired KB Medical for its AQrate™ Robotic Assistance system ▸ 2018: acquired Nemaris and its Surgimap surgery planning software
TransEnterix	▸ 2015: acquired surgical robotics division of SOFAR S.p.A. for its ALF-X Surgical Robotic System for US$100 million ▸ 2018: acquired Medical Surgical Technologies for US$33 million to add to the company's Senhance digital laparoscopy platform
CMR surgical	
Johnson & Johnson	▸ 2019: acquired Auris Health for it Monarch system in $3.4 billion deal; companies had existing collaboration to combine Auris' Monarch Platform with J&J's Neuwave Flex Microwave Ablation System
	▸ 2015: partnership with Google (Verb Surgical) to develop digital ecosystem ▸ 2018: acquired Orthotaxy for its orthopedic-surgery digital prototype
Siemens Healthineers	▸ 2019: announced acquisition in September of Corindus for US$1.1 billion (deal expected to close by end of 2019)

> The volume of M&A activity from Asia-Pacific buyers surged 239%, to 61 deals — more than the total number of Asia-Pacific-based deals over three previous years combined.

Acquisitions and innovations in the Asia-Pacific market

The headline M&A figures, for the 12-month period ending 30 June 2019, conceal one significant development: a big uptick in medtech M&A deals with buyers based outside the US and European markets. The Asia-Pacific region was notably busy. Despite the total deal value slipping 17% (to just under US$4 billion) the volume of M&A activity from Asia-Pacific buyers surged 239%, to 61 deals — more than the total number of Asia-Pacific-based deals over three previous years combined. Seven of these deals concentrated on targets within the US and European markets — most prominently, Japan's PHC Holdings acquired Thermo Fisher Scientific's anatomical pathology business for US$1.14 billion. This deal forged a new stand-alone entity named Epredia, and accounted for the bulk of the US$1.7 billion, (spread across nine M&A deals) involving Japanese buyers. China was a far larger presence in the M&A market, with 36 deals involving Chinese buyers, constituting US$2.0 billion in total deal value.

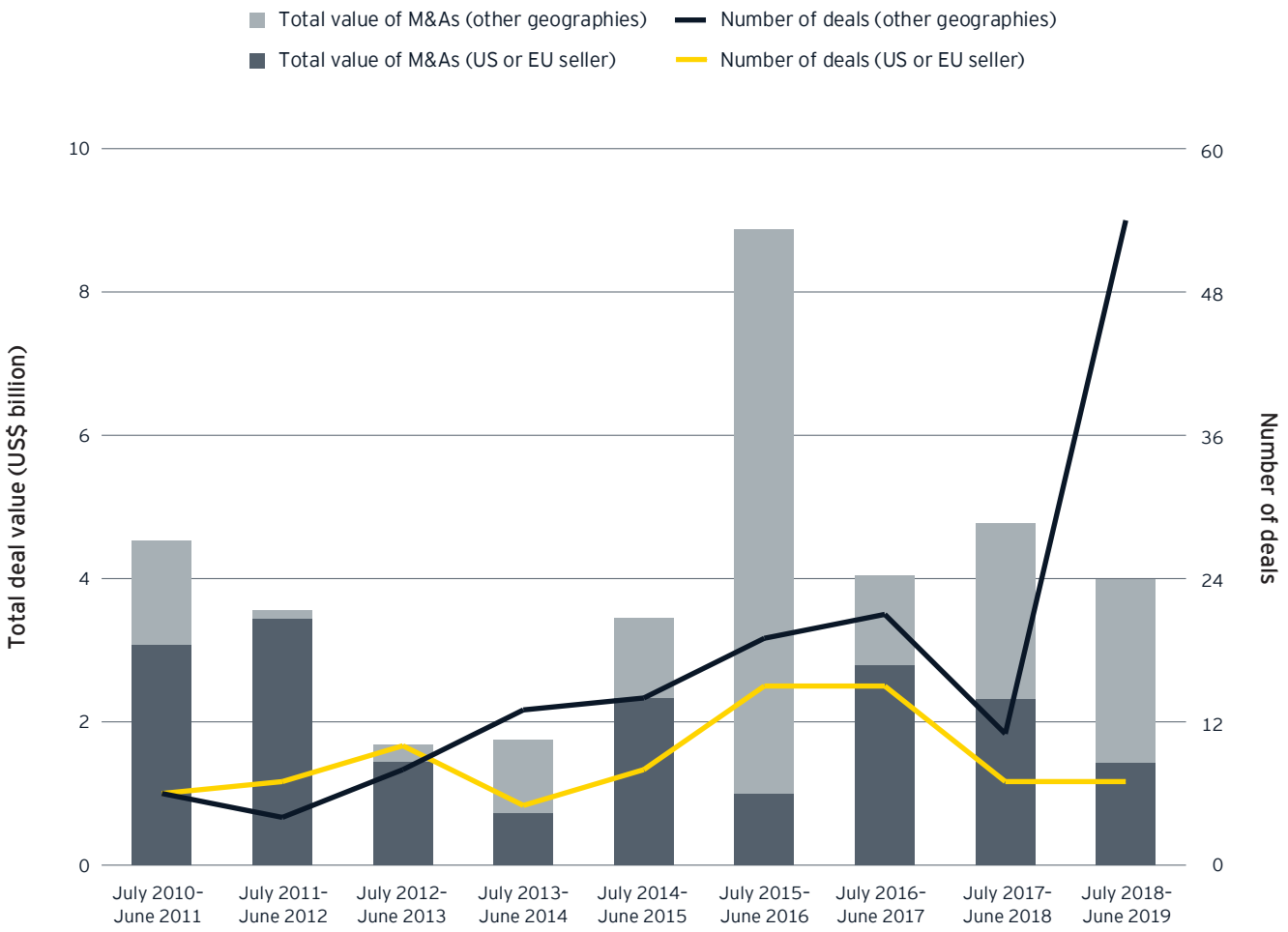
US and European medtech draw an increasing share of their revenues from Asia-Pacific, and the expansion of health coverage in these geographies in recent years will only increase the market opportunity. Witness the launch of Ayushman Bharat (National Health Protection Scheme) in India in 2018 and Jaminan Kesehatan Nasional (JKN) in Indonesia in 2015, both aiming to

provide universal health coverage. Meanwhile, over the past decade China has been able to provide basic health insurance coverage to almost all its people, and is now aiming to increase the extent of the coverage. As the increasing investment in M&A from Asia-Pacific-based companies suggests, the domestic industry in this region continues to grow to meet this rising demand, and may increasingly become an important source of competition to the US and European medtech sector.

The domestic companies looking to capture the Asia-Pacific market opportunities are also investing heavily in R&D to innovate and launch new products. The Asia-Pacific region may soon become a powerhouse of affordable innovation. Pioneering work in surgical technologies in 2018-19 notably took place in the region. For example, Corindus's CorPath robotic surgical platform was used in the first in-human telerobotic intervention study in India in 2018 and CMR Surgical tested its Versius robotic surgical system in India in 2019, while China hosted the first remote brain surgery in January 2019.

During the same period, the Asia-Pacific region contributed 24% of the medical device approvals outside the US market in 2018 (57 out of 240 such approvals; up from 42 out of 242 (17%) in 2016). Six countries accounted for the bulk of these new devices (up from three in 2016), with China at the forefront. China's 17 device approvals were exceeded only by Israel

Figure 11. M&As with APAC Buyer (deals greater than equal to US$5 million)



Source: EY, Capital IQ and Thomson ONE.
Chart includes all deals (including the deals without value) where buyer is from APAC region, and either the buyer or seller company is a medtech.

(28 approvals) and the US itself with 97. MicroPort Scientific Corporation was responsible for 12 of China's new launches, and has established itself as one of the leading players in the cardiac interventional devices market, recently winning CE approval for its next-generation targeted drug eluting stent, Firehawk Liberty. In 2018, the company became the one of the top five cardiac rhythm management device manufacturers in the world and established headquarters in France.

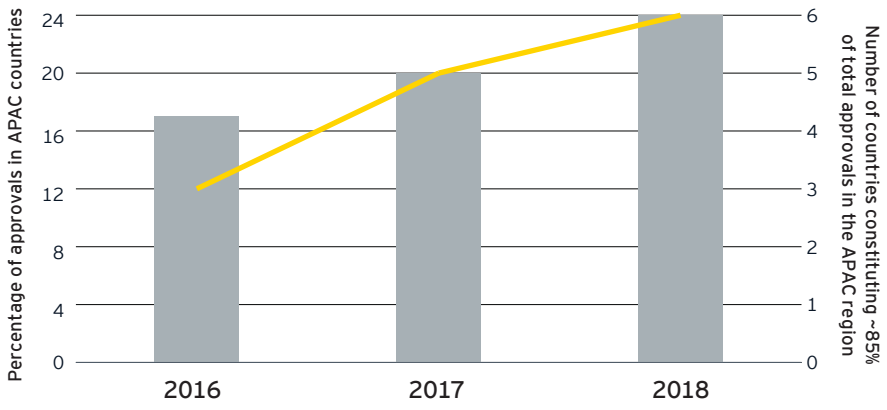
China at the forefront of digital health

With its widely-noted expertise and heavy investment in genomic and AI technologies, and its rapidly growing digital economy, China is widely anticipated to be a key player as medtech and its surrounding health care ecosystem move towards a digital, connected future. In all, Chinese investment accounted for 37% of global digital health funding in Q2 2019, according to Rock Health. One of the largest 2019 investments in digital health funding to date came from Bejing-based Tencent Trusted Doctors, which picked up US$250 million in a funding round.

Tencent Trusted Doctors originated as Tencent Doctorwork, a business unit of the Chinese internet giant Tencent Holdings. Tencent's health market activities include supplying public users with health information, online consultations and registrations and other medical services, enabling providers to take payments through WeChat and to link health records between hospitals, and supplying AI tools to doctors. The scale and scope of Tencent's strategy and investment in health care illustrate why the company (and other Chinese competitors, most notably Tencent's equally large and ambitious rival Alibaba) are expected to remain key players in the digital era of health --- both in Asia-Pacific and in the wider global market.

> "The Asia-Pacific region may soon become a powerhouse of affordable innovation.

Figure 12. OUS medtech approvals in APAC countries



Source: Informa Medtech Insight Approvals Tracker, EY analysis

> Interoperability isn't just about enabling two devices to connect with each other: they need to be able to connect securely, without data being lost, stolen or corrupted.

A secure ecosystem for data exchange

Medtech already has the opportunity to improve the connectivity capabilities of its devices and increase the level of trust they hold with stakeholders. Seizing this opportunity requires an emphasis on secure devices, especially cyber protection. Interoperability isn't just about enabling two devices (or a device and another system) to connect with each other: they need to be able to connect securely, without data being lost, stolen or corrupted.

David Klonoff, Medical Director of the Mills-Peninsula Diabetes Research Institute (Sutter Health), led the teams that created the first two consensus medical device cybersecurity standards, with FDA input. He notes, "for two medical devices to be interoperable, they must be able to exchange information safely, effectively, and securely." That means designing devices that can withstand hostile action from malware. Vulnerabilities extend beyond the potential to directly hack into and externally control a device to more likely threats associated with misused or corrupted data.

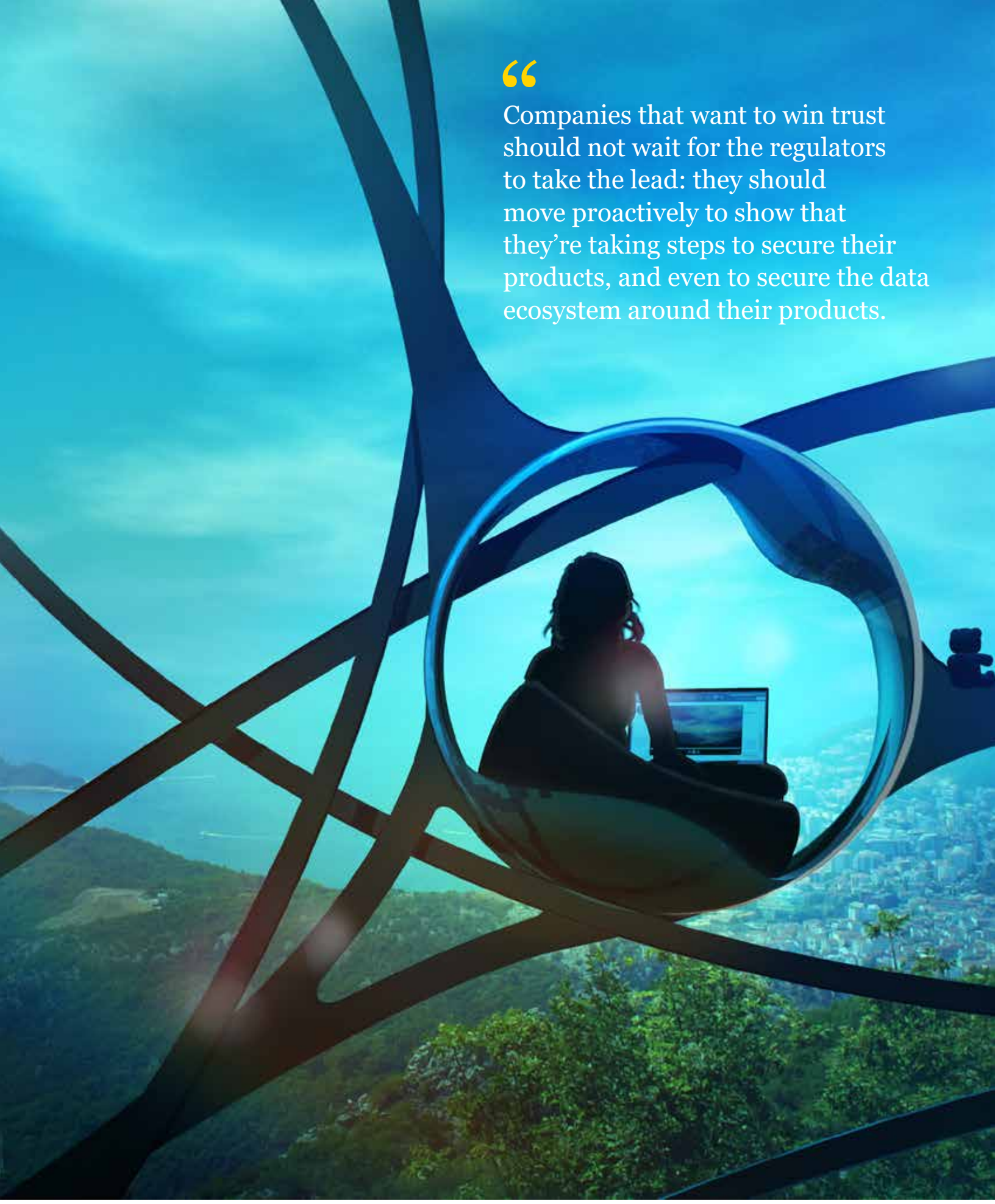
While the so-called "Homeland" scenario of a medical device being directly hacked remains a theoretical anxiety, the bigger issue is the lack of data security. Across the US alone, health care data breaches have been recorded at a rate of about one per day across 2018-19, according to a report from Protenus and DataBreaches.net. The report states that more than 31 million health care records were breached in the US in the first six months of 2019 – more than double the number recorded in 2018. This level of vulnerability in the health information architecture needs fixing

before a connected ecosystem can be achieved. Medical devices need to become part of the solution.

For now, compliance with cybersecurity standards is optional for industry players. But as connectivity becomes ever more integral to how health care works, expect to see a tougher line from regulators. Suzanne Schwartz, Associate Director for Science & Strategic Partnerships, Center for Devices & Radiological Health at the FDA, has already suggested that in the future the agency may "require coordinated vulnerability disclosure through legislation in order to level the playing field." At present, medtechs can opt not to declare known vulnerabilities; and there are business incentives not to be transparent. Companies that disclose potential vulnerabilities may be penalized by investors, for instance.

But companies that want to win trust should not wait for the regulators to take the lead: they should move proactively to show that they're taking steps to secure their products, and even to secure the data ecosystem around their products. Customers may well be reluctant to switch away from a trusted partner with the right cyber protection strategy, since the downside risk is too great. The companies that are thinking beyond their own vulnerability to the bigger question of building safe networks to move data around the ecosystem will be best positioned to become the trusted partners of the future — and benefit from the network effects that have proven key to digital platform dominance in other sectors.

As the industry moves rapidly into a new technological landscape, trust will be increasingly critical. Stakeholders are more likely to embrace unfamiliar technologies if they come via trusted partner companies. This principle is even likely to become part of the regulatory landscape: the FDA suggested in July 2019 that in the future it may approve software as a medical device (SAMD) for the market not by evaluating individual software products but by evaluating the culture and practices of manufacturers themselves. The FDA describes this as a "total product lifecycle (TPLC) approach" that can allow devices onto the market "which have the potential to adapt and optimize device performance in real-time to continuously improve health care for patients." Companies that win trust for high standards of technical excellence as well as a commitment to transparency and close real-world monitoring of their own products will potentially have a streamlined fast-track to market in the connected ecosystem of the future.



> Companies that want to win trust should not wait for the regulators to take the lead: they should move proactively to show that they're taking steps to secure their products, and even to secure the data ecosystem around their products.

> E-commerce has dramatically changed the way all industries are running their supply chain. Health care has been one of the last industries to really figure it out.

Securing the supply chain

The supply chain that enables the industry to generate products and bring them to market forms the basic structure of the medtech ecosystem. But the deficiencies in data availability and trust between stakeholders limit the effectiveness of the medtech supply chain for all partners and make it a prime target for transformation. Outside of medtech, technology giants such as Apple and Amazon have made headlines and boosted margins by strategically rethinking supply chain management. While no such revolution has affected the medtech sector to date, companies are recognizing the potential for liberating value through supply chain reform.

The inefficiencies within health care supply chains are well established. Dan Gagnon, VP of Global Healthcare Strategy and Marketing at supply chain giant UPS, says, "E-commerce has dramatically changed the way all industries are running their supply chain. Health care has been one of the last industries to really figure it out." Medtech is no exception. For example, in the orthopedic sector, "trunk stock" has traditionally been carried by company field reps, who hold the kit and deliver it as needed to doctors and hospitals. This kind of approach means that the reps have to hold a great deal of inventory; even with this inefficient inventory management, it is difficult to cover all contingencies. Provider groups confront their own supply chain issues: committed bulk contracts with group purchasing organizations and distribution organizations can leave providers with supply chain set-ups that are inflexible and entrenched.

As UPS's Gagnon explains it, the fragmented and "convoluted" nature of the health ecosystem drives these issues in supply chain: "There are

so many parties in the health care supply chain. There are three flows; you have physical flow, but there's also information flow and financial flow. In tech or fast-moving consumer goods, those three flows are somewhat integrated and driven by the same parties. In health care you have different parties."

This complex situation is an ongoing logistical headache for all ecosystem partners. Some provider groups have begun to address this problem themselves — Mercy Health, for example, formed an alliance with Medline in 2017, and has since consolidated and condensed its supply chain, cutting margins and reducing the number of manufacturers with which it deals by up to 50%.

Medtech needs to aim to partner with providers and its other stakeholders to try to enable this kind of supply chain improvement while also reforming its own inefficiencies. The good news is that the growth of connected devices, and the increased opportunities they offer to capture and share real-time data, should give them the opportunity. Rather than "adding digital" to medical devices and unloading product into the market, medtechs should seek to tap the potential of digital, data-capturing technologies to rethink the entire value chain. With connected devices enabling a two-way dataflow along the supply chain, companies will have the tools to build more nimble and responsive logistical processes, drawing on dynamic real-time data to not only capture where products are in the market, but predicting where they'll be needed to next.

Connected devices will be able to continuously interact with the patient-consumer, with provider and payer data systems, and with the broader ecosystem. As care increasingly decouples from traditional channels and institutions, real-world monitoring and management devices will become increasingly pivotal to how care is delivered — particularly in a health care environment where remote chronic disease management is becoming ever more important.

Moreover, these software-dependent devices will involve regular updates and consequently shorter product cycles; software will be continually upgraded to optimize its functionality and security, and this will entail continual updating of products in the market. All of these evolutions in the nature of medical devices will both demand and enable much faster, more flexible and multidirectional supply chains, which can meet the real needs of the customers. Ultimately, to deliver anytime, anywhere care to the patient-consumer, the data supply chain will become as critical as the product supply chain, and medtech must position itself to secure those data streams for itself and its stakeholders.

> Building a working, linked-up ecosystem isn't a task for the industry to undertake alone — it needs to be a collaborative effort between industry, regulators, providers, payers and patient-consumers together.

> In the future, data will become critical to determining whether or not an innovation represents a real breakthrough.

Securing value

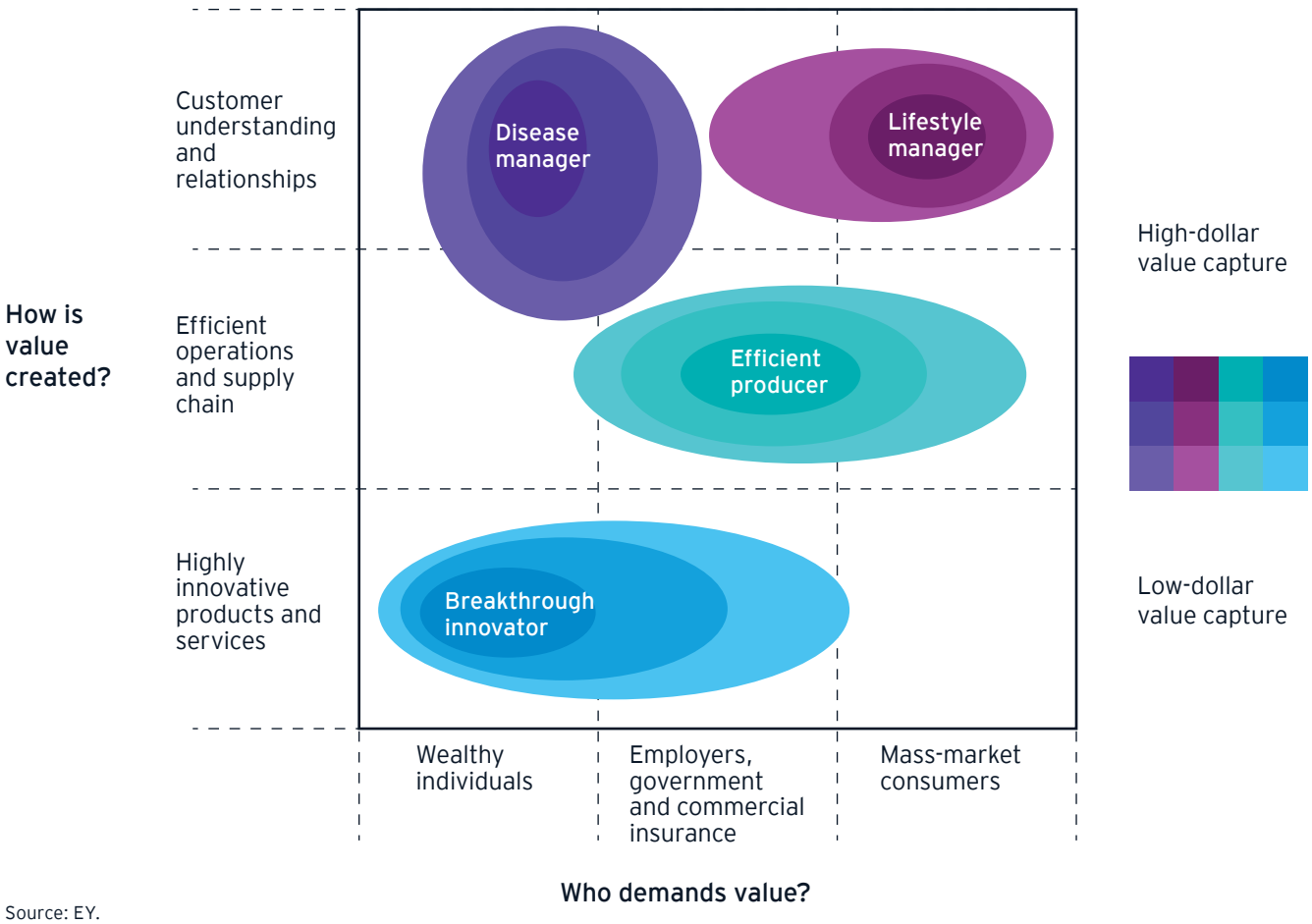
As the sector evolves toward a more dynamic ecosystem built on data sharing, medtechs will need to answer two key questions. First, who is the customer they are best-placed to serve? Second, what data will they need to maximize the value to bring to this customer?

When they can answer these questions, medtechs will be able to identify the business model that represents the best vehicle for them to deliver value in future. Our analysis characterizes four distinct emerging business models associated with medtechs (see Figure 14). Each of these models will have highly specific data and analytics needs as medtech companies embrace a data-driven future (see Figure 15).

At present, most large medtechs rely both on high-end innovation and on delivering significant volumes of less differentiated products. In the future, data will become critical to determining whether or not an innovation represents a real breakthrough. Data will also change the way many product classes work, driving them toward a more personalized, high-touch data relationship with patient-consumers. In addition, data will also (as described in *"Securing the supply chain" article*) transform the efficiency with which companies can supply commodity products with minimal marginal cost.

The specialized data needs and complex business model adaptations needed to excel in any of these approaches means that few, if any, companies will be able to pursue multiple business models. Capital constraints mean that companies will need to zero in on the approach that fits with their own culture and capabilities, and focus on delivering in this niche.

Figure 13. Business models for the future



Source: EY.

Breakthrough innovators

Medtech has traditionally generated value through creating innovative devices through high investment in R&D. While this is still the default business model for many leading companies in the sector, a lack of major market breakthroughs in recent years highlights the challenges confronting medtechs dependent on device innovation. Innovations such as Abbott's growing MitraClip "toolbox" for structural heart repair, or Intuitive Surgical's da Vinci platform demonstrate that stand-out technological breakthroughs can still carve out significant opportunities for medtech players. But in increasingly crowded markets, with payers and providers pushing for clear evidence of improved outcomes, medtechs aiming for breakthrough innovation will need to focus on capturing the data that can validate their products' effectiveness. The success of future robotic surgery platforms, for example, will depend not just on the cutting-edge hardware but on its ability to connect into a wider data ecosystem, including imaging technologies and patient monitoring devices, to help deliver better surgical training, better services and ultimately better health outcomes. Increasingly, it will not be just a question of creating innovative devices, but of demonstrating how their use benefits the wider ecosystem.

Disease managers

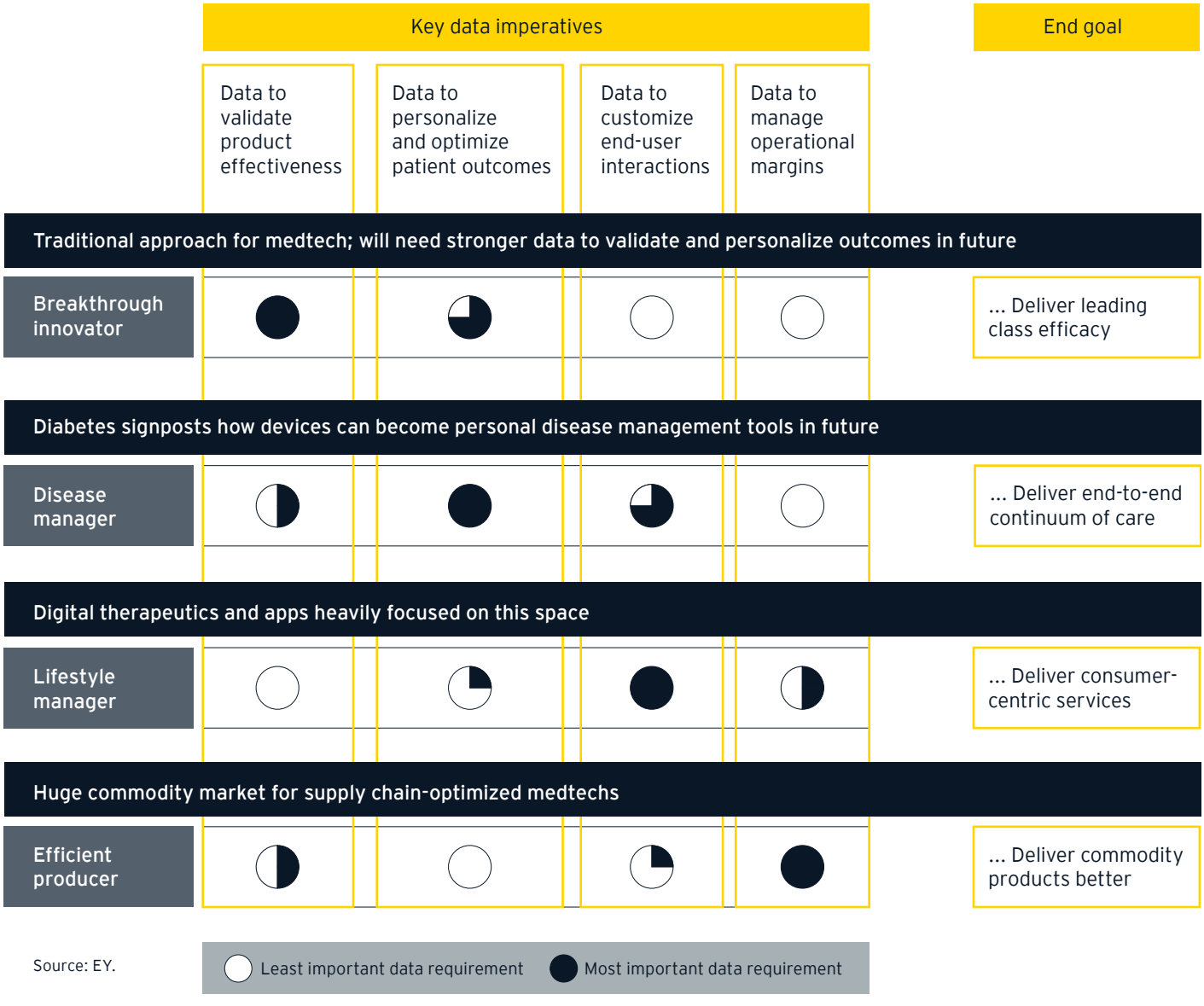
The imperative to look beyond the product to the wider possibilities of the data ecosystem around the product may push many device innovators toward embracing a "disease manager" approach to medtech. The focus in the diabetes market has already moved beyond the product to the level of

connected, convenient care that the product can help enable for the patient. Infusion pumps, smart pens and CGMs are now competing not just as differentiated products in the market, but as potential components in an interoperable system personalized to manage the patient-consumer's chronic disease as effectively and conveniently as possible. The same approach will be needed across the chronic disease spectrum, with personalized, ongoing monitoring and management the key to improving treatment outcomes. In the future, as data capture opportunities increase via connected devices, and unlocked algorithms increasingly give analytics the chance to learn indefinitely more about patients, devices may become highly personalized tools for the individual patient to manage their disease. Future disease managers will need to look beyond therapeutic area silos to deliver care holistically, maximizing the use of data to best manage all of the patient's chronic conditions and comorbidities.

Lifestyle managers

Data capture and analysis aren't just essential for the management of chronic diseases such as diabetes or heart failure. They are also important for lifestyle decisions that increasingly have health implications. As such,

Figure 14. Data needs for different potential medtech business models



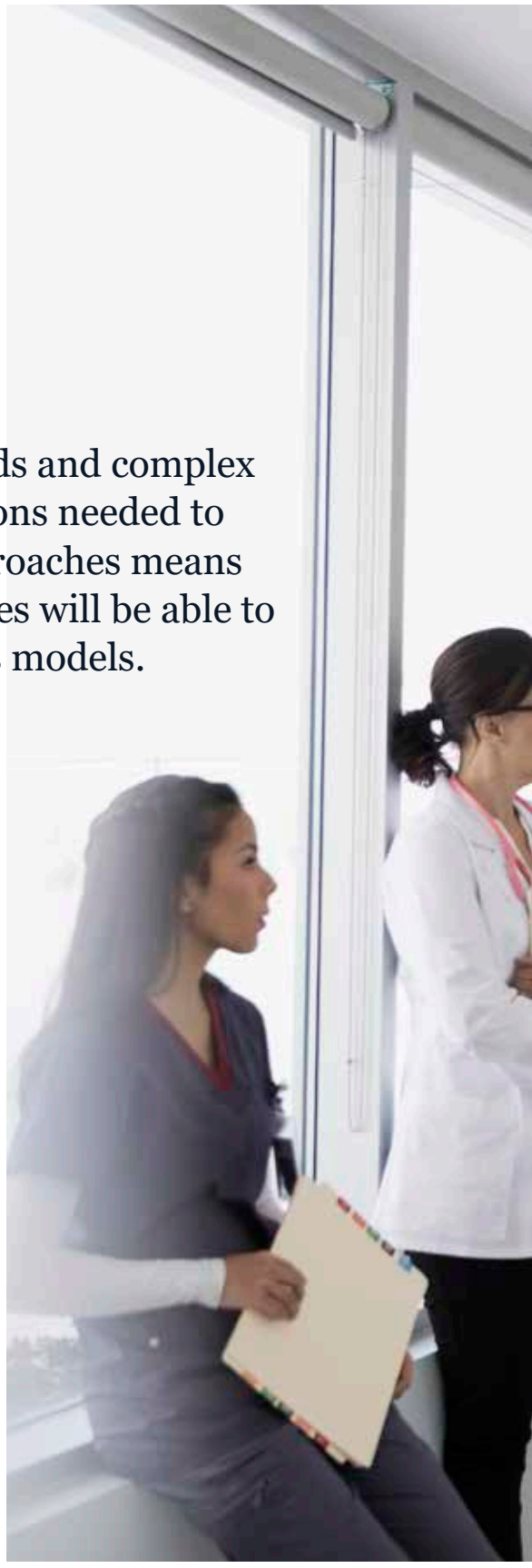
Source: EY.

it's not surprising that consumer electronics devices are evolving beyond fitness and nutrition applications to provide real-time, medical-grade feedback that can help patient-consumers manage their lifestyles more effectively. Consider the Apple Series 4 Watch, 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 to blood-pressure monitoring. The ubiquity of sensors, wearables and smartphone software represents a huge opportunity for companies to develop this "softer" side of personalized medtech for managing the patient-consumer, using data to optimize personalized, holistic lifestyle guidance.

Efficient producers

Companies that focus primarily on cutting margins via supply chain transformation can target the significant market in low-tech, commodity medtech products. Numerous commodity product lines represent medtech staples that are needed by hospitals and clinics worldwide, but command low margins: from gauzes or syringes to maturing product categories such as stents and even basic imaging devices. Despite the relatively "low-tech" nature of the commodity device segment, to succeed in this market medtechs will need to utilize sophisticated data analytics to run operations on as lean and efficient a basis as possible. This means monitoring and predicting demand and distributing products rapidly and seamlessly wherever they need to be — whether inside or out of traditional health care delivery settings. While some companies have made significant steps toward streamlining the business model, the efficient producer model for medtech has yet to see the kind of radical logistical reform that has delivered new efficiencies in, for example, the retail sector.

> "The specialized data needs and complex business model adaptations needed to excel in any of these approaches means that few, if any, companies will be able to pursue multiple business models.



Kevin Lobo

Chairman and Chief Executive Officer, Stryker Chairman, AdvaMed Board of Directors

The journey so far for medtech — and the road ahead

Medical technology represents one of the most misunderstood elements of modern health care.

On the one hand, medtech is everywhere. There is not a medical procedure or health care setting — from the ambulance to the ER to the OR from the hospital bed to the doctor's office and even in our own homes — where medical technology does not play a vital role.

Diagnostics, monitors, surgical tools and equipment, implantable devices and even record-keeping systems — all these medical technologies and many others touch patients multiple times during an episode of care. Physicians, too, rely on the tools the medical technology industry provides to constantly improve patient care. We are there when it matters.

Everyone knows someone who has benefitted from our products. But if asked "What is medical technology?" or "How important is medtech to modern health care?" chances are most people might be able to give a few examples and generally agree it's a positive.

But how many people truly understand the incredible diversity of our industry, how we innovate and the benefits we provide that allow for earlier disease detection, less invasive procedures and more effective patient care?

With health care so often a topic of national interest and conversation, it is more crucial than ever for policymakers and the public to better understand what our industry does if we are to continue providing life-changing innovations to patients.

We as an industry have a lot to be proud of. Over the last 30 years, medtech advancements have helped:

- Lengthen life expectancy by over 5 years;
- Lower heart disease fatalities and stroke deaths each about 60 percent;
- Reduce breast cancer mortality by a third; and
- Cut the number of days people spent in hospitals by 59 percent.

These advancements have also yielded incredible savings and efficiencies across our health care system by detecting disease earlier, when it is more easily and successfully treatable; replacing more invasive procedures; reducing doctor visits through remote monitoring technologies; and countless other ways.

At Stryker, our mission is to make health care better by addressing the needs of providers and their patients. For instance, our mechanical thrombectomy products, which remove clots from blood vessels, combined with better pathways for care for stroke victims has the potential to significantly reduce disability and change the paradigm of care globally. As another example, Mako, our robotic arm-assisted surgery product, enables surgeons to have a more predictable surgical experience when performing joint replacement surgery.

Data-driven medical devices will be at the forefront of that transformation, collecting individual patient information that can be used to improve outcomes and efficiency, better manage chronic conditions, deliver more targeted therapies and avoid hospitalizations.

Our industry provides all this innovation, efficiency and improved patient care, and we do it in a cost-effective manner. Data show that medical device prices in the U.S. over the last 10 years have increased at an average annual rate that is much less — one-quarter the rate — of prices in the overall economy.

Spending on advanced medical technology has also remained virtually constant as a percentage of national health expenditures — at roughly 6 percent or less — for decades. In fact, the percentage dropped to just 5.2 percent by 2016, a 30-year low. For instance, major categories of implantables have seen continued, substantial declines in average selling prices on both a nominal and inflation-adjusted basis of late. In recent years the prices for artificial hips and knees have declined 23 and 18 percent, respectively.

And yet, as far as we have come, we have only just begun to explore the potential of medical technology to combat disease and end human suffering. The hallmark of our industry is rapid innovation, building on the successes that have come before and incorporating advances in other disciplines to push the boundaries of what is possible.

Just recently, the world learned that researchers in Israel have created the first-ever, 3D-printed heart using a patient's own cells. While tiny, the same process could theoretically 3-D print a human-size heart. Think how that could revolutionize transplants.

Similarly, we are at the beginning of a digital transformation of health care. Data-driven medical devices will be at the forefront of that transformation collecting individual patient information that can be used to improve outcomes and efficiency, better manage chronic conditions, deliver more targeted therapies and avoid hospitalizations.

Without question, the U.S. health care system and systems worldwide face challenges. But I am optimistic that the innovation and value the medtech industry routinely provides will offer solutions to these challenges. The commitment, imagination and enthusiasm of the people in this industry to improve people's lives is unmatched. We have done so much for patients; let's do more.

John Liddicoat, M.D.

Executive Vice President and President, Americas Region,

Medtronic

Collaborations fueling the future of health care

At Medtronic, we are committed to transforming health care, but we know we can't do it alone. In the journey toward delivering better patient outcomes, improving access and lowering overall costs of care, collaborations in risk-based contracting, operational alignment and data transparency are foundational requirements.

Innovating to drive better value

Many large hospital systems are starting to make the shift toward value-based health care (VBHC) models. Private health plan industry leaders like UnitedHealthcare, Cigna and Aetna have accelerated the shift toward value-based care, helping provide patients with access to the latest in medical technology and delivering savings to the broader health care system through innovative reimbursement models.

Medtronic is meeting partners where they are on the journey toward VBHC and working together to develop solutions uniquely tailored to their needs. Through in-depth discovery sessions and multiyear program development, we've seen some of our long-standing partners — including Maastricht University Medical Centre in the Netherlands and Southlake Regional Health Centre in Ontario — shift toward this new model to achieve their goals. In the United States, Lehigh Valley Health Network in Pennsylvania is building out programs that could revolutionize the way care is delivered, implementing risk-based contracts and unique care delivery models.

Through our Integrated Health Solutions (IHS) team, Medtronic works with key hospital staff within developed and emerging markets to identify root causes, develop solutions and measure results of programs, protocols and procedures. Horizon Health Network in New Brunswick, Canada, has seen strong results from work that started in 2016: six months in, the Heart Centre saw a 14% increase in operating room capacity and a 44% reduction in average wait times.

Partnerships powered by data and technology

We must combine our expertise in medical technology design and delivery with the knowledge and insights of experts leading in other areas of health care innovation. At the core of these collective efforts to accelerate progress lies a common resource: data. Not just raw data, but actionable data that informs decisions.

Medtronic Care Management Services (MCMS) helps empower clinicians with timely information that may help them treat complex, chronic, co-morbid patients by addressing risk factors before they lead to complications. MCMS runs patient selection and risk stratification algorithms to help identify patient cohorts benefiting most from remote monitoring. Once identified, MCMS begins the enrollment, engagement, monitoring and care management support services. We use advanced data reporting and analytics to monitor program success factors such as patient engagement rates, reduction in hospitalization, time in range for specific biometrics and other measures.

Partnerships in the medical technology evolution with hospital leaders, technology experts, payers and health care innovators are key to making progress possible.

Over the past two years, Medtronic has contracted with multiple health plans that utilize our end-to-end offering in an at-risk business model. To date, Medtronic has enrolled more than 9,000 patients on the MCMS service and delivered 54,000 patient months of service.

Taking health care further, together
Putting the full power of data and technology into the transformation of health care requires continuous input and feedback from stakeholders.

As we continue to explore the impact of data on the future of health care, our IT and Digital Health teams have created the Medtronic Hospital IT Advisory Board. The group, made up of hospital CIOs, chief technology officers and other IT stakeholders, meets regularly with Medtronic to discuss the challenges hospitals face related to data and IT solutions.

We also continue to seek out R&D partners who help us build patient-centric solutions. With 21 R&D global facilities and more than 46,000 patents, we are committed to ongoing physician training and collaboration, and have forged strong R&D partnerships with leading universities.

From collaborations spanning the last seven decades, we've learned that partnerships that deliver clinical and economic value:

- Aren't just about product innovation, but process innovation, and building new ideas with inclusive, multidisciplinary teams.
- Require a willingness to share data and insights, sometimes without predefined outcomes or agendas.
- Take patience and persistence, investing in quality to deliver consistent, integrated care and better patient outcomes.

As global health care evolves, it is our responsibility to evolve with it. We see great opportunities ahead to help more patients around the world. Partnerships in the medical technology evolution with hospital leaders, technology experts, payers and health care innovators are key to making progress possible.

Dr. Mark Boxer

Executive Vice President and Global Chief Information Officer,

Cigna

How data is fueling a new approach to whole person health

As Bob Dylan famously wrote, "... the times they are a-changin'." I would amend that slightly when it comes to today's health care ecosystem: the times they are a-changin', massively. When we consider the significant advances taking place in science and technology, we cannot be anything but optimistic about a future where better managing or even eradicating the high-cost, high-impact disease states, such as cancer, heart failure and diabetes, is a reality. Today we understand more about the underlying basis of disease than ever before and have the opportunity to apply targeted specialty therapies, personalized medicine and genomic therapeutics that dramatically improve how we care for the sickest of the sick. Over the next five years, this will improve even further. We now have powerful artificial intelligence (AI) tools and algorithms that enable a data-driven model of whole person population health. Data-based initiatives built around neuro-computing hold the promise to transform care even further.

Yet while we have access to data and analytics at scale, only about 50% of the care in this country is based on scientific evidence rather than a doctor's personal preferences and background. Sadly, cost does not equate to quality. While the US spends more per capita on health care than any other developed nation, our ranking on quality puts us near the bottom of the pack of industrialized countries.

We are seeing higher incidence of chronic and lifestyle-based disease, while the social determinants of health place underserved populations at the highest risk. Treatment still focuses on siloed episodes of care, rather than on holistic health and wellness.

Fortunately, our changin' times give us an opportunity to address these challenges. As both a public health professional and a tenured technologist, I fundamentally believe that technology and innovation hold much promise to improve the system through sustaining, disruptive and quantum innovation. Innovation can provide the interconnectivity, integration and intelligence to make real and meaningful improvements to the system. Most importantly, with more than 125 million Americans suffering from chronic illnesses, these innovations can improve the quality of life.

When we apply technology that connects consumers with care, and apply real-time insights and AI, we can move toward the "triple aim" of improving quality, managing affordability and optimizing the patient experience to ultimately deliver better health outcomes.

At Cigna, we are tackling these challenges today and in the process redefining health care for the better. Our mission is quite clear: to improve the health, well-being and peace of mind of those we serve. We are using data and analytics to make this a reality.

Our mission is quite clear: to improve the health, well-being and peace of mind of those we serve. We are using data and analytics to make this a reality.

Through the combination of Cigna and Express Scripts, we have access to longitudinal clinical data sources that are unmatched. For example, Cigna is using AI to predict whether patients might abuse or overdose on prescription opioids. Cigna's proprietary algorithms are saving lives and decreasing the health care costs for those patients.

Cigna has also developed a machine learning-enabled tool called One Guide that analyzes data from medical claims, medical procedures, biometric data, benefits and pharmacy claims to anticipate customer needs. For example, the tool can help identify customers that have not used financial incentives for annual checkups or free health coaching. The tool creates personalized messages for customers, who are then notified through the myCigna mobile app.

Other initiatives like Answers by Cigna, an AI-enabled chatbot available on our leading mobile search platform, use natural language processing to understand and respond to more than 150 common health and coverage questions with personalized information. This effort is not only driving engagement, but also leading to greater customer satisfaction.

One final example is Cigna's launch of the first AI-driven, end-to-end stress management solution. This is a completely new system where stress can be detected in real time using biometric measurements from a wearable device and a machine learning algorithm. We have developed a proprietary tool and set of measures that include facial movement emotional analysis, tone analysis and perceived stress score. Based on these insights, targeted interventions are introduced before stress impacts whole person health.

It is clear that health care now, and in the future, requires a different orientation, different investments and different skill sets. Health care leaders need to manage massive change; they need to be agile and flexible in their approach; and they require a portfolio of skills that balance health improvement and technology savviness, along with a keen eye for the discipline of data. The health care industry will experience ongoing change, from new government reform, globalization, groundbreaking drug development, delivery system consolidation and disruptive digital innovation. Cigna stands ready to tackle all of these challenges, and our data-first orientation holds the promise to change health care for the better.

Susan Tousi

Senior Vice President, Product Development, **Illumina**

The end of data for data's sake is now: driving the digital transformation of biology through the establishment of "the internet of genomics"

The software code of life

The human genome contains approximately three billion base pairs of DNA, which is housed within the depths of every one of your cells. Your genome is what makes you uniquely you, through the translation of the DNA code (genes) into proteins and other molecules that act throughout the body. Genomics is the study of those genes and what they do. Historically, the path to understanding the relationship between a gene and biology or disease was long and arduous, requiring highly complex laboratory work to find and map a few genes across a limited number of samples. Today's genomic revolution is powered by genome sequencing technology that reads your DNA – whether you are studying one gene or the entire genome – and can be instrumental in identifying everything from inherited disorders to characterizing genetic mutations that drive cancer progression and tracking disease outbreaks.

Accelerating in the generation of digital health data

The time is right to transform health care through genomic technology – a vision Illumina has already begun to realize with the launch of our NovaSeq 6000 System. It provides users with the throughput, speed and flexibility required to complete genome sequencing projects faster and more economically than ever before. To put that in perspective, while the first human genome sequence ever completed took a team of scientists roughly 10 years at a cost of nearly US$3 billion, each NovaSeq 6000 System can produce 48 high-quality whole human genome sequences in about two days, which means a single instrument can read more than 5,000 whole human genomes per year. This is the genomic revolution.

Previously, gene mapping efforts were so challenging and limited in size that an entire study could be managed in an Excel spreadsheet. Today, our products are now among the largest generators of data in the world, and that will continue to accelerate. For example, this year our customers will generate as much data each quarter as in all of 2016. Our sequencing platforms generate about 100 petabytes of data each year, which is about 25 times the size of today's entire Netflix catalog.

As a leader in genomic sequencing, we are leveraging our expertise in technology and data science to enable genomics to improve lives and change how health care is delivered. We understand better than anyone that this journey requires Illumina to continue to address cost and accessibility of genomic technology, but also to protect and standardize genomic data as a means to turn it into actionable and meaningful biological insights as quickly and as accurately as possible.

Integrating genomic data with other digital biology and clinical data is essential to drive the next wave of scientific breakthroughs and help develop the next generation of precision medicines.

We recognize that generating genomic data is only the first step in unlocking the mysteries of biology, health and disease. Integrating genomic data with other digital biology and clinical data is essential to drive the next wave of scientific breakthroughs and help develop the next generation of precision medicines. This requires a new model and software capabilities for biological data sharing and interoperability across the spectrum of basic, translational and clinical research. We must build the "Internet of Genomics" to connect these rich data streams, open up new analytical possibilities and usher in the era of digitized biology.

Software is like oxygen to life. It creates a lot of opportunity and a lot of applications. To power the next generation of scientific inquiries and insights from genomic data, our team is developing Illumina's Operating System (OS) to connect our smart sequencers to the internet, to each other and to our partners' applications. We believe that the Illumina OS, coupled to a connected infrastructure for genomic data exchange with the ability to bring in complementary partners' analysis applications, will lay the foundation for more integrated and accessible products to drive breakthrough scientific discoveries and health care applications.

Today, genomics is helping solve some of the most challenging problems of humankind and inspiring new hope for people around the world. We believe the Internet of Genomics has the capacity to connect genomic data and specialized analytics with personalized medical solutions, pharmaceutical drug development and much, much more, with the promise of insights to improve human health in a way that transcends all previous digital revolutions.

Abdul Hamid Halabi

Director of Healthcare, **NVIDIA**

The AI opportunity in health care

Higher quality care, faster care, personalized care for all — AI has the potential of changing the way health care is practiced. As the Director for Healthcare at NVIDIA, I work with an inspiring ecosystem of academics, startups, physicians and commercial partners who share the goal of bringing AI to the industry and who are enabling caregivers to add AI to the toolbox they use daily.

NVIDIA started in 1993 as a graphics company. The graphics processing unit (GPU) we created was and is used to enable amazing experiences in gaming. It turned out that graphics capability was also an ideal platform to enable faster computation in general. While a CPU can do a few tasks in parallel, a GPU can do many thousands. As a result, many supercomputers today are full of GPUs.

Starting in 2012, we saw a cascade of amazing deep learning innovation. It's a method of machine learning, but a unique one, enabled especially by GPUs. Our platform is really well-suited for it and we pounced on the opportunity. Deep learning based on neural networks was historically very difficult to execute because it required a lot of compute and time. We made it work for everybody.

The reason NVIDIA is uniquely positioned goes back to our history. We made a conscious decision more than 20 years ago to make sure that the interface of all NVIDIA GPUs would be the same. The involvement of NVIDIA in health care, specifically, started back with computation and simulation in life sciences: when you're simulating molecules in the body or trying to model the HIV capsid, it requires a lot of compute. As a result, scientists moved toward using the GPU.

On the medtech side, we were embedded from the beginning inside instruments like CT, MRI and ultrasound. Today, it's very difficult to come by a CT machine without multiple GPUs inside for image reconstruction. Real-time 3D ultrasound was only possible because that visualization inventory was moved to GPUs. The fact that we're inside all of these devices, inside data centers, that every cloud provider has GPUs, makes this platform ubiquitous.

I think of software development in general as automation. AI is the process of automating automation: taking something and making it create automation for itself. Where can this be used in health care? Automating certain tasks for the physician is something that's going to happen. We'll also increase quality of care by making sure there's a computer as a second opinion.

Some of the most exciting use cases today are in the imaging world: in genomics, to accelerate analysis and figure out mutations earlier; in drug discovery; and in EHR data, to understand patterns of patients and figure out best care pathways.

Another exciting area is intelligent instruments. NVIDIA has partnered with some of the leading instrument manufacturers to incorporate AI into their products. It's not only making

Higher quality care, faster care, personalized care for all — AI has the potential of changing the way health care is practiced.

these instruments smarter, faster and more reliable, but it is also making them more portable and mobile. Doctors don't have the capacity to give consultations around the world. AI can take their knowledge and transform it into tools that other physicians can use to expand access to care. With enough examples, the computer figures out things even you didn't know — that's the big revolution with deep learning.

To make AI work, the whole ecosystem has to get together, because it's a different way of doing business. Everybody needs to be involved, starting with the research community. Today, more than 70% of medical imaging research is using deep learning, and we work closely with this community using our AI platform. We also have about 400 health care startups we're working with closely on AI. Together, they've raised more than US$4 billion.

We work with the leading instrument manufacturers and leading societies like the American College of Radiology to help them build their AI platforms. We bring a unique perspective they like because of the diversity of the industries we work in and the fact that we can bring knowledge from other industries like autonomous vehicles, robotics and smart cities into health care.

We also built a consortium of amazing hospitals, including Massachusetts General Hospital, King's College London, Mayo Clinic and others, so that their doctors are able to contribute to the creation of these algorithms. And as we get into that regulatory side, the latest thing we did was deepen our partnership with the American College of Radiology. We formed a consortium with them and seven other hospitals to show that this is doable. We need the whole ecosystem to move together.

What I'm most excited about is the prospect of seeing the unseen; doing things we haven't done in the past, bringing sciences together so that we finally can actually provide the precision medicine that people need. There is an unbelievable opportunity for AI in health care.

Wende Hutton

General Partner,
Canaan Partners

EY: What do you see as the main characteristics of this investment climate at the moment within medtech?

Wende Hutton: There are probably three major themes in the medtech venture capital world. First, the venture community is somewhat more optimistic than it has been in the last four or five years, where medtech investing had moved out of favor. In the last 12 months there's been some rotation of venture capital back into medtech; some renewed optimism that there are opportunities in medtech.

Second, if you're a life sciences fund or investor, the returns profile — in terms of the number AND the scope of opportunities — we think still pales in comparison to biopharma.

Third, there is still a dearth of syndication partners because so many life sciences funds have permanently rotated out of the sector.

So, it is still a careful walk if you're an early-stage venture investor to find the right kind of opportunities with the right potential exit scenarios, with the right syndicate partners.

EY: What is it that's limiting the opportunities for early-stage medtech, from an investor's perspective?

Wende Hutton: The cycle of innovation has not just stood still; there are entrepreneurs and innovations occurring that need to be brought forward. There are still unmet clinical needs. What we look for is market opportunities that have the potential for worldwide crest at US$1 billion. Those are really hard to find in devices; by the time you've narrowed down a label to go to FDA, those US$500 million–US$1 billion revenue opportunities are few and far between.

Valuations have improved in this space, and that has made these companies more attractive. But two big issues still create significant headwinds when you're talking about series A or series B investment. First, the more innovative the technology — or the change in business model that technology might drive — the more you fall into new CPT codes, uncharted pathways on reimbursement. Which, by definition, still require a three- to four-year timeframe; we've been unable to re-engineer reimbursement in the same way we've re-engineered the regulatory side, in partnership with the FDA. To drive new codes with the AMA is very difficult and very expensive. After you get a new code, the timeframes to drive approval through Medicare, plans and insurers is a whole other cycle. For a small company that has a single product, this can be a five- or six-year timeframe. It is very protracted and very expensive. Overall, the reimbursement climate is very daunting.

Second, there are few exit opportunities on the acquisition side because of the consolidation in the industry. Most of the big strategic medtech players have been slow to use their balance sheets to buy companies before they see the reimbursement cycle being driven through that pipeline. That has made financial returns very difficult to achieve, because of the slow nature of the exits.

You can make really good money in medtech investing but it must be very selective to work around those two dynamics.

Companies that are at the forefront of interoperability are starting to take market share away from companies that are wedded to a proprietary siloed approach.

EY: Do you see much opportunity for digital health companies, and what challenges will they face in cutting through to the market?

Wende Hutton: We do think there's an opportunity for small companies to innovate in the digital health area. It is a very interesting opportunity and, certainly, a swim lane we stepped into with Glooko and Chrono Therapeutics. In an area dominated heavily by franchise players that have large market shares, what Glooko has done is partner up with several significant players in diabetes to solve providing patient device data efficiently to providers and patients. We're integrated with more than 170 devices. All those alliances and partnerships are with established players and the only way it's possible for a company like a Glooko to succeed in an area like diabetes and drive key insights for improved patient care.

One of the interesting dynamics in medical devices overall is that it used to be possible, 10 to 15 years ago that a startup could hire a direct sales force, go into the hospital or the clinic and sell. With the consolidation, distribution has become much more challenging. And the provider side has put up value-added technology assessment committees, so you also have to get through that barrier; you're now dealing with HIPAA compliance, and cannot always go elbow to elbow with the surgeon in the OR to train and discuss and determine if this device is appropriate for their practice. A startup can't deploy 10 reps against 400 reps and ever hope to gain access to that conversation. Hospitals have put hurdles in the road that have made it very difficult for innovators to get access to physicians.

EY: You mention Glooko being integrated with many other devices. How important will interoperability be for medtech in future, and have the leading medtechs been slow to push for interoperable systems?

Wende Hutton: They're very steeped in a tradition of proprietary silos. Where the industry has come from is: if I can put a proprietary three-pronged plug in a connector, I will make that unable to be accessed by anyone unless they buy my proprietary device. That's a mind-set that is very embedded.

On the positive side, a company like Dexcom or Insulet has decided to get in front by saying our physician customers really do want interoperability of device data and want to enable patients sharing what's coming off the continuous glucose monitoring or pump. They're very partnership-oriented and focused on the need to integrate into the flow of devices. Companies that are at the forefront of interoperability are starting to take market share away from companies that are wedded to a proprietary siloed approach.

Interoperability is also where physicians who are at the forefront of quality metrics and quality outcomes for improved care want to drive the integrated delivery system. So, if we, the industry side, are trying to address what leading clinicians need, we need to provide this interoperability, provide data off of connected devices and give clinicians that data in a format they can use seamlessly. The health care system can only benefit from a frictionless way to access useful, real-world patient data.

Databook

“

2018’s 7% revenue growth was the highest since the financial crisis, though still well below the pre-crisis average of nearly 15%.

FINANCIAL PERFORMANCE

Medical technology at a glance

(US$ billion, data for pure-plays except where indicated)

Public company data	2018	2017	Change	% change
Revenues	$ 407.1	$ 379.7	$ 27.3	**7%**
Conglomerates	$ 171.9	$ 163.6	$ 8.3	**5%**
Pure-play companies	$ 235.1	$ 216.1	$ 19.1	**9%**
Commercial leaders	$ 217.6	$ 199.0	$ 18.6	**9%**
Noncommercial leaders	$ 17.6	$ 17.1	$ 0.4	**2%**
R&D expense	$ 17.8	$ 15.9	$ 1.8	**11%**
SG&A expense	$ 82.6	$ 72.5	$ 10.0	**14%**
Net income	$ 20.3	$ 15.0	$ 5.3	**36%**
Market capitalization	$ 1,056.7	$ 927.5	$ 129.3	**14%**
Number of employees	857,900	809,700	48,200	**6%**
Number of public companies	446	427	19	**4%**

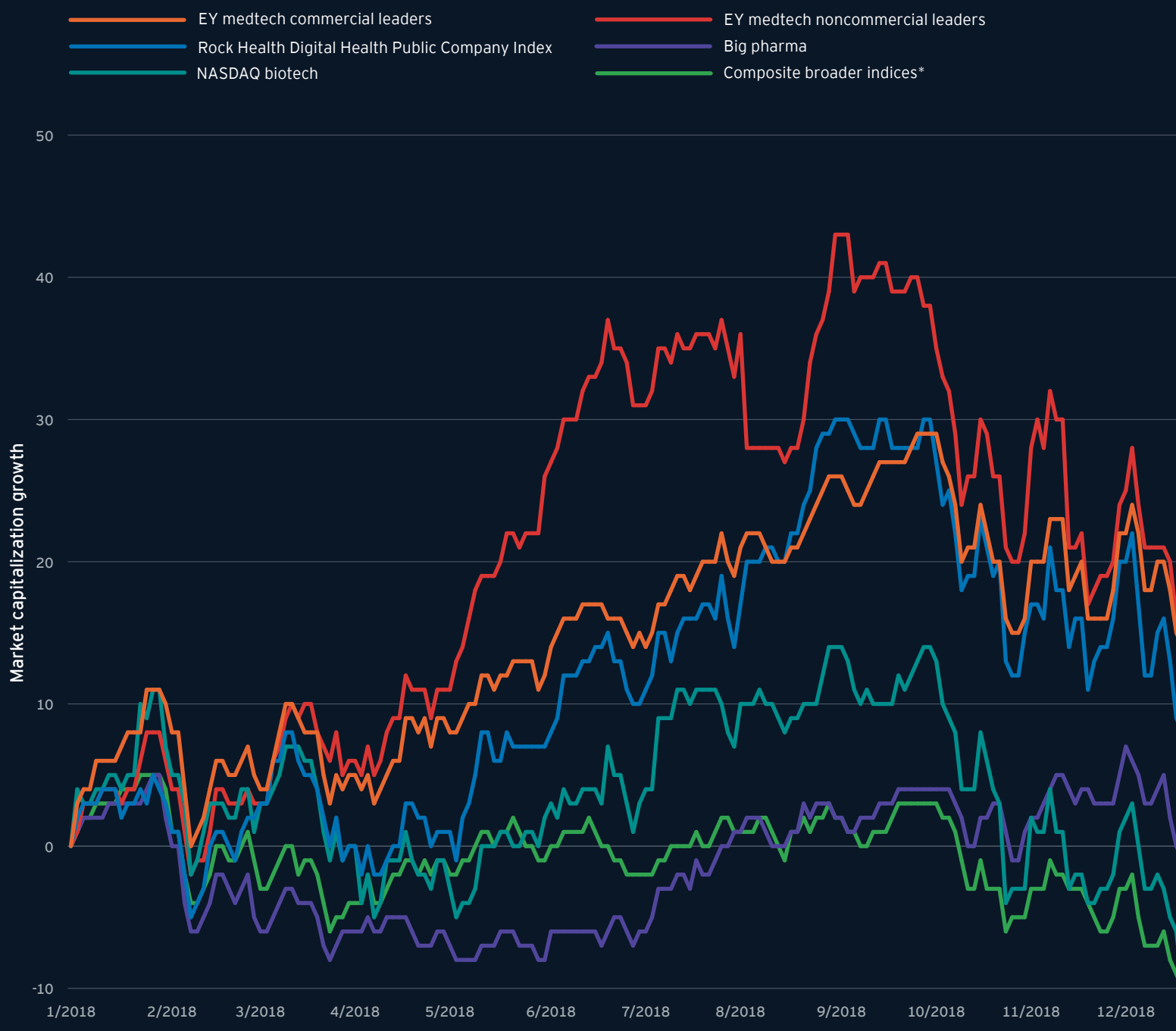
Source: EY, Capital IQ and company financial statement data.
Numbers may appear to be inconsistent due to rounding.
Data shown for US and European public companies.
Market capitalization data is shown for 31 December 2018 and 31 December 2017.

Positive revenue, income and R&D performance

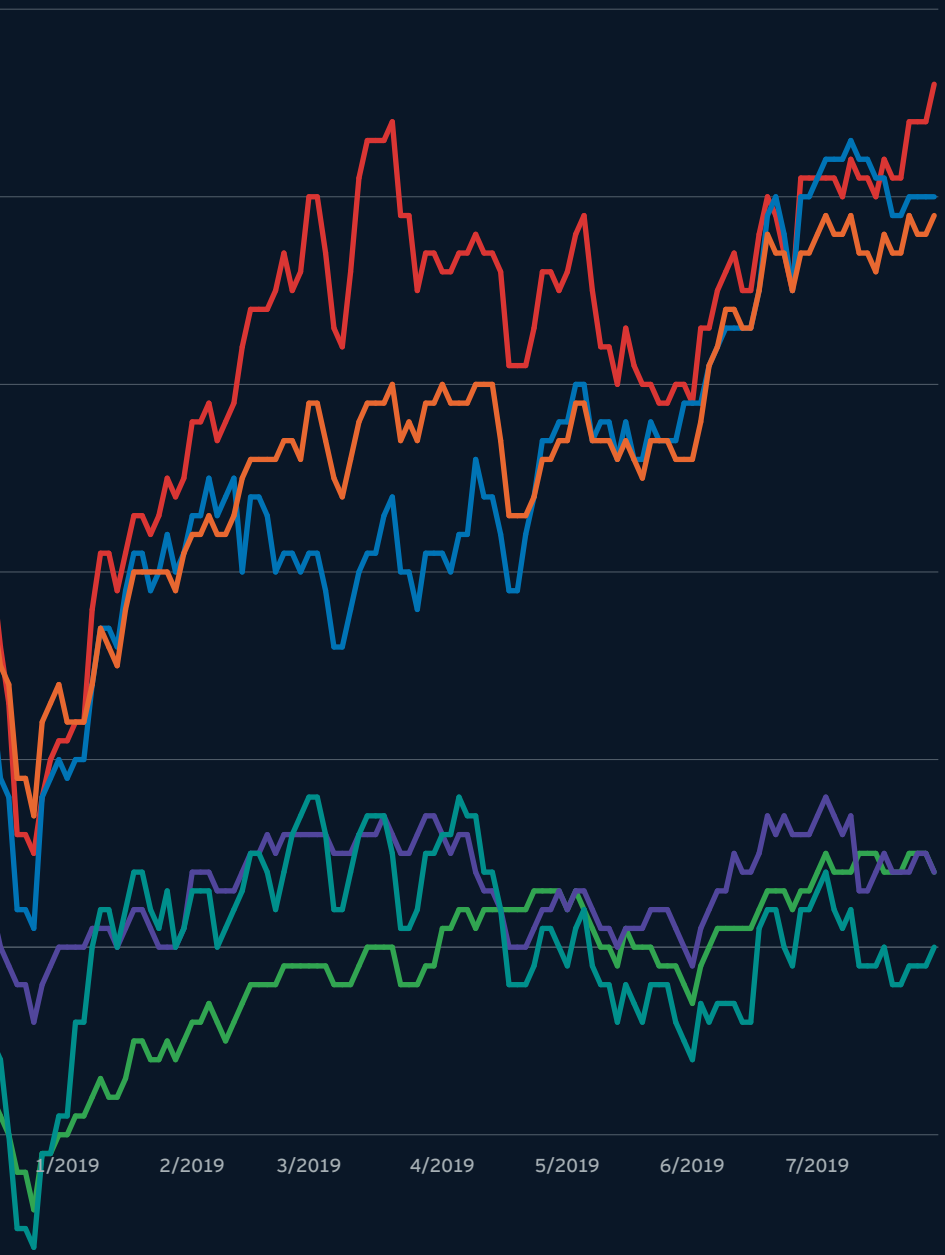
- 2018's 7% revenue growth was the highest since the financial crisis, though still well below the pre-crisis average of nearly 15%.
- Net income surged 36%, driven by increases of more than US$1 biilion for Stryker, Medtronic and Boston Scientific. However, nearly all of the gains were the result of tax benefits, divestiture adjustments, adjustments to foreign currency and other one-time charges. Without these one-time events, net income growth would have been in the low-to-mid single digits.
- Though medtech returned more cash to shareholders than it invested in R&D in 2018, R&D spending still grew 11% compared with 2017. Top leaders in total R&D growth spending included Thermo Fisher Scientific (driven by previous M&As), as well as Intuitive Surgical and Edwards Lifesciences, two organizations that have invested heavily in their respective robotic surgical and cardiovascular-focused technologies.

FINANCIAL PERFORMANCE

US and European medtech market capitalization relative to leading indices



Source: EY and Capital IQ.
Charts includes companies that were active on 31 July 2019.
*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.



Medtech and digital health valuations outperform other life sciences sectors

- Despite concerns about its investment in future growth, medtech has continued to attract investor attention with the industry's cumulative public valuation soaring 38% since the beginning of 2018.
- Medtech's valuation growth surpassed that of both biotech (-1%) and big pharma (4%) and easily outpaced the broader US and European indices (3%). Digital health company valuations grew at essentially the same pace (39%) as medtech.
- Investors' positive view of medtech is likely to be informed by a number of factors, including the relative lack of political pressure on medical device pricing (by contrast to the tensions in the ongoing biopharmaceutical pricing debate). Fundamentally, investors recognize that connected devices and the data they produce will be critical for the consumer driven, value-based health ecosystem of the future.

FINANCIAL PERFORMANCE

Top 10 changes in market capitalizations, H2 2014–H1 2019 (US$ million)

Company	Market cap 30 June 2019	Market cap 1 July 2014	Market cap change	CAGR
Thermo Fisher Scientific*	117,466	47,458	**70,009**	20%
Medtronic*	130,615	63,639	**66,976**	15%
Intuitive Surgical	60,559	15,611	**44,948**	31%
Becton Dickinson*	67,975	23,142	**44,833**	24%
Stryker	76,703	32,413	**44,290**	19%
Boston Scientific	59,770	17,182	**42,589**	28%
Essilor International*	56,797	22,491	**34,306**	20%
Illumina	54,118	23,459	**30,659**	18%
Edwards Lifesciences	38,519	9,193	**29,326**	33%
Align Technology	21,897	4,683	**17,215**	36%

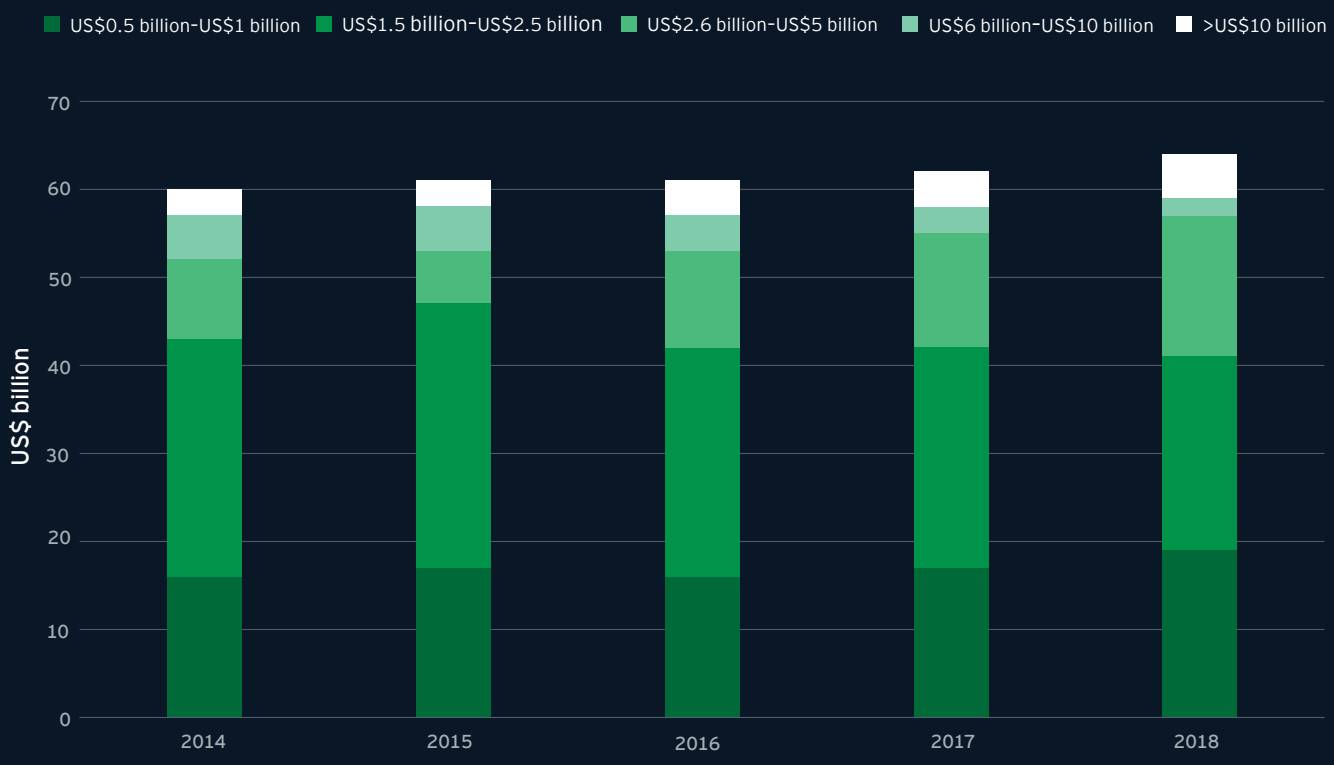
Source: EY, Capital IQ and company financial statement data.

Big acquisitions drive bulk of major market cap changes

- Significant acquisitions helped spur three of the four largest gains in companies' market capitalizations in the past years.
- Thermo Fisher Scientific had the largest value change in market cap as of June 2019; its capitalization increase was driven by a combination of acquisitions, especially the 2017 acquisition of Patheon for US$7.2 billion, and organic growth. Medtronic (Covidien in 2015) and Becton Dickinson (CR Bard in 2017) market values grew thanks to megadeals.
- Powered by the continued strength of its da Vinci Surgical System, Intuitive Surgical enjoyed the largest organic growth (US$45 billion) among all medtechs. While the market for robotic surgical systems is expected to significantly expand over the next decade, competition among peers is also expected to increase as medtech majors such as Johnson & Johnson and Medtronic enter the space via acquisitions.

FINANCIAL PERFORMANCE

US and European commercial leaders



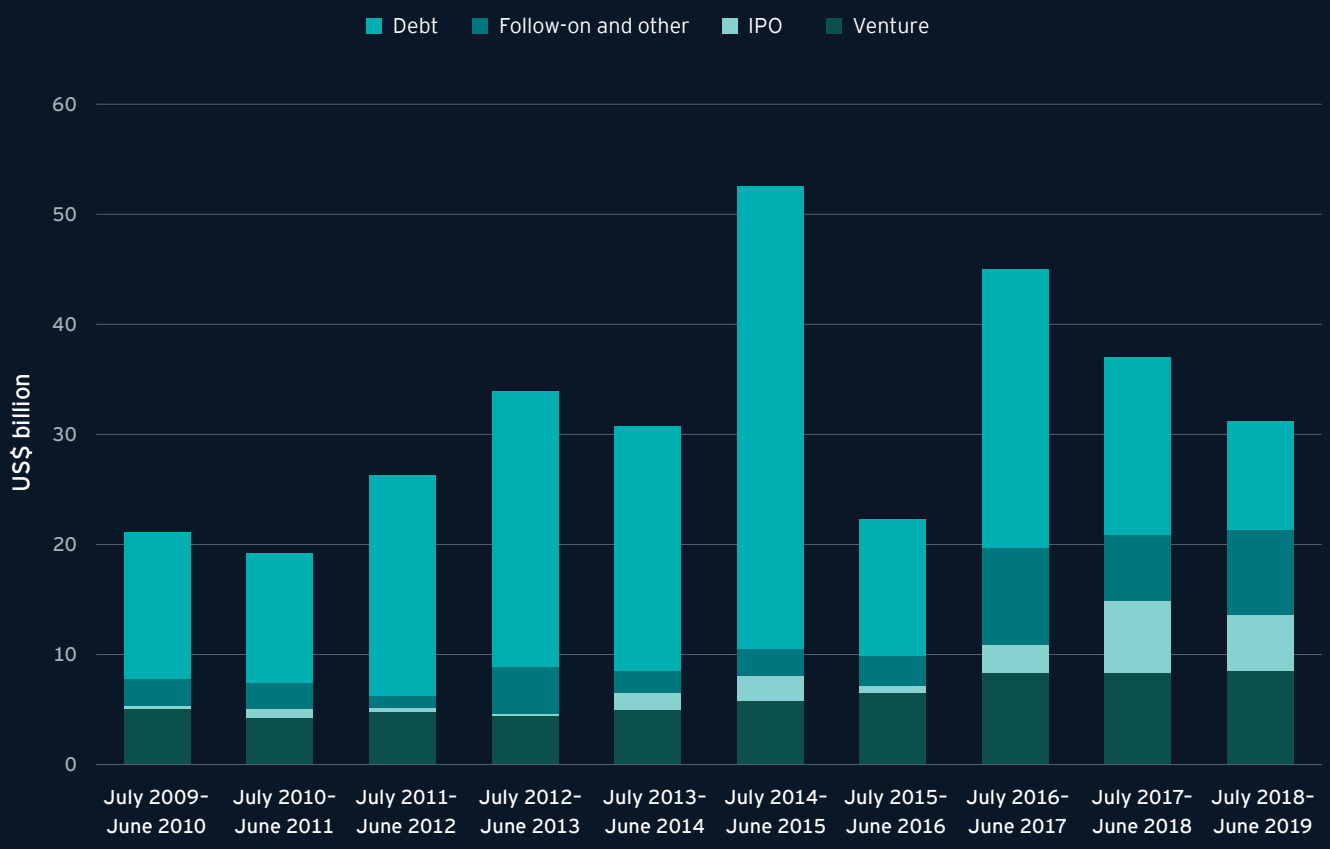
Source: EY, Capital IQ and company financial statement data.
Commercial leaders are pure-play companies with revenues in excess of US$500 million.

Increased number of commercial leaders drive revenue growth

- There were 64 commercial leaders in US and European medtech in 2018, up from 62 in 2017, despite Becton Dickinson's acquisition of CR Bard. The continued maturation of the industry is good news for younger medtechs that rely on more established counterparts for exits and financings.
- Pure-play companies outperformed conglomerates, with revenue increases of 9% vs. 5%. Commercial leaders accounted for nearly two-thirds of medtech's total revenue growth of US$27 billion.
- Essilor became the fifth medtech to amass more than US$10 billion in annual revenues, following its acquisition of Luxxotica, while Thermo Fisher Scientific joined Medtronic and Johnson & Johnson in passing the US$20 billion revenue marker.
- Cardiac implant company, Abiomed, and Insulet, maker of the Omnipod diabetes platform, appear among the commercial leaders for the first time this year through strong organic growth. Diagnostic health care manufacturer, Quidel, which acquired Alere's rapid diagnostic testing solutions in 2018, also joined the list, posting an 88% year-over-year increase in revenue growth. In all, these three newcomers contributed just 9% of the commercial leaders' total revenue growth of US$18.6 billion.

FINANCING

Capital raised in the US and Europe by year



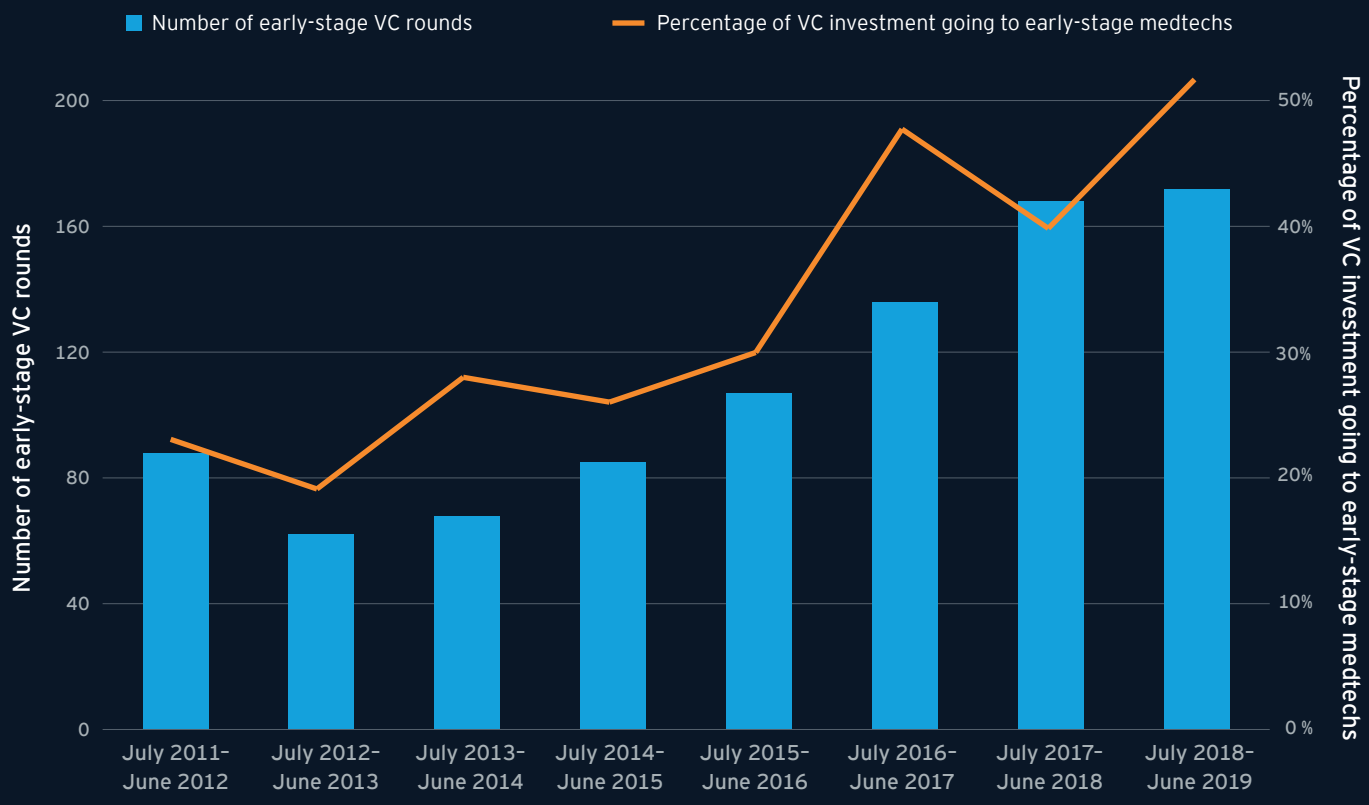
Source: EY, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.
Numbers may appear to be inconsistent because of rounding. Private investments in public equity (PIPEs) included in "follow-on and other."

Venture investment reaches record levels, but overall financing falls

- Total industry financing fell for the second year running, down 15% to US$31.3 billion, below the aggregate average of US$37.5 billion from the previous five years; innovation capital (capital raised by companies with less than US$500 million in sales) slipped 13%, to US$18.9 billion. However, this total accounted for 60% of the total financing, the highest percentage in at least a decade.
- The decline in total financing was largely the result of a 38% decrease in debt offerings. The US$10 billion raised in debt was the lowest in at least a decade, and well under the US$20.9 billion annual average seen during that same period. While large M&A have been behind a significant portion of debt activity the past several years, there was also a significant drop of small debt offerings this past year. The number of debt offerings greater than US$250 million dropped from 18 in both 2016-17 and 2017-18 to just 5 in 2018-19. With borrowing rates still hovering near historic lows, was this drop an early warning sign of a cooling off period, or will it merely be a one-year anomaly?
- On the positive side, venture investment inched up 2% to a record US$8.5 billion, while public follow-on financing levels increased 27% to US$7.7 billion, as the number of US$100 million follow-ons jumped from 9 to 13 year-over-year. Even the 21% drop in IPO values had a silver lining.
- US medtechs accounted for 87% of the total US and European financing, up from 73% over the previous 12-month period.

FINANCING

US and European early-stage VC rounds >US$5 million



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

Early-stage venture capital surges

- While total venture capital funding only grew by 2%, early-stage venture financing skyrocketed 33% to US$4.4 billion; the number of early-stage VC rounds also reached at least a 10-year high of 172, up from 168 the year before, and a decade average of 96.
- In all, 52% of all venture dollars went to early-stage investment, up from 40% the year before; the 52% is also at least a decade-long high, as the cumulative average was 31%.
- Outside of the "other" category (24%), non-imaging diagnostic companies once again attracted the most amount of early-stage capital (22% of total), followed by imaging (15%), and therapeutic devices – cardiovascular/vascular (7%).

FINANCING

Top US and European venture rounds, July 2018–June 2019

Company	Region	Product type (disease)	Gross raised (US$ million)	Quarter	Round type
Verily Life Sciences	US-Northern California	Other	1,000	Q1 2019	Early stage
SmileDirectClub	US-Tennessee	Therapeutic devices (dental)	380	Q4 2018	Early stage
Butterfly Network	US-Connecticut	Imaging	250	Q3 2018	Early stage
Auris Health	US-Northern California	Therapeutic devices (oncology)	220	Q4 2018	Late stage
Outset Medical	US-Northern California	Therapeutic devices (hematology/renal)	132	Q3 2018	Late stage
Thrive Earlier Detection	US-Massachusetts	Non-imaging diagnostics	110	Q2 2019	Early stage
Click Diagnostics	US-Northern California	Non-imaging diagnostics	101	Q2 2019	Late stage
Acutus Medical	US-Southern California	Therapeutic devices (cardiovascular/vascular)	100	Q2 2019	Late stage
GC Aesthetics	Ireland	Therapeutic devices (aesthetics)	97	Q4 2018	Late stage
EarLens	US-Northern California	Therapeutic devices (ear, nose and throat)	87	Q4 2018	Late stage
uBiome	US-Northern California	Non-imaging diagnostics	83	Q3 2018	Late stage
Nuvaira	US-Minnesota	Therapeutic devices (respiratory)	79	Q1 2019	Late stage
Ablative Solutions	US-Northern California	Therapeutic devices (cardiovascular/vascular)	77	Q1 2019	Late stage
Gynesonics	US-Northern California	Therapeutic devices (women's health)	75	Q1 2019	Late stage
NorthStar Medical Radioisotopes	US-Wisconsin	Imaging	75	Q2 2019	Early stage
BioSerenity	France	Non-imaging diagnostics	73	Q2 2019	Early stage
MeMed Diagnostic	Israel	Non-imaging diagnostics	70	Q3 2018	Late stage

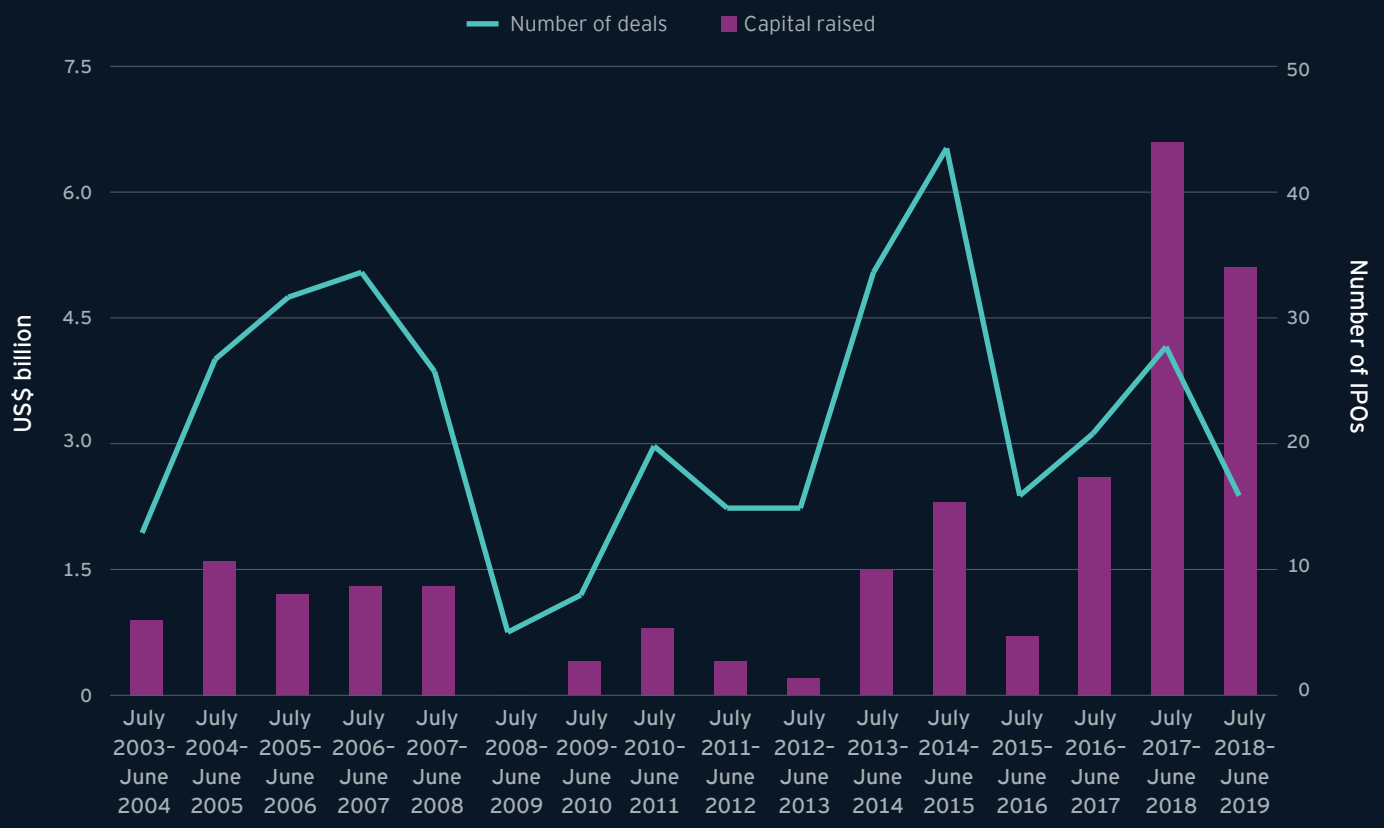
Source: EY, Dow Jones VentureSource and Capital IQ.

Tech giant leads venture financing rounds

- Imaging and non-imaging diagnostics accounted for 7 of the top 15 funding rounds in the US and Europe, signaling the growing focus on data capture and personalization.
- Verily Life Sciences, the life sciences arm of Alphabet, raised US$1 billion in fresh capital from private equity firm Silver Lake and other investors. The round was the largest VC round, affirming the continued high potential for technology entrants into the medtech space. This latest round comes two years after Singapore-based Temasek invested US$800 million in Verily. Verily maintains partnerships across the health and life sciences sector in areas ranging from diabetes management to surgical robotics. The company often provides the technical talent, while counterparts in health care bring clinical research and regulatory expertise.
- The cardiovascular therapeutic area led the therapeutic devices segment in terms of number (66) and value (US$798 million) of venture capital deals this year, though only Acutus Medical and Ablative Solutions, which both develop ablation systems for hypertension, garnered enough to make the leader board.

FINANCING

US and European medical technology IPOs



Source: EY, BMO Capital Markets and Capital IQ.

Smaller IPO class attracts significant amount of capital

- Although the total value of IPOs fell 21%, the US$5.1 billion raised in 2018-19 was still the second highest IPO value in the past decade.
- Of the US$6.5 billion raised in 2017-18, US$5.2 billion (80%) was generated by the Siemens Healthineers IPO; discounting both the Siemens offering and Avantor's US$3.3 billion IPO this year, 2018-19's US$1.8 billion total surpassed that of 2017-18 (US$1.3 billion), as well the US$1.1 billion average over the previous 15 years.
- The total number of IPOs dropped from 28 to 16 – the lowest figure in five years; however, the average size of US$120 million (even when omitting Avantor) was the second highest in at least 15 years.
- Every US medtech's IPO either priced within or above its expected price range. These accurate valuations and the high number of exercised overallotments were signals of strength for these companies and their investors.

FINANCING

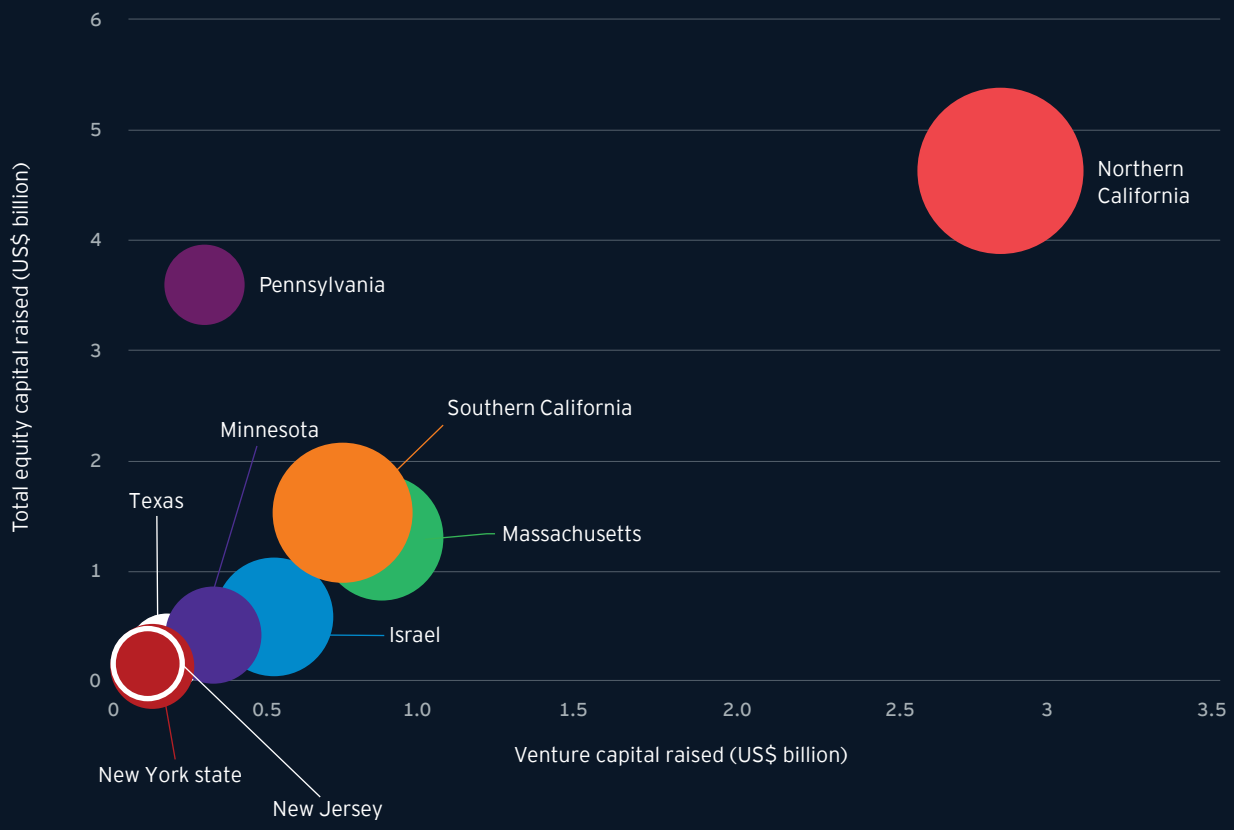
US and European IPOs, July 2018–June 2019

Company	Ticker	Region	Product type (disease)	Gross raised (US$ million)	Quarter
Avantor	AVTR	US-Pennsylvania	Research and other equipment	3,333	Q2 2019
Medacta	MOVE	Switzerland	Therapeutic devices (orthopedic)	590	Q2 2019
Guardant Health	GH	US-Northern California	Non-imaging diagnostics	273	Q4 2018
Silk Road Medical	SILK	US-Northern California	Therapeutic devices (cardiovascular/vascular)	138	Q2 2019
Axonics Modulation Technologies	AXNX	US-Southern California	Therapeutic devices (urology/pelvic)	138	Q4 2018
SI-BONE	SIBN	US-Northern California	Therapeutic devices (orthopedic)	124	Q4 2018
ShockWave Medical	SWAV	US-Northern California	Therapeutic devices (cardiovascular/vascular)	111	Q1 2019
TransMedics Group	TMDX	US-Massachusetts	Other	105	Q2 2019
Ra Medical Systems	RMED	US-Southern California	Therapeutic devices (multiple)	76	Q3 2018
Avedro	AVDR	US-Massachusetts	Therapeutic devices (ophthalmic)	70	Q1 2019
Vapotherm	VAPO	US-New Hampshire	Therapeutic devices (respiratory)	64	Q4 2018
Sequana Medical	SEQUA	Belgium	Therapeutic devices (multiple)	31	Q1 2019
Bionano Genomics	BNGOU	US-Southern California	Research and other equipment	21	Q3 2018
OssDsign	OSSD	Sweden	Therapeutic devices (orthopedic)	16	Q2 2019
NeoDynamics	NEOD	Sweden	Non-imaging diagnostics	6	Q4 2018
S2Medical	S2M	Sweden	Therapeutic devices (multiple)	4	Q4 2018

Source: EY, BMO Capital Markets and Capital IQ.

FINANCING

Capital raised by leading US regions excluding debt, July 2018–June 2019



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

California and Massachusetts still dominate medtech venture capital

- Northern California again dominated the financing landscape in terms of total rounds (120), total equity raised (US$4.6 billion) and total venture raised (US$2.8 billion).
- As in previous years, Massachusetts (US$812 million) and Southern California (US$687 million) were a distant second and third, respectively, in venture capital raised, while Israel once again achieved the top spot in Europe with US$468 million.
- Driven by the US$3.3 billion Avantor IPO, Pennsylvania raised the second highest total financing (US$3.6 billion), followed by Southern California (US$1.5 billion).
- Swiss-based companies led total financing in Europe with US$840 million.

Select US and European M&As, July 2018–June 2019

Acquiring company	Location	Acquired company	Location	Value (US$ million)	Buyer's deal driver
Danaher	US-District of Columbia	GE Healthcare (biopharma division)	US-Massachusetts	21,400	Build scale (research and other equipment)
3M: Health Care	US-Minnesota	Acelity	US-Texas	6,725	Build scale (wound care)
Johnson & Johnson (Ethicon)	US-Ohio	Auris Health	US-California	5,750	Diversification (surgical robotics)
Boston Scientific	US-Massachusetts	BTG	UK	4,240	Build scale (cardiovascular/vascular)
Colfax	US-Maryland	DJO Global	US-California	3,150	Diversification (orthopedic)
Grifols	Spain	Grifols Diagnostic Solutions	US-California	1,930	Geographic expansion (hematology/renal)
Medtronic	Ireland	Mazor Robotics	Israel	1,700	Diversification (surgical robotics)
Thermo Fisher Scientific	US-Massachusetts	Brammer Bio	US-Massachusetts	1,700	Build scale (services)
Stryker	US-Michigan	K2M	US-Virginia	1,400	Build scale (orthopedic)
Illumina	US-California	Pacific Biosciences	US-California	1,200	Build scale (research and other equipment)
Astorg Partners	France	Nemera	France	1,150	Diversification (non-disease specific)
PHC Holdings	Japan	Thermo Fisher Scientific (pathology business)	US-Massachusetts	1,140	Diversification (research and other equipment)
ResMed	US-California	MatrixCare	US-Minnesota	750	Build scale (health IT)
Smith & Nephew	UK	Osiris Therapeutics	US-Maryland	659	Build scale (regenerative medicine)
Amplifon	UK	GAES Group	Spain	617	Build scale and geographic expansion (ENT)

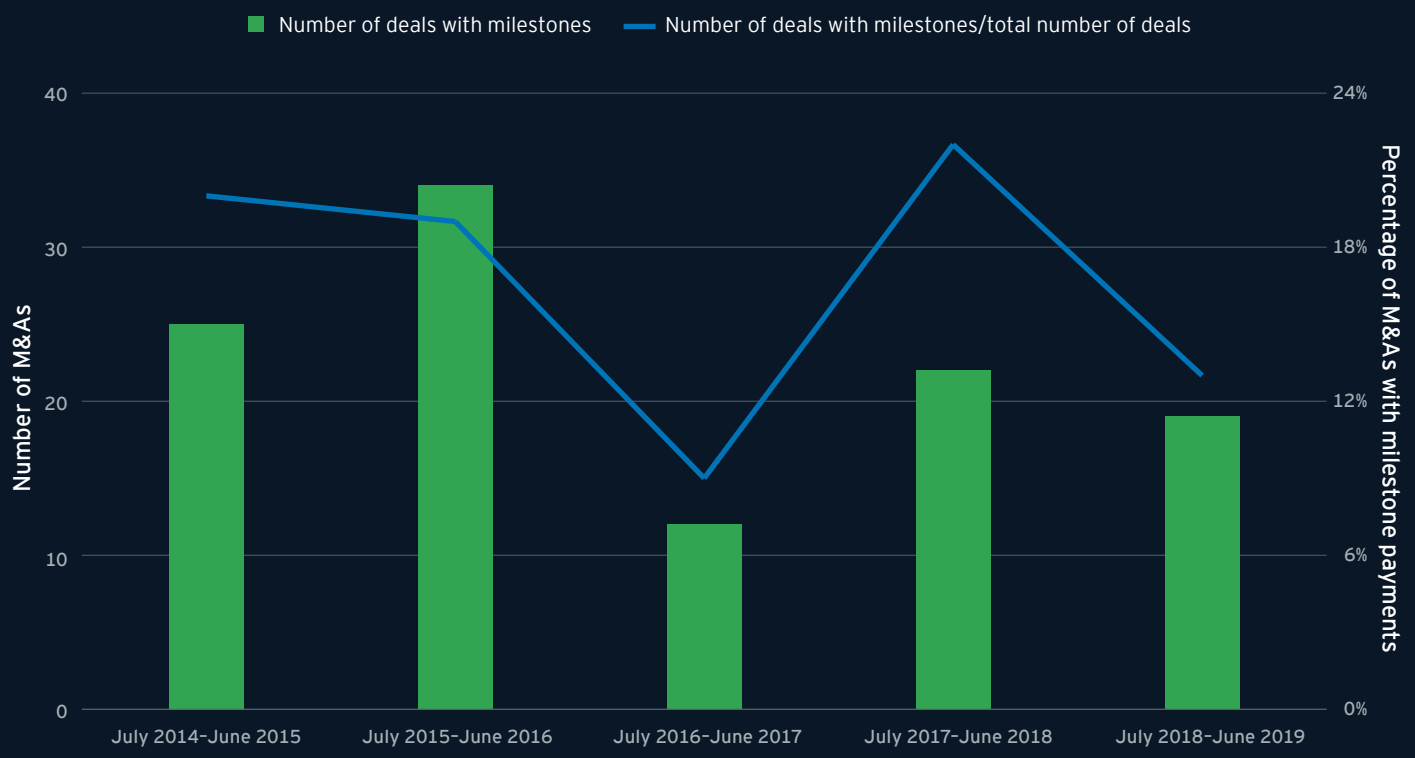
Source: EY, Capital IQ and Thomson ONE.

Assets beyond therapeutic devices were highly targeted

- GE Healthcare's Biopharma portfolio of instruments, consumables and software, which support the research, discovery, process development and manufacturing workflows of biopharmaceutical drugs, aligned with Danaher's long-held goal of increasing recurring revenue in life sciences. The February 2019 deal was the year's largest to date and illustrates the importance of placing strategic bets. In an effort to further optimize their portfolio, Danaher also announced the eventual spin-out and IPO of Envista, a collection of three existing dental businesses.
- Sixty percent of the year's largest M&As targeted assets outside of the traditional therapeutic device focus, including companies focused on surgical robotics, life sciences tools, services and health IT.
- Both Johnson & Johnson and Medtronic were just the latest companies making substantial investments in surgical robotics with their respective acquisitions of Auris Health and Mazor Robotics. Johnson & Johnson also purchased French Surgical surgery company Orthotaxy in February 2019, and continues its partnership with Verily Life Sciences on Verb Surgical. Both J&J and Medtronic are attempting to close the gap with other players like Intuitive Surgical and Stryker.
- Boston Scientific was the most active acquirer, announcing seven transactions valued at US$6.4 billion. These deals spanned assets in the cardiovascular/vascular, oncology and orthopaedic fields and solidified the company's foothold in these spaces.
- Led by 3M's purchase of Acelity (private consortium led by Apax Partners), private equity was once again active in 2018-19. Four of the top 12 deals (US$12.1 billion) involved a PE as either a buyer or a seller.

M&A

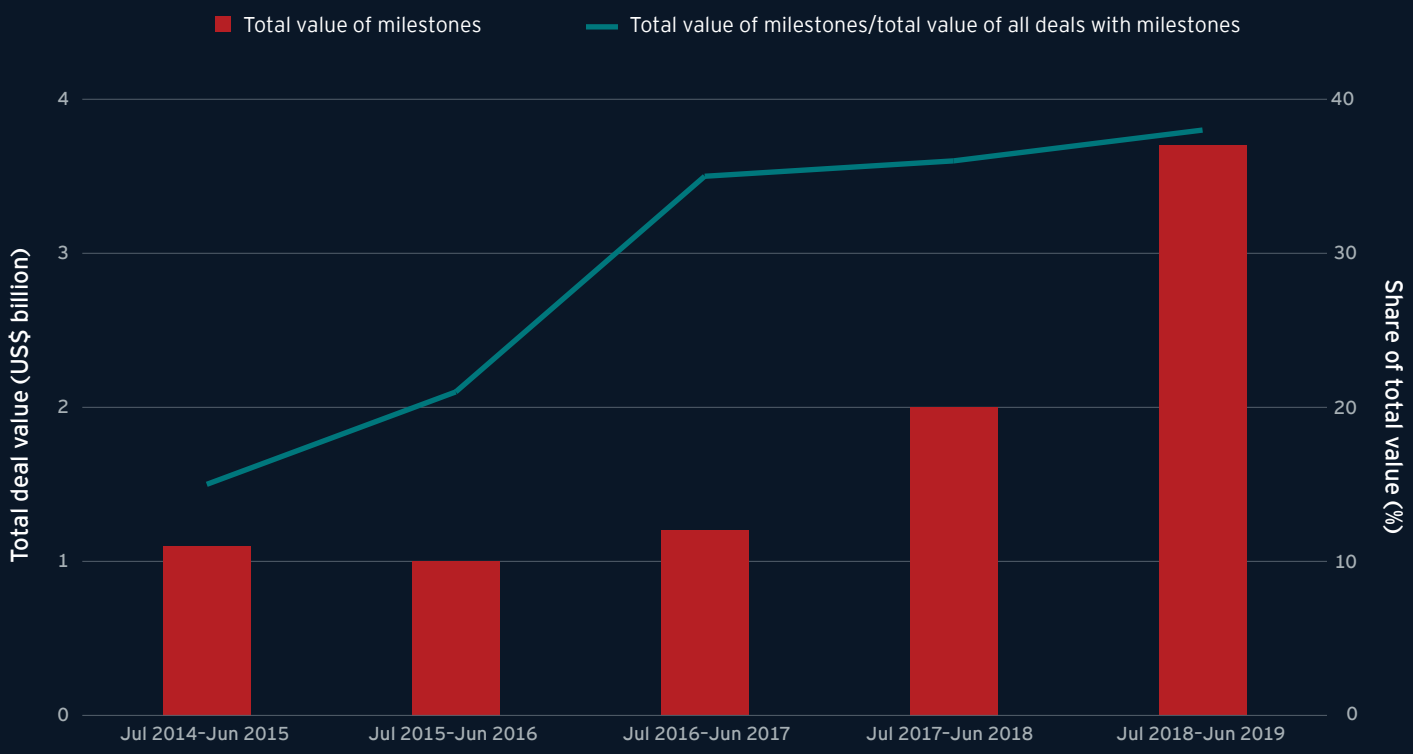
Milestone payments in US and European medtech M&A



Source: EY, Capital IQ and Thomson ONE.

M&A

Milestone share in US and European medtech M&A



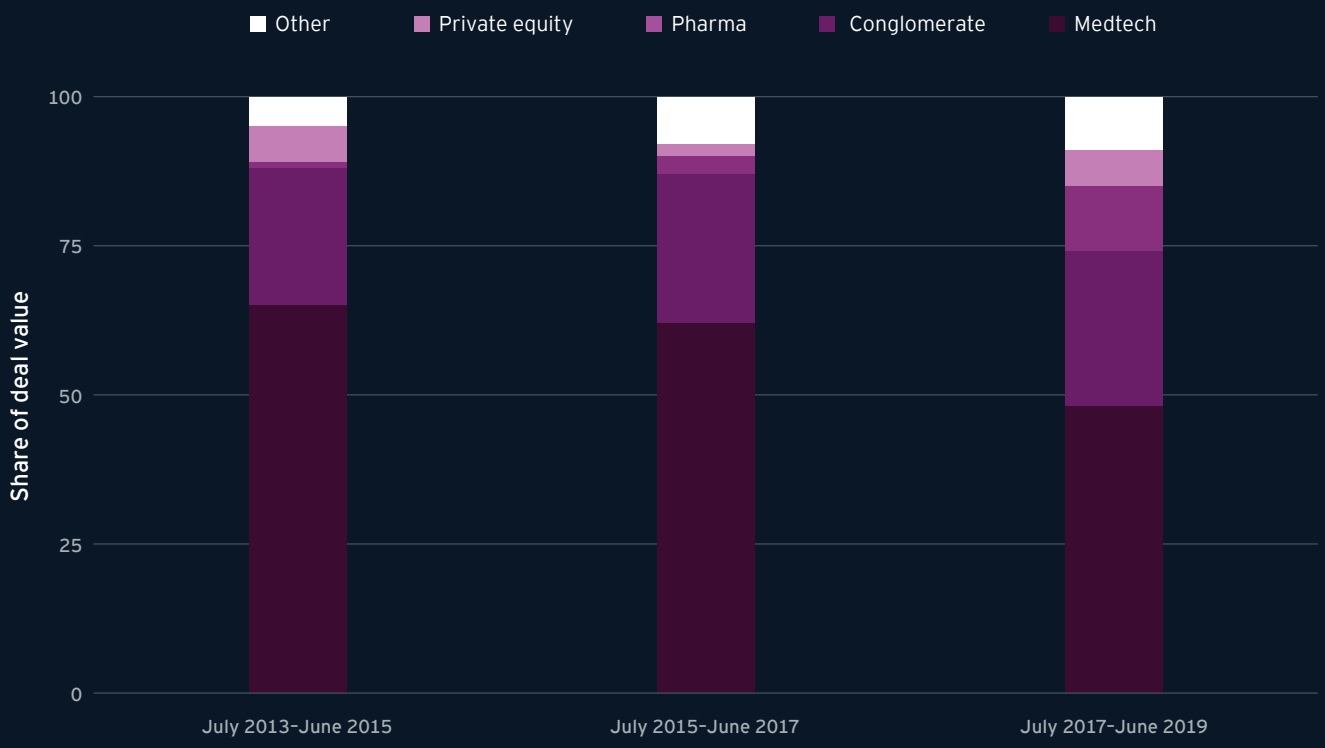
Source: EY, Capital IQ and Thomson ONE.

Milestone values soar in medtech deals

- Milestone-driven deals were less prominent in 2018-19 than in years past when analyzed by deal number (19 vs. 23) and as a percentage of all deals (13% vs. 17%).
- Mainly driven by Johnson & Johnson's (Ethicon) acquisition of Auris Health (US$2.35 billion potential milestone), the total amount of milestones increased 81% in 2018-19 to US$3.7 billion, the highest in at least five years.
- Excluding the Johnson & Johnson/Auris Health transaction, average potential milestones for medtech deals were US$74 million, below the US$97 million average seen the previous two years.

M&A

US and European M&A by type of buyer

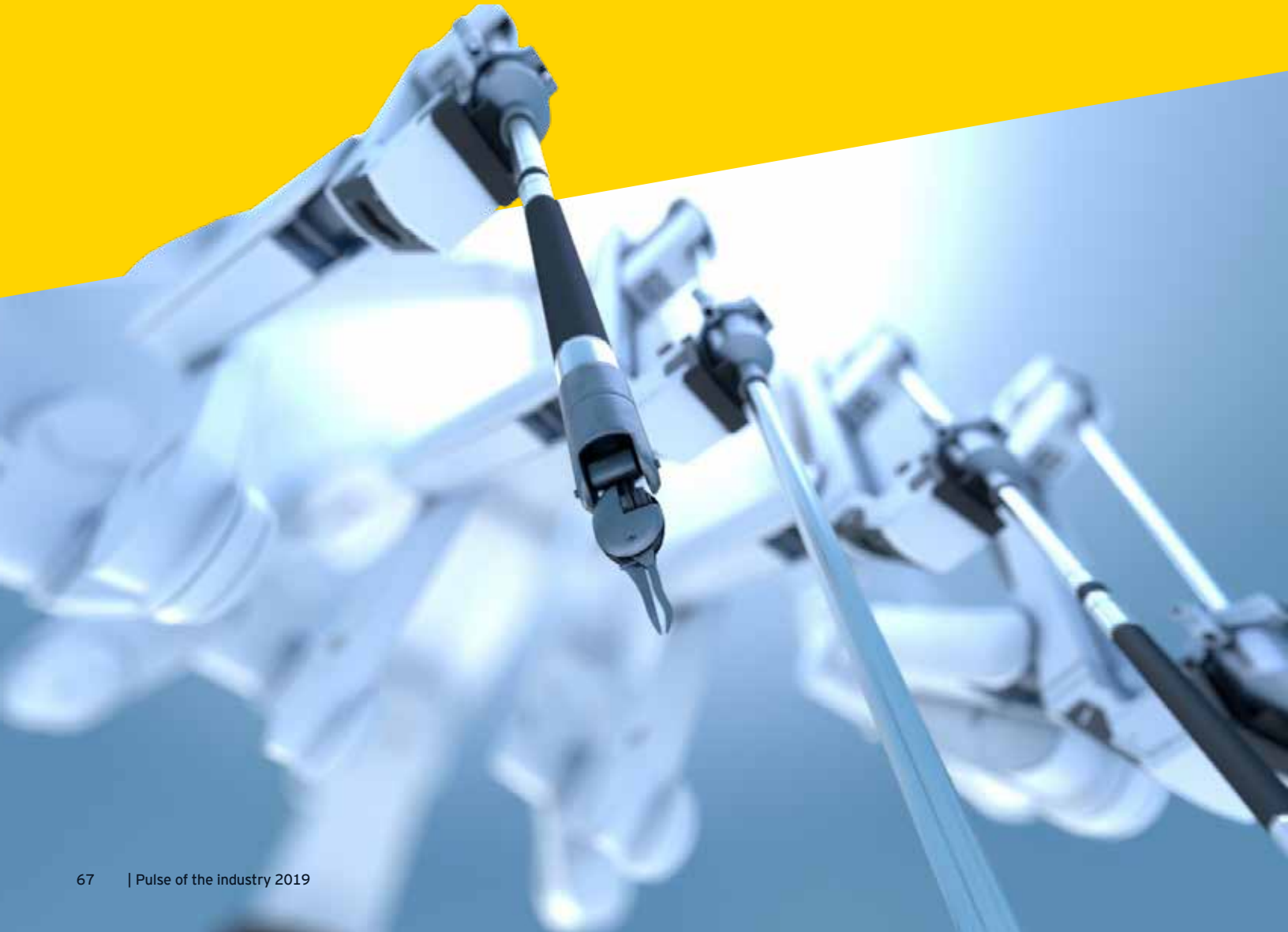


Source: EY, Capital IQ and Thomson ONE.

With medtech buyers reluctant, PE and pharma step in

- The past two years have witnessed the continuing diversification of medtech M&A buyers; pure-play medtechs represented only 45% of the total deal value, down from 62% in the previous two-year period.
- With medtechs reluctant to acquire, private equity has returned to fill the gap, funding nearly 8% (US$8.4 billion) of deals. PE buyers featured in 3 of the year's largest 12 deals.
- Pharma companies were also major buyers, accounting for 11% of the year's M&A deals as measured by deal value. From July 2015-June 2017, pharma buyers were responsible for 3% of medtech deal spending and just 1% from July 2013 to June 2015.
- In all, 30% of the total M&A value came from buyers outside the medtech sector (traditional pure-play or conglomerate).

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 (CT) 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 drug delivery/infusion technologies
- **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 Allergan 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 analysis tracks the digital alliances and acquisitions signed by leading pure-play and conglomerate medtechs by therapeutic area, technology capability (e.g., sensors or artificial intelligence) and strategic purpose. Direct investments by medtechs in digital health companies have been excluded from this analysis.

Conglomerate companies

United States

- 3M: Health Care
- Abbott: Diagnostic, Cardiovascular, Neuromodulation and Other
- Agilent Technologies: Life Sciences & Applied Markets and Diagnostics & Genomics
- Baxter International: Renal Care, Medication Delivery and Advanced Surgery
- Corning: Life Sciences
- Danaher: Life Sciences, Diagnostics and Dental
- General Electric: GE Healthcare
- IDEX: 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
- Novartis: Alcon Surgical
- Royal Philips: Philips Healthcare
- Lumibird Group: Quantel Medical
- Roche: Roche Diagnostics
- Sanofi: Genzyme Biosurgery
- Semperit: Sempermed
- Siemens: Siemens Healthineers
- Smiths Group: Smiths Medical

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Rajni Sadana, Health Sciences & Wellness Analyst, wrote "Robotic surgery: an emerging battleground" and "Acquisitions and innovation in the Asia-Pacific market."

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

Ellen Licking, Health Sciences & Wellness Lead Analyst, served as managing editor.

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How the EY 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 17,000 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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