



**When the human body  
is the biggest data  
platform, how will  
medtech companies  
capture value?**

Pulse of the industry 2018

[ey.com/lifesciences](http://ey.com/lifesciences)



The better the question. The better the answer.  
The better the world works.



**EY**

Building a better  
working world

# When the human body is the biggest data platform, how will medtechs capture value?

That is a key question that medtech companies must address as they strive to deliver better, more engaging health care to consumers. In particular, as data and analytics become central to the value proposition, EY believes medical device companies must adapt their business models to create systems that move beyond product-centric definitions of innovation to data-centric definitions.

Historically, the medical device industry has created tremendous value via the creation of therapeutic devices. It is now time for the industry to invest more effort in analytics-based solutions that enable seamless, real-time care management. We now have the technologies to deliver high-quality care when and where the consumer wants it, not just in a traditional office or hospital setting.

Such rising consumer expectations build more urgency for change in the medical device industry. The companies that survive and grow in this dynamic environment will be those that create personalized products and services that use data to inform and deliver better outcomes, with a growing emphasis on coordinated care.

While some medtechs are investing for this data-driven future, analysis presented in the EY 12th annual *Pulse of the industry* report suggests most medtechs remain overly focused on investors' near-term growth expectations to the detriment of their longer-term ambitions. In 2017-18, medtech companies continued to use dealmaking to create scale in must-win therapy areas, a necessary first step when reimbursement remains challenging and new entrants

---

**Sensors in devices and on – or within – the human body have the power to link data collection to powerful algorithms, which will transform existing practices and take us into a new paradigm of individualized care.**

threaten their leading positions. However, to create future value, medtechs cannot ignore deals to acquire new digital capabilities. Unfortunately, there is little evidence that those deals are happening at the scale or speed required for transformation.

As we discuss in this year's report, there are clear signs of the digital transformation already underway. Artificial intelligence is already sweeping through the imaging sector and shaping a new generation of smart, robotic surgical devices, for instance. The 2018 regulatory approval of a fully automated algorithm to diagnose diabetic retinopathy without physician assistance shows the rapid evolution of digital diagnostics.

For the moment, investor confidence in medtech is high, driven by a buoyant financing climate, including a growing base of private investment capital in Asia. We believe medtechs have a unique opportunity to capitalize on the current digital transformation to get even closer to their customers, particularly consumers. Sensors in devices and on – or within – the human body have the power to link data collection to powerful algorithms, which will transform existing practices and take us into a new paradigm of individualized care.

Harnessing the power of data, the industry will reshape itself around the empowered patient-consumer, rather than forcing the patient to fit into today's current industry infrastructure. But if medtech companies continue to underinvest in digital capabilities, they could become less important as the health ecosystem continues to evolve.

As medtech companies develop new technologies and new business models, the global EY organization continues to track the pulse of the industry.



**Pamela Spence**  
EY Global Life Sciences  
Industry Leader  
psplice2@uk.ey.com



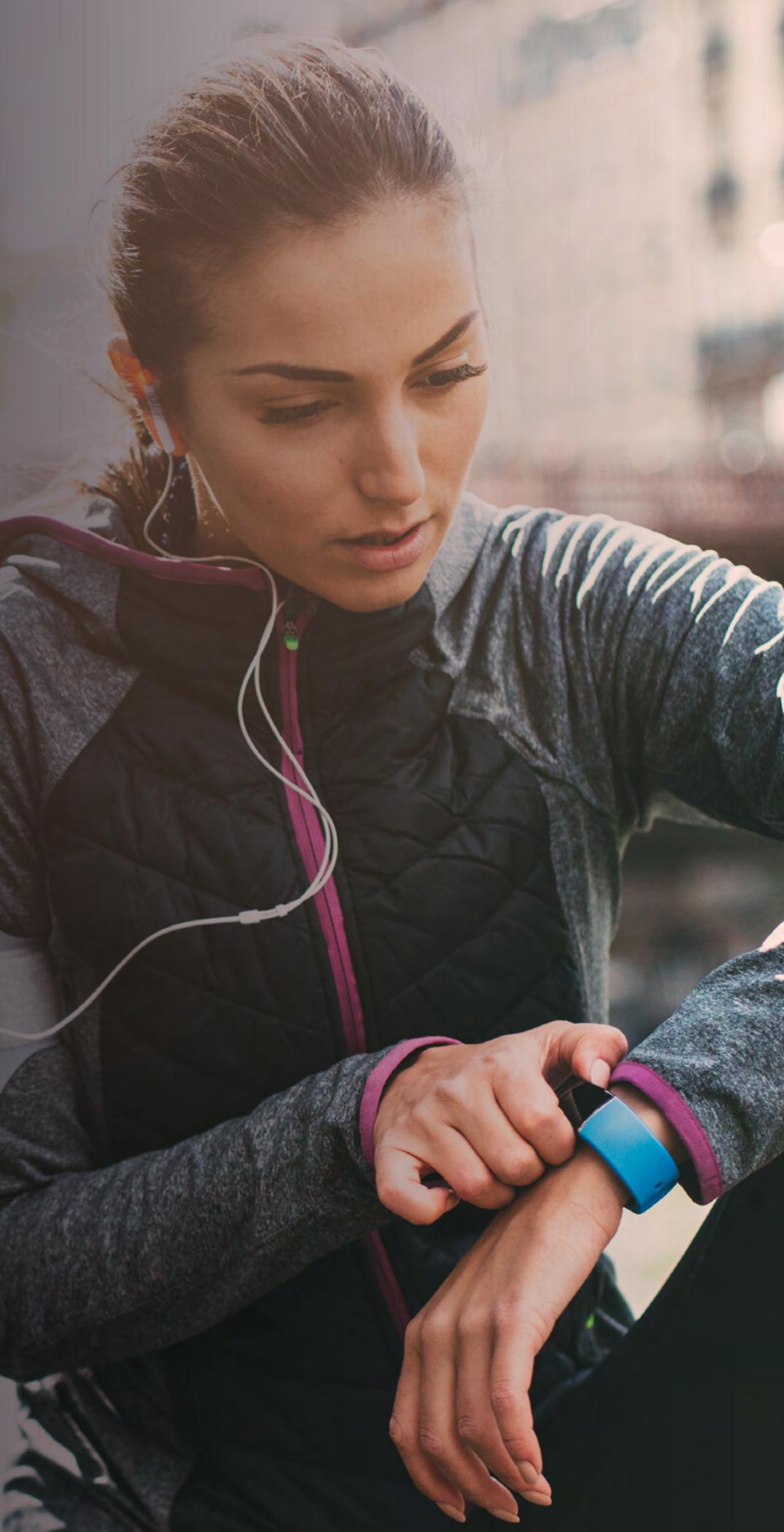
**James Welch**  
Life Sciences Leader,  
US Central Region  
james.welch@ey.com



**John Babitt**  
Life Sciences Transaction  
Advisory Services Partner, US  
Ernst & Young LLP  
john.babitt@ey.com



**Lucien De Busscher**  
Life Sciences  
Advisory Partner  
Ernst & Young Special  
Business Services CVBA  
lucien.de.busscher@be.ey.com



## CONTENTS

### 06 | **Chapter 01**

A new wave of digitization will reshape the medtech industry

### 12 | **Chapter 02**

Is medtech investing enough to meet the future challenge from the tech sector?

### 20 | **Chapter 03**

Advances in imaging and non-imaging diagnostics show how the medtech industry could evolve

### 24 | **Chapter 04**

Future success requires greater participation in the health ecosystem

### 28 | **Guest perspectives**

### 38 | **Databook**

### 57 | **Scope of this report**

### 58 | **Contacts**

### 60 | **Acknowledgments**

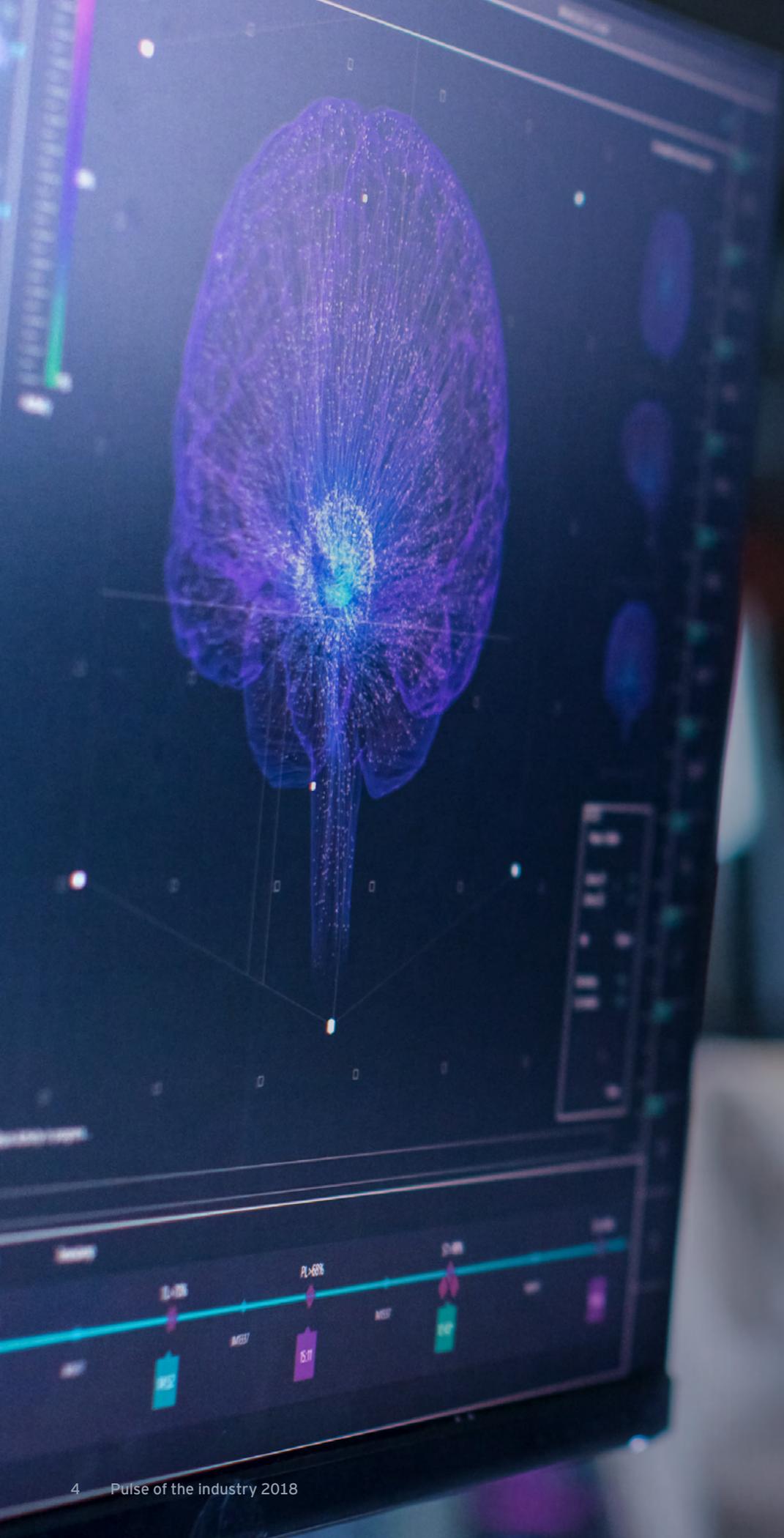
## Connect with us!



@EY\_LifeSciences



[ey.com/lifesciences](https://ey.com/lifesciences)



# Key findings

## What the Fourth Industrial Revolution means for the medtech industry

The Fourth Industrial Revolution will permanently change how medical device companies do business. This is the message that clearly emerges from EY analysis of the industry's 2018 key performance metrics and discussions with leading medtech executives and thought leaders.

- ▶ **Data and algorithms are tomorrow's value-creating products:** Data will be the engine of future medtech growth, and thus, value creation. The growing importance of data and algorithms will accelerate a power shift already underway in the industry that gives technology and digital health entrants the advantage.
- ▶ **Medtech leaders are overly focused on the short term:** At present, medtech capital allocation is too focused on short-term growth. There is too much emphasis on returning cash to shareholders and not enough effort devoted to new kinds of innovations that aren't product-centric.
- ▶ **Portfolio optimization remains the core driver of M&A:** Medtech leaders continue to refine their portfolios, using M&A and divestitures to create scale in must-win therapeutic areas. Given reimbursement challenges and threats from new entrants this is a necessary first step to creating agile businesses that can compete over the next 5-10 years. Focusing on fewer therapeutic areas allows companies to achieve synergies and deepen customer engagement in these spaces. However, to create future value, medtechs also need to invest in digital capabilities, and there is little evidence suggesting those deals are currently happening at scale.
- ▶ **Advances in imaging, diagnostics and diabetes point the way forward:** Medtech companies in the imaging and diabetes space are investing in new innovations such as artificial intelligence and consumer-centric platforms that use data to provide more personalized health care. In the meantime, investments in diagnostics, especially the consumer genomics space, show the growing importance of personalization for medtech companies.
- ▶ **Investor confidence in medtech means high levels of innovation capital:** Investment continues to flow into medtech, with venture and IPO funding buoyant in 2017-18. Venture investment from China promises to be a key factor in the industry's future, with Chinese capital invested in international medtech firms and domestic companies seeking to globalize their innovations.
- ▶ **Rethinking the business model is an imperative:** To deliver on investor expectations and create value in this transformative age, medtechs must rethink their business models, building agile end-to-end services that put their customers at the center. It is not enough to develop services that are product add-ons. Provider and payer customers want new approaches that optimize both the efficiency and outcomes of care; consumers want individualized solutions personalized for their specific health needs.



# A new wave of digitization will reshape the medtech industry

Increasingly, medtech's future growth will be driven by the ability to connect, combine and share data quickly and at scale to create secure solutions that deliver clinical and economic benefits. Indeed, to create a sustainable path for future growth, medtechs must look to capture value not only through the manufacture and sale of products, but also via the data those devices generate. As Donald Jones, Chief Digital Officer of the Scripps Translational Science Institute, says, "In this environment, the value is in the clinical insights and trend analysis that the devices spit out, rather than in the med device itself."

Increasingly, customers of the medical device industry – especially payers, providers and consumers – are defining that value in new ways. As presented in Figure 1, future value (FV) for all stakeholders will come from innovations (I) that unlock the power of data (D) to deliver personalized health outcomes.

Ultimately, this emphasis on health outcomes data will lead the industry from a product-centric to a patient-centric orientation, where digital platforms allow seamless delivery of care. It will also align with the rising expectations of medtech's customers, particularly consumers who have experienced the wholesale restructuring of other areas of their lives as a result of the democratization of data.

As peer-to-peer sharing and mobile have transformed the banking, mobility and retail industries, the growing importance of data and algorithms will force medtech companies to adapt their traditional offerings to create personalized products and services that are person-centric. (See Figure 2 and box, "Important definitions.")

As health care budgets tighten across all markets, the increased availability and importance of health data skews the traditional balance of power within health care away from traditional medtech companies and toward medtech's core customers and new entrants.

Traditional utilization-based payment models will not survive this power shift.

Indeed, consumers are already using data to demand greater voice in how their care is delivered, putting pressure on providers and payers to adapt with data-centric solutions of their own that provide more personalized coaching. In addition, these providers and payers are also using data to increase the efficiency and standardization of care delivery, important actions to improve outcomes and lower health care costs. As these two groups become more sophisticated in their management and use of data, they will broaden their focus from the sickest and most costly patients to the general population, enabling improved outcomes at scale. (For more see the Progressions 2018 report, "*Life Sciences 4.0: Securing value through data-driven platforms.*")

# New thinking for a new age

Figure 1. A new equation for delivering value

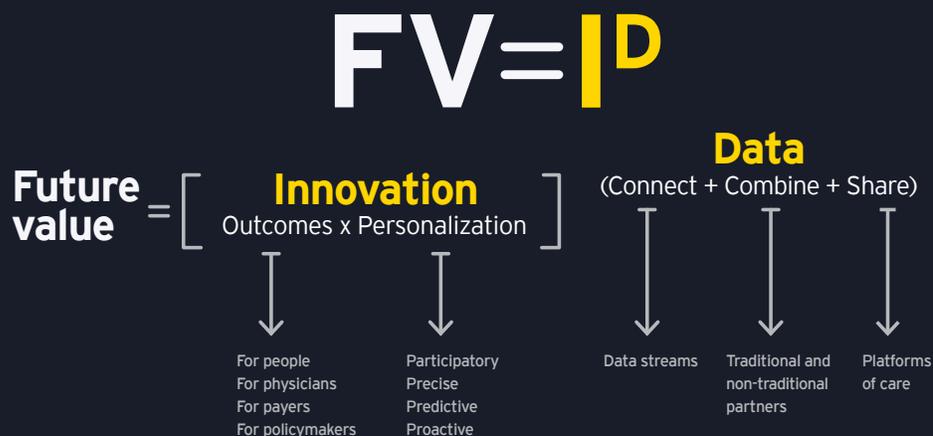


Figure 2. Changing customer expectations combine with technological advances to create the the future medtech market

## What's now



**Payers, consumers and new entrants** have the power



**Connected devices** allow continuous disease management



**Medical devices** are the highest value products



Value is captured by **owning all the data**



Health ecosystem is **static and well-defined**

## What's next



**Super consumers** demand convenient, seamless care



**New technologies** allow "pre-disease" identification and treatment



**Data and algorithms** are the highest value product



Value is captured by **sharing the data with ecosystem stakeholders**



Health ecosystem is a **dynamic network**

## Important definitions

- **The Fourth Industrial Revolution:** A fusion of the physical, digital and biological worlds that redefines innovation and blurs the traditional lines between industries. This advancement is driven by the ability to combine a range of new technologies and the safe and rapid generation and dissemination of data.
- **Health ecosystem:** A number of different stakeholders provide goods or services to consumers in today's networked health environment. These stakeholders include primary and specialty care physicians, public and private payers, and a range of technology, retail, telecom, mobility and life sciences companies.
- **Platform:** A mechanism to connect different stakeholders in order to combine and share data easily and securely to deliver a shared goal: improved health outcomes.
- **Power shift:** Tightening health care budgets, technological disruption and democratized data change the traditional power balance in health care. Life sciences companies may cede power to more informed and connected payers, providers and consumers – and potentially to new entrants who can better meet the needs of these stakeholders.
- **Super consumer:** The empowered consumer is at the center of the way companies increasingly do business in networked, platform-driven markets. Able to access goods and services with minimal frictions, the super consumer represents a potential disruptive force in health care markets.

As patients increasingly embrace the opportunity to take a proactive role in their own health care, wearables, sensors and new digital interfaces will become critical tools for personal health care management. Providers will use these data, with workflow-friendly analytics layered on top, to maximize clinical insights and deliver optimal and efficient care. Payers, meantime, will have greater transparency on the benefits achieved for the health care dollars spent. This information will provide payers with

increasing evidence to prioritize funding for tools and technologies that enable earlier intervention and prevention.

As payers, providers and consumers embrace the data and tools to make personalized health management a reality, new entrants will gain the opportunity to deliver the solutions all parties are seeking. In particular, technology companies with expertise in digital platforms and customer outreach will be well-placed to capitalize on the industry's shifting balance of power.

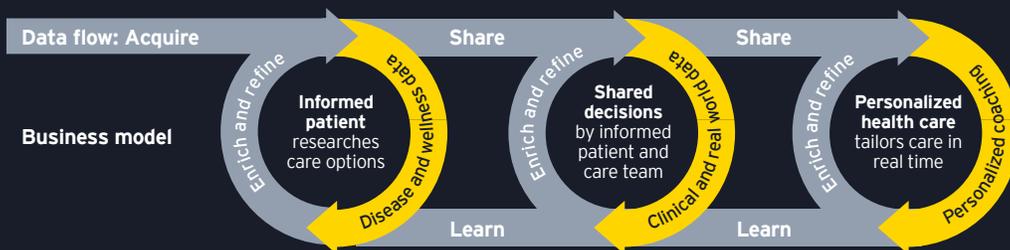
Entrants from the tech sector are already eyeing the health space as a fertile area for new growth. In the consumer and search spaces, technology companies have honed their customer engagement and advanced data and analytics skills, including the ability to acquire and securely maintain information, to create more satisfying and personalized customer experiences. They can do the same in health care.

## Data will drive a health care power shift

Figure 3. Stakeholders empowered by data

As stakeholders acquire, share and utilize data, new ways of delivering personalized health care emerge, shifting the power away from traditional medtechs.

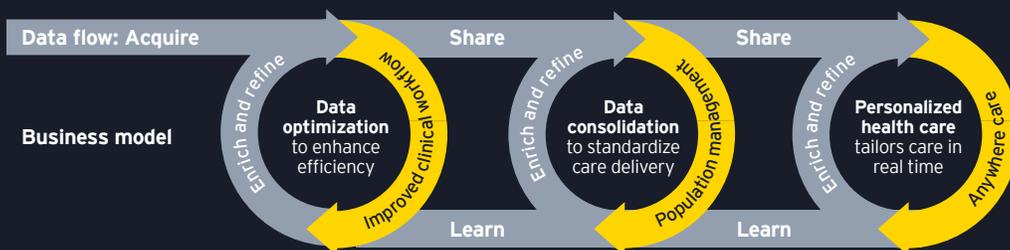
### Patients/consumers



### Power shift in action

- ▶ Nearly 60% of adults consult internet first to research health conditions
- ▶ 56% of US adults have used some form of digital technology to interact with care team<sup>1</sup>
- ▶ 92% of US individuals want the ability to use wearable/sensor data to personalize interventions<sup>2</sup>

### Health providers



### Power shift in action

- ▶ Improved AI reduces duplicative documentation, creating time for patient care
- ▶ Combining big data with clinical evidence to manage patient health is top 2018 physician priority<sup>3</sup>
- ▶ Global virtual care industry will grow from US\$18.1b in 2015 to US\$41.2b in 2021<sup>4</sup>

<sup>1</sup> EY Future of Health Survey, Spring 2018. <sup>2</sup> Tung, J. Y et al. 2018. Accelerating precision health by applying the lessons learned from direct-to-consumer genomics to digital health technologies. NAM Perspectives, Discussion Paper, National Academy of Medicine, Washington, DC.

<sup>3</sup> 2018 HealthCare Executive Group (HCEG) Top 10 List of critical opportunities <sup>4</sup> Statista. Global telemedicine market size (2015-2021)

There are clear signs that leading tech companies are moving beyond fitness and wellness tracking to care management using easy-to-use, consumer-facing devices. In September 2018, for instance, Apple announced its newest watch incorporates an electrical heart rate sensor that can take an electrocardiogram (ECG) using an app that has been granted a De Novo classification by the U.S. Food & Drug Administration.<sup>1</sup>

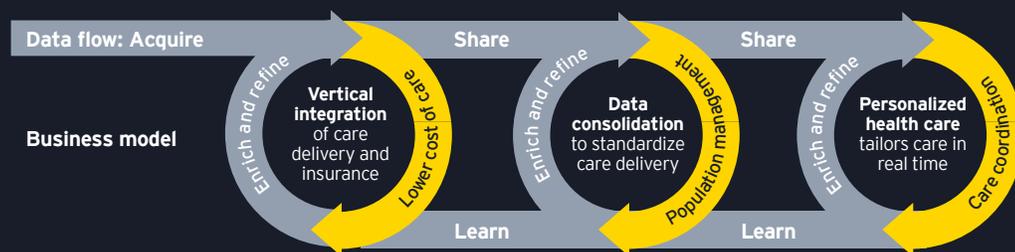
Other technology companies are also developing data-rich platforms that make it easy to share data proactively with consumers and providers to avoid adverse health events and optimize care management at the individual level. (See Figure 3.)

The challenge from tech companies is likely to be all the greater given their serious financial firepower. Tech's biggest players wield M&A firepower on a level

even medtech's leaders can't match. (See Figure 4.) This will be a major advantage as companies seek to assemble the breadth of talent, technology and expertise needed to take the next steps towards personalized health care.

<sup>1</sup> Press release. "Apple Watch Series 4: Beautifully redesigned with breakthrough communication, fitness and health capabilities," Apple, September 12, 2018.

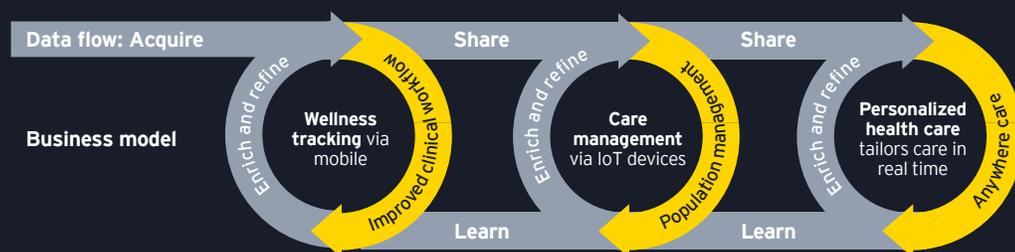
**Health payers**



**Power shift in action**

- Recent deals: CVS/Aetna, Optum/DaVita, Humana/Kindred Healthcare
- 90% of payers surveyed by the Society of Actuaries say they will adopt predictive big data analytics tools in next five years<sup>5</sup>
- Insurers invest in mobile tools to help consumers manage disease and wellness

**New entrants**



**Power shift in action**

- Smart phones track sleep, fitness
- Apple/Stanford launch heart study; Amazon pilots diabetes management as Alexa skill
- Amazon/JPM/Berkshire Hathaway partnership

<sup>5</sup> Survey by Society of Actuaries. 2017 Predictive analytics in HC Trend Forecast.

## Data will replace devices as medtech's key value driver

In today's rapidly changing environment, medtech companies have no choice but to use data to deliver improved outcomes and a better customer experience to consumers, providers and payers.

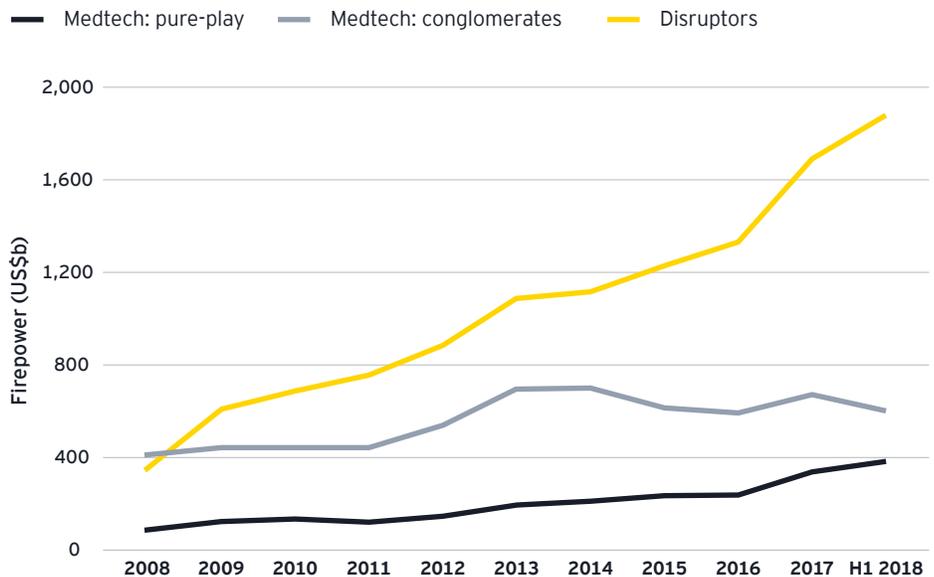
Multiple medical device manufacturers are already incorporating digital capabilities into their products. For instance, many medical devices are connected to the Internet of Things (IoT), potentially allowing continuous disease monitoring and management. Unfortunately, these efforts tend to be wrap-around services that don't necessarily position new connected technologies and the data they generate at the heart of the medtech company's strategic business goals. And, because investments are made in isolation from each other rather than across a business portfolio, medtechs are at risk of underinvesting in the technologies that could drive future top-line growth.

Near-term digital opportunities worthy of greater medtech investment include:

- ▶ Collecting and managing growing volumes of patient data in the cloud: patient data remains a largely untapped source of value and one of the biggest near-term opportunities for the industry if they can create secure systems to manage and use it.
- ▶ Building analytics into care management algorithms using AI.
- ▶ Recognizing that the clinical insights captured in connected devices will increasingly be the real source of value – rather than the device itself.

Historically, these skills have not been medtech companies' core capabilities.

**Figure 4.** New tech and consumer entrants have dealmaking firepower that medtech can't match



The disruptors include Alphabet, Amazon, Apple, CVS Health, Intel, IBM, Microsoft, Samsung, Verizon and Walgreens Boots Alliance. Sources: EY and Capital IQ.

Instead, medtechs understand how to operate in complicated, regulated markets and develop sophisticated clinical evidence to support regulatory approval.

If medtech companies can not – or choose not to – accelerate their digital agendas, it is likely that new market entrants will benefit from, and capitalize on, the data-driven transformations of the Fourth Industrial Revolution. These new

entrants will have to adapt to the stricter regulatory environment in health care to succeed. As Anand Iyer, Chief Strategy Officer of the digital health company WellDoc observes, "Digital health solutions need to meet the same standards as traditional drugs and medical devices." But if technology companies can meet this benchmark, they have every chance of challenging the market position of medtech incumbents.

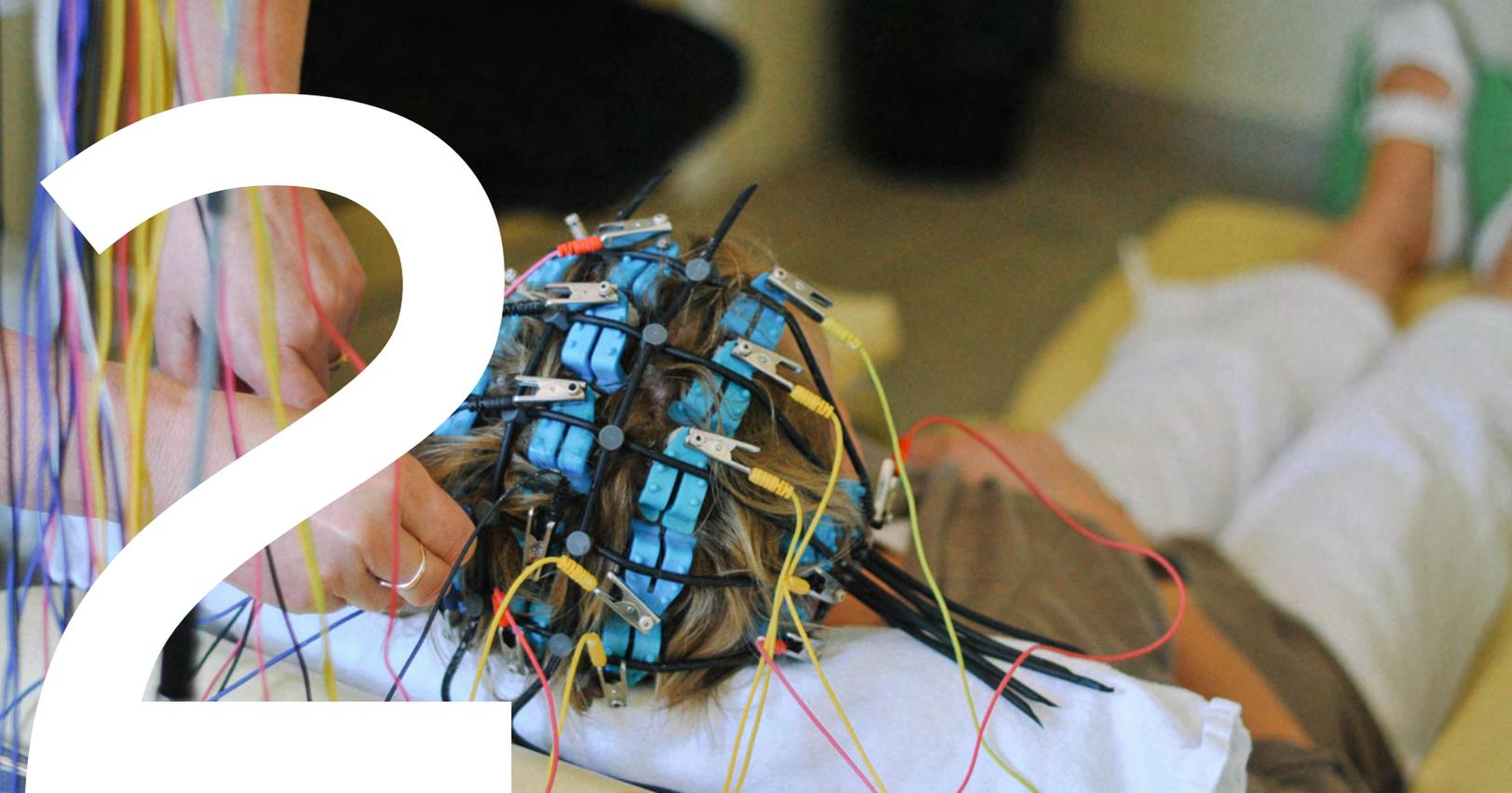
### Questions for medtech companies to consider

- ▶ How will medtechs leverage data to improve outcomes for all stakeholders in the health ecosystem?
- ▶ How are medtechs moving from selling devices and tests to monetizing data and algorithms?
- ▶ Are medtech C-suites and boards strategically thinking about and planning for digital change, or simply reacting?

---

**“In this environment, the value is in the clinical insights and trend analysis that the devices spit out, rather than in the med device itself.”**

**Donald Jones**  
Chief Digital Officer  
Scripps Translational Science Institute



# Is medtech investing enough to meet the future challenge from the tech sector?

Based on a number of annual metrics that EY tracks, there are signs that the industry, in aggregate, is overinvesting in short-term business activities to the potential detriment of its long-term growth. Over-emphasis on returning cash to shareholders at the expense of R&D spending leaves the industry with a looming “innovation gap.” While medtech companies continue to develop new generations of products, these are, increasingly, niche additions that do not offer sufficient or lasting new market opportunities for companies to sustain their historic growth rates.

This is particularly true for companies developing therapeutic devices, which generate the majority of the industry’s total revenue. Although the industry’s 2017 aggregate revenues hit a new high of US\$379.1b and medtech valuations outperformed the industry’s broader indices, a deeper analysis of medtech’s

top-line growth and capital allocation practices raises important questions about the long-term sustainability of the industry given the technological changes of the Fourth Industrial Revolution. (See “*The Pulse of the industry data book*,” page 38.)

At first glance, the medtech industry appeared to deliver a healthy performance in 2017 and the first half of 2018. A closer analysis of indicators such as revenue growth and R&D spending, however, raises questions about opportunities for future growth.

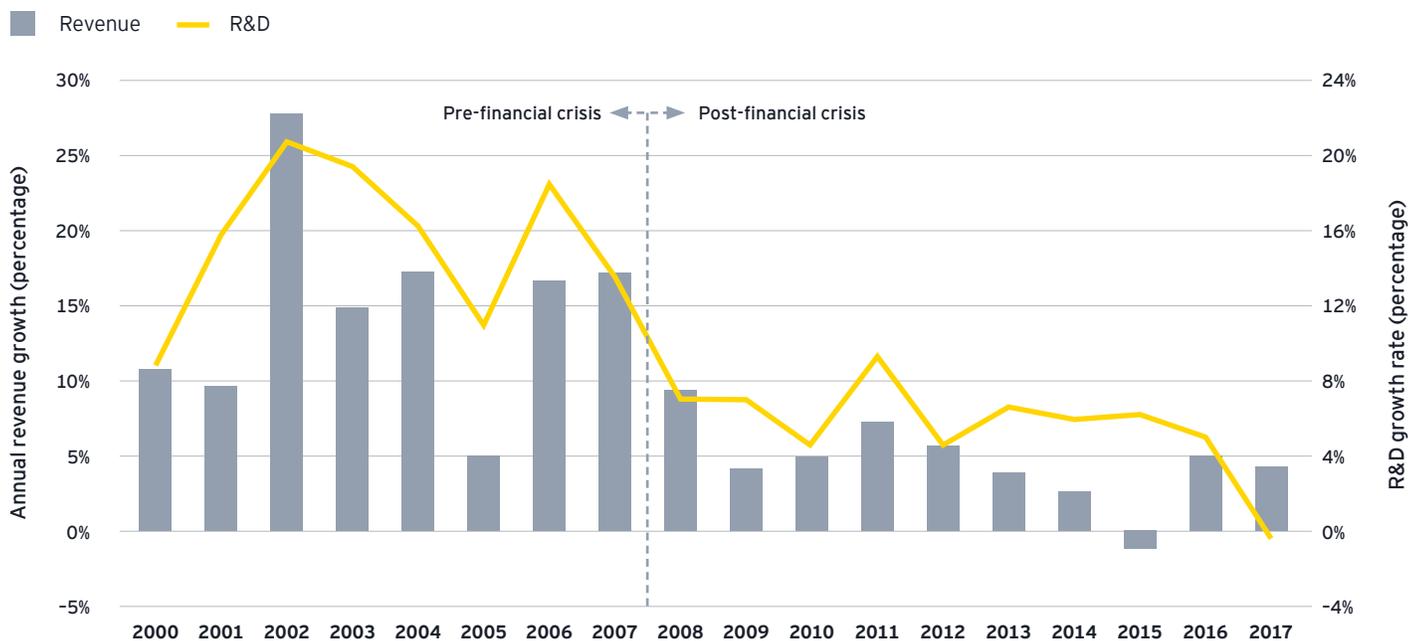
For instance, the industry’s 2017 4.0% growth rate suggests that it has reached a new equilibrium of solid, if unspectacular single-digit growth. However, this rate compares poorly with the 14.9% average annual revenue growth rate achieved in the 2000-07 era. (See Figure 5.)

In part, this decline reflects rising payer skepticism. As a senior medtech executive told EY, “Investors talk about the four

Medtech companies that fail to adopt data-driven strategies may find it increasingly difficult to mount the kind of returns necessary to remain top performers.

## New products aren't enough for medtech companies to return to growth

Medtech companies that fail to adopt data-driven strategies will find it increasingly difficult to post the returns necessary to remain top performers. An analysis of a number of key metrics suggests this hypothesis.

**Figure 5.** Industry growth pre- and post-2007

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

Ps: patient, physician, provider [i.e., hospital system] and payer. When we started out, we didn't worry about the last one. That was the least of our problems. Now it's number one."

Payers' demands to demonstrate the value of new, expensive devices or tests are not receding. Hit hard by budgetary pressures linked to aging populations and the rising incidence of chronic diseases, payers must make hard decisions about what to cover – and what to deny. As a result, they have developed more sophisticated mechanisms to determine whether new innovations merit reimbursement. As David Van Sickle, Co-founder and CEO of the digital health company Propeller Health, observes in an accompanying guest perspective, "Payers don't want to buy medicines; they want to buy the outcomes the medicines bring about."

Van Sickle and other health care leaders believe digital therapeutics that capture data about the way patients use their products, as well as real-world outcomes, are critical as value-based reimbursement becomes more important in health markets around the globe. "The more that this information gets wired into billing and health care delivery systems, the more the model will evolve from unit sales to companies providing therapeutics as a service to the organizations," says Van Sickle.

However, most leading medtechs struggle to transition from selling products to selling outcomes. Part of the issue is the needed capital investments to properly capture and proactively use such outcomes data come at the cost of satisfying short-term investor expectations. Indeed, an analysis

of capital allocation trends suggest medtechs are caught squarely in the conundrum of balancing short-term investor expectations with longer-term growth needs.

### Growth in R&D spending continues to decline, raising questions about future medtech innovation

In an industry built on constant innovation, R&D spending is a key parameter defining future growth. Alongside M&A, organic investment is critical to creating the next wave of innovations that will return revenue growth to double-digit levels. Importantly, as digital technologies are embedded in a wider array of products, medtechs must develop capabilities that enable them to

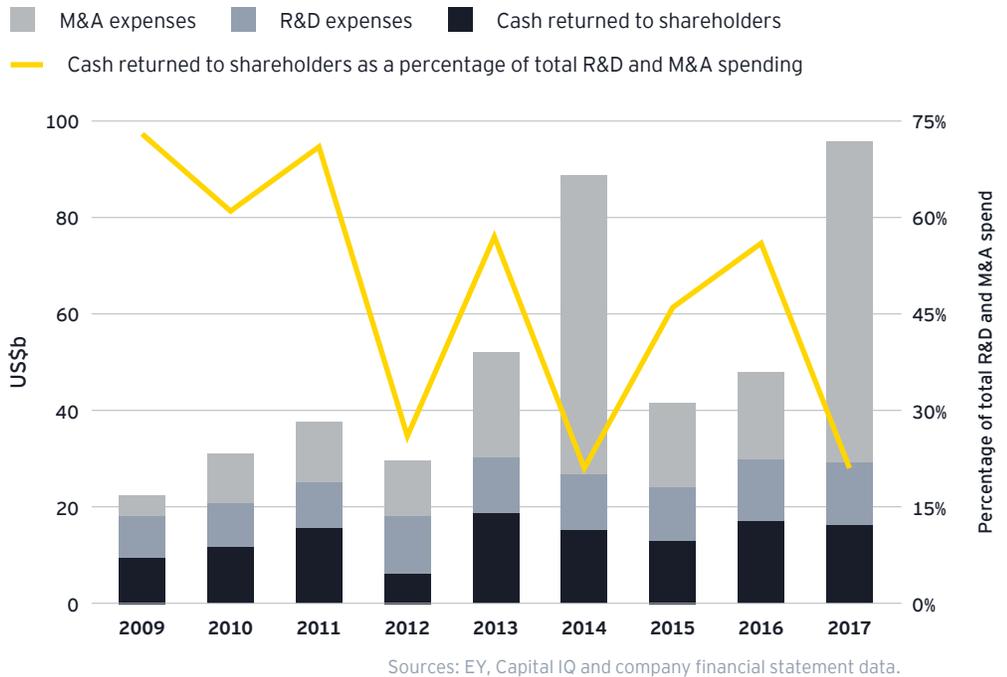
keep pace as product cycles compress and connected devices and analytics grow in importance.

Yet, despite the urgency to invest in new capabilities, medtech companies in aggregate are under-investing in R&D. Year-over-year investment in R&D held steady in 2017, but – as with revenue growth – the longer view shown in Figure 5 reveals that the rate of R&D investment growth has dwindled in recent years, declining to 4.7% in 2013-17 from an average of 15.5% in 2000-07.

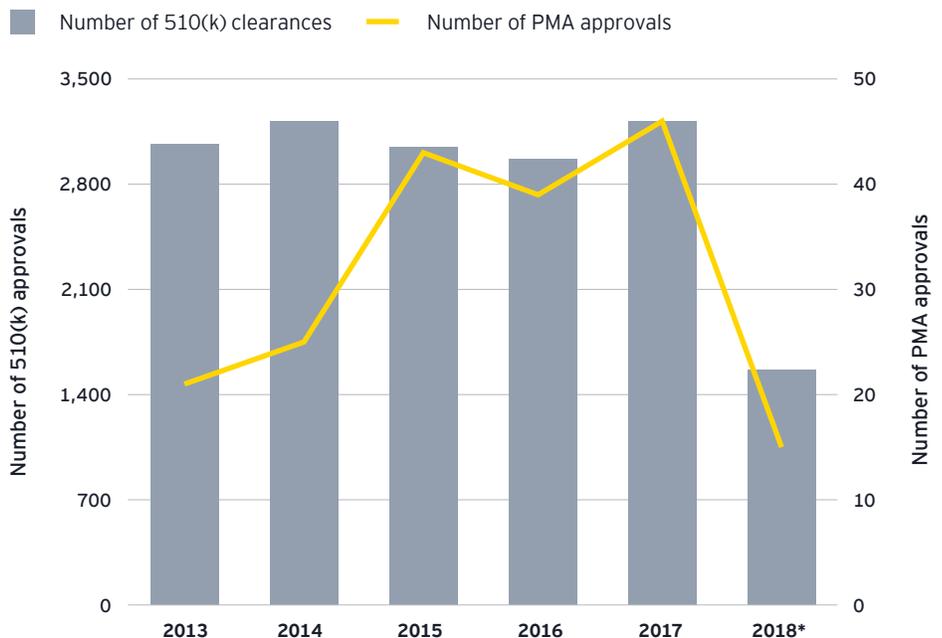
Meantime, capital allocation strategies align closely to historical trends, with an emphasis on returning cash to shareholders. In 2017, medtech companies rewarded their shareholders with share buybacks and dividends worth US\$16.4b, more than the total amount invested in R&D activities during the same 12-month period. The question is, where will future growth come from if companies don't invest more aggressively in new innovations? (See Figure 6.)

Recent numbers for FDA premarket approvals (PMAs) and 510(k) clearances are another sign that it is time to rebalance R&D investment and cash returned to shareholders. Premarket approvals hit a high in 2017, but to date, 2018 results have been less impressive. (See Figure 7.) There were just 21 PMAs through 31 August 2018, and the number of 510(k) clearances issued in the first half of 2018 declined as well, despite steps taken by the U.S. Food & Drug Administration (FDA) to improve the efficiency of the medical device approvals process.

**Figure 6.** US and Europe medtech commercial leaders spending trend, 2009-17



**Figure 7.** FDA premarket approvals (PMAs) and 510(k) clearances, 2013-18



Number of 510(k) clearances are shown through 30 June 2018. PMAs are shown through 31 August 2018. Source: US FDA.

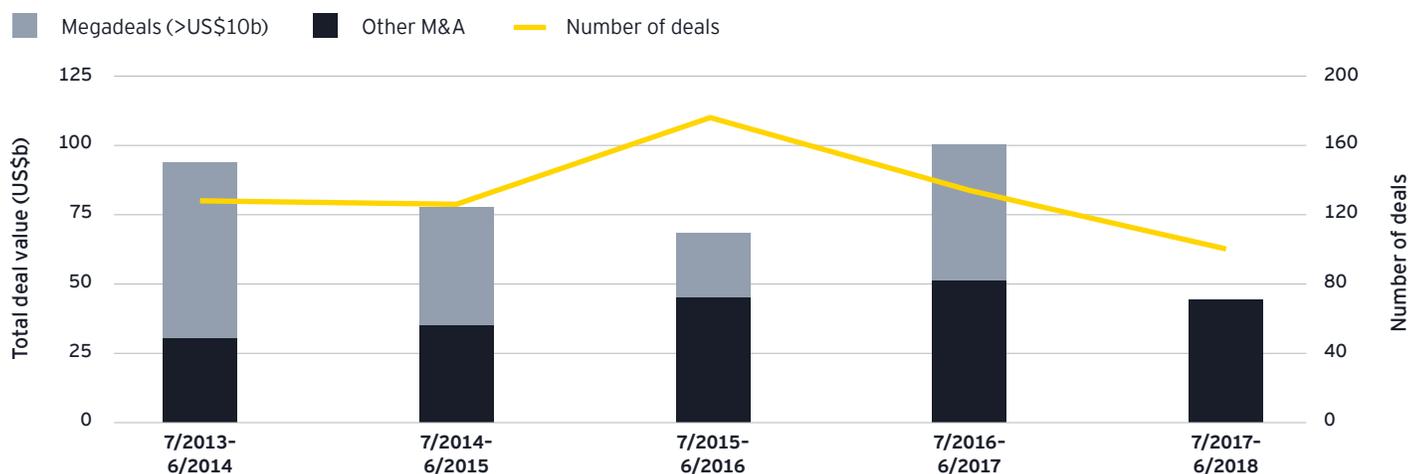
**Figure 8.** M&A in the US and Europe by year, July 2013-June 2018

Chart includes deals >US\$5m (medtech deal where either acquirer or target is located in the US or Europe).

This lackluster performance sharpens the question over whether companies are investing sufficiently in R&D to secure their future revenue growth.

Note also that most of the new wave of approvals make little or no use of digital technologies or data analytics: only 16 of the 43 therapeutic devices approved between January 2017 and June 2018 include any digital health component. This shows that these pivotal new capabilities are yet to be embedded in medtech innovation.

Perhaps the relatively low PMA numbers are not yet a cause for concern. They may partly be explained by the FDA's October 2017 simplification of its De Novo review process, which provides novel products with an alternative path to market without PMA or 510(k) approval. Moreover, the amount of venture capital raised by earlier-stage medtechs means the industry has high levels of funding that can potentially support future innovation. Financing reached record levels in 2017-18, with US\$21.7b of innovation capital raised (US\$8.2b of venture

investment), up 64% against the five-year average. (See *"The Pulse of the industry data book,"* page 38.)

However, medtech companies still face fundamental challenges as they try to maintain growth. As markets become more crowded with competing products and payers become increasingly cautious about reimbursement, there is simply less scope for the kind of product-centric growth that fueled the industry in past years. The devices that medtechs have depended on for revenue growth, from stents to knee and hip implants, are now mature, and there are diminishing returns for next-generation successor products. For the leading players, traditional product-focused R&D may no longer be enough to achieve revenue growth in line with these companies' current sizes.

### Is medtech M&A overly focused on business as usual?

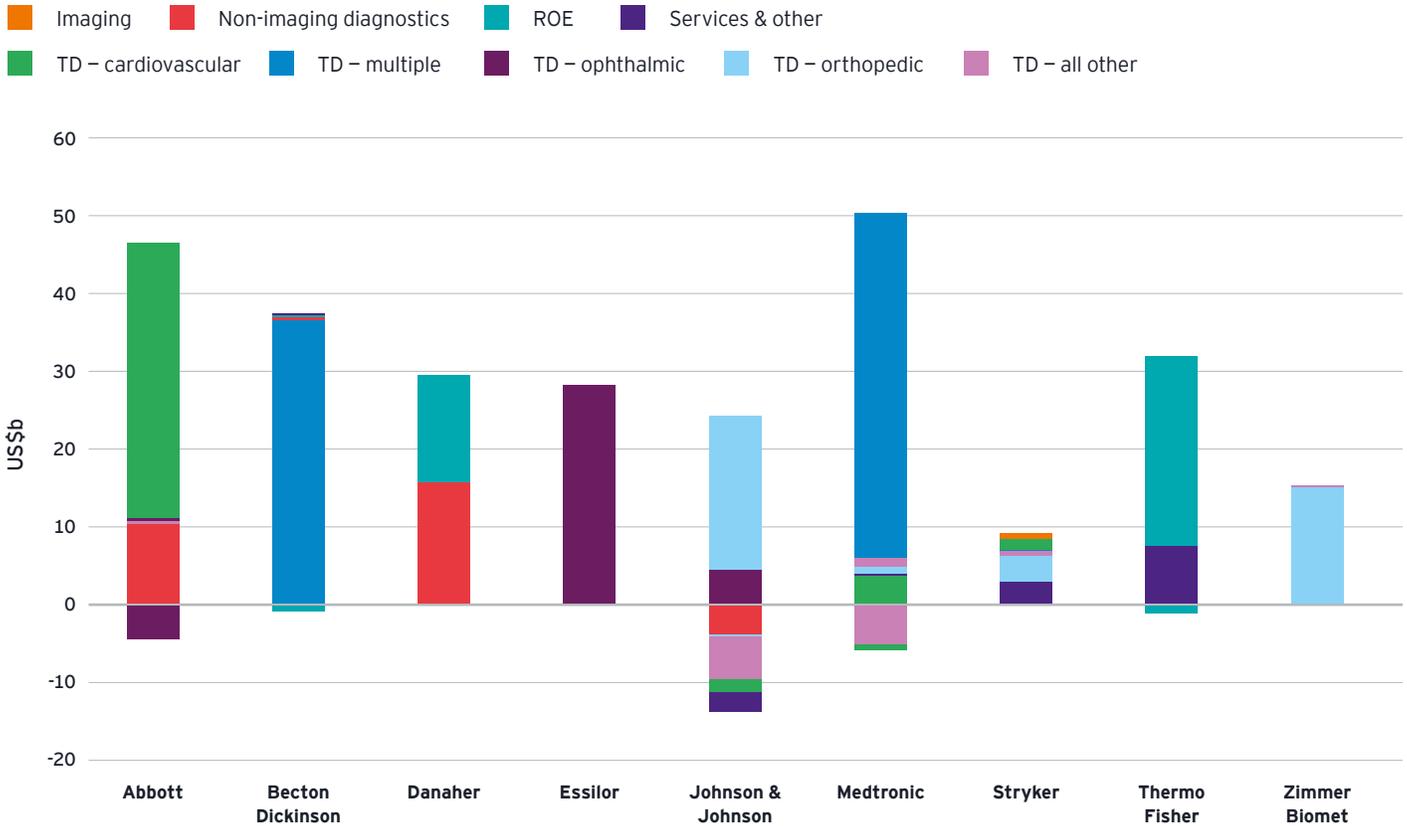
The ongoing under-investment in R&D suggests some medtechs could struggle to innovate their way out of the current

status quo and will have to resort to inorganic means to maintain growth. Historically, the industry has used M&A to bolster near-term revenue growth, and as Figure 6 shows, medtech M&A investment was solid in 2017.

Most of this 2017 total went to two major deals: BD's purchase of Bard and the pending Essilor-Luxottica business combination. Between July 2017 and June 2018 there were no additional megadeals, defined as transactions valued greater than US\$10b. As a result, the deal value for 2017-18 looks modest compared with the previous 12 months, falling 56% to US\$44.1b. This total was spread across 101 deals, itself a 42% decline versus the previous 12 months. (See Figure 8.)

More important than these fluctuations is the overriding question of where the M&A spend is being directed. The data suggest that in 2017-18 medtech's commercial leaders focused on tuck-in acquisitions that added scale in areas of therapeutic interest.

**Figure 9.** Tuck-in acquisitions and divestitures by select medtechs, 2011-H1 2018



The values of acquisitions are shown on the positive y-axis; values of divestitures are shown on the negative y-axis. The figure includes previous M&As of companies that were later acquired. The therapeutic device (TD) category was subdivided by relevant therapeutic area. TD - multiple refers to deals that include assets from multiple therapeutic areas. TD - all other refers to a deal in a single therapeutic area that is not cardiovascular, ophthalmic or orthopedic.

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

This relatively defensive approach to M&A is not surprising, largely because it is the early days for the digital revolution and many C-suites may question the wisdom of spending significant cash on unproven technologies that can't help bolster the top-line any time soon. It is also true that before companies can adequately invest in digital technologies that will drive future growth, they must first build scale in the therapeutic areas that are top priorities.

Having commercial scale not only improves a company's capital efficiency by building expertise in specific therapeutic areas, but also gives companies the ability to deepen their offerings by, for instance, building value-added services and forming closer relationships with end-users to improve product development. These efforts allow organizations to build end-to-end capabilities that will derive maximum benefit when digital and data-centric skills are fully embedded.

A necessary first step for some companies, therefore, is to shed non-core assets or business units, either through spin-offs or divestitures. Johnson & Johnson was among the most active in this regard in 2017-18, selling its LifeScan and Advanced Sterilization Products business units to private equity groups. (See Figure 9.)

## Can digital deals close the innovation gap for medtech?

Even if consolidation is entirely rational, it doesn't eliminate the need to invest in data-centric capabilities. Since many medtechs lack the in-house capabilities to develop personalized health care offerings, there is even more need to acquire these skills via dealmaking. Unfortunately, EY analysis suggests that in terms of dollar values and deal numbers, most medtechs have yet to make such digital collaborations a significant part of their dealmaking agendas.

To better understand how medtech companies use business development to create digital capabilities, EY has constructed a proprietary data base

of alliances and acquisitions from life sciences company financial statements and press releases.

For the purposes of this analysis, EY has defined digital to include a range of technologies, including: digitally enabled devices (e.g., wearables and implants); software applications that provide physician or consumer support; telemedicine infrastructure; and analytics capabilities that use AI to support diagnosis and care management.

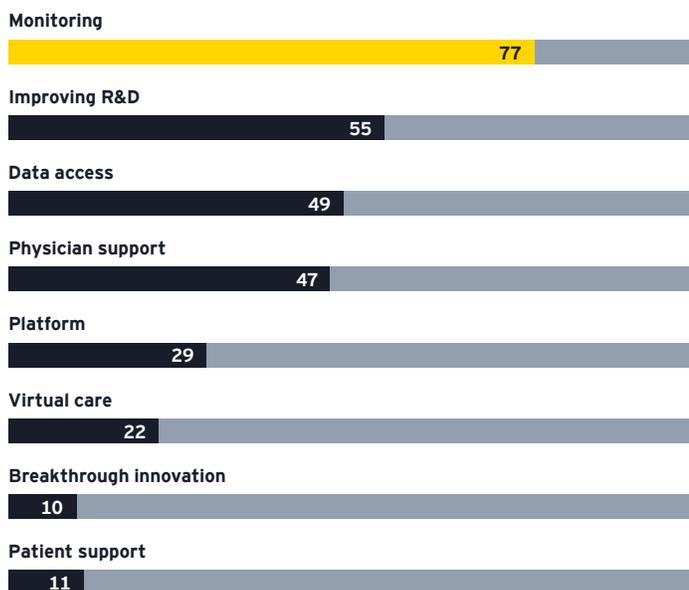
Some of these capabilities (for instance, the use of wearables) are natural extensions of the kinds of products medtech companies have historically developed. Others, such as the integration of non-medical data into electronic health

records, are more novel and will require medtechs to think about how to use data, not devices or tests, as their primary currency for reimbursement.

Despite the growing strategic importance of digital technologies, medtech companies have not been particularly active dealmakers in this space. From the beginning of 2014 to the end of June 2018, life sciences-focused companies signed 292 alliances or acquisitions to access digital technologies, with building capabilities in monitoring, refining R&D and accessing data the most common goals. (See Figure 10.) Of this total, medtech companies were responsible for just over a quarter (76) of the transactions, including 13 acquisitions.

Figure 10. Understanding the drivers of life sciences digital dealmaking

### Broad purpose of all life sciences digital deals



### Most active medtech companies



Because some digital deals were motivated by more than one driver, numbers in the analysis exceed the total number of deals in the data set. Sources: EY, Capital IQ and company financial statement data.

Because companies disclosed deal values for very few of these arrangements, the overall level of investment is hard to gauge. However, the lack of digitally targeted M&A – and the undisclosed nature of the financial transactions involved in the digital deals that have been announced – suggest that overall, medtech companies' interest in this space has been limited compared to their investment in traditional sources of innovation.

Some companies appear to be paying more attention to digital deals, particularly in certain therapeutic areas such as diabetes and cardiovascular disease. (See sidebar, "Using technology to create high touch chronic disease management.")

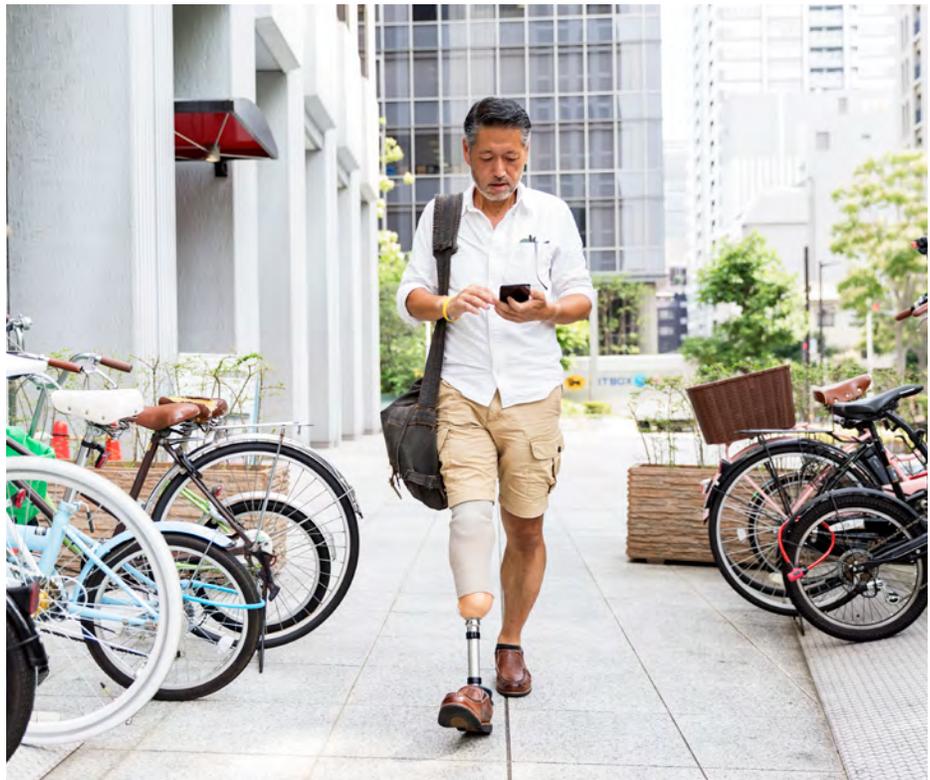
Players such as Philips and Medtronic, for instance, may have a greater opportunity to secure their position in the ecosystem given their investments in digital, data-driven business models. (See Figure 10.) Companies pursuing these strategies may also find greater collaborative synergies with each other in the future. Philips and Medtronic, have for example, entered into a business relationship to develop and commercialize the LungGPS Patient Management Platform, a comprehensive patient and data management platform designed to streamline the management of lung nodule patients from identification through diagnosis, treatment, and long-term survivorship.

### Questions for medtech companies to consider

- ▶ Are medtechs investing for the future or just consolidating for the short-term?
- ▶ As health care evolves, what innovations give medtechs a lasting edge?
- ▶ Is your company right-sized and focused on its core areas for value creation?

"The more that value-based reimbursement gets wired into billing and health care delivery systems, the more the model will evolve from unit sales to companies providing therapeutics as a service to the organizations."

David Van Sickle  
Co-founder and CEO  
Propeller Health



# Using technology to create high touch chronic disease management

EY analysis suggests that most medtechs have focused their digital efforts in chronic diseases such as diabetes and cardiovascular disease, areas where the need to improve the consumer experience through data-driven approaches is more pressing. Indeed, since 2014, 23 of the 48 therapeutically-focused medtech digital deals with a defined therapeutic area focus address these conditions. (See Figure 11.)

Diabetes, the principal target for medtech's digital deals, has been the testing ground for the pure digital solutions that may be central to medtech's future growth. Predictive analytics and customer-facing software are beginning to supply diabetics with the personalized treatments and high-touch engagement tools that over-stretched physicians cannot. Indeed, some studies estimate that diabetics spend just six hours a year in face-to-face interactions with their care teams. For the remaining 8,730 hours in a year, these individuals must cope on their own.

This is where digital technology can make a major difference. By focusing on user experience, digital devices can get much closer to the patient, and provide continuous effective care management. As Welldoc's Anand Iyer says, "When solutions are intuitive and fit into clinical workflows and daily life, higher user engagement can result" – even without the human touch of a clinician closely overseeing the patient.

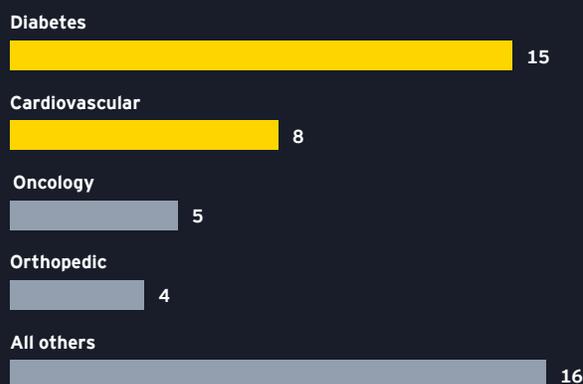
The rapid rise of smart insulin delivery pens and automated continuous glucose monitoring (CGM) systems have allowed patients to better monitor themselves on a daily basis and take control of their care. Software applications from Livongo, Onduo and Welldoc have also been an important step forward. These solutions allow individuals to better integrate diet, weight and blood sugar metrics with medication schedules, allowing consumers to better manage their condition.

They are also beginning to rival traditional therapeutic interventions. Welldoc's BlueStar, for instance, has won FDA approval and reimbursement from payers,

by demonstrating outcomes that are better than more standard therapies. (See "Scientific rigor will drive digital health success," a guest perspective by Anand Iyer, Chief Strategy Officer of Welldoc.)

As tools for mobile monitoring, smart delivery and real-time analytics converge, fully automated diabetes management will become a reality. Medtronic's MiniMed 670G system, launched in 2017, still requires the consumer to manually enter dietary data, but its ability to automatically adjust insulin dosages based on predictive analytics suggests that the "artificial pancreas" is nearer to reality than before.

**Figure 11.** Diabetes and cardiovascular disease dominate medtech digital dealmaking



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



## Advances in imaging and non-imaging diagnostics show how the medtech industry could evolve

The most obvious signs of the growing importance of digital capabilities, especially AI-enabled analytics, are apparent in the imaging and non-diagnostic imaging segments. While AI enables medtechs to extract more value from imaging and other data, innovations in non-imaging diagnostics allow medtechs to build data-rich profiles of individuals, not just in a formal clinical setting, but in the real world. Indeed, diagnostics represent an opportunity to get close to the patient and provide the customized high-touch care individuals want to better manage disease symptoms and overall health.

### AI is already transforming imaging

Among the most striking developments in 2018 was Siemens Healthineers' initial public offering (IPO). Raising US\$5.2b, the Siemens Healthineers flotation was the largest IPO in the medtech industry's history, and boosted the total value of IPO transactions since July 2016 to US\$9.1b – more than the previous decade's combined total IPO value. (See Figure 12.)

Investors' appetite for the Siemens Healthineers' IPO underscores the potential of digitally enabled monitoring and diagnosis tools to personalize health care. Siemens' own statements

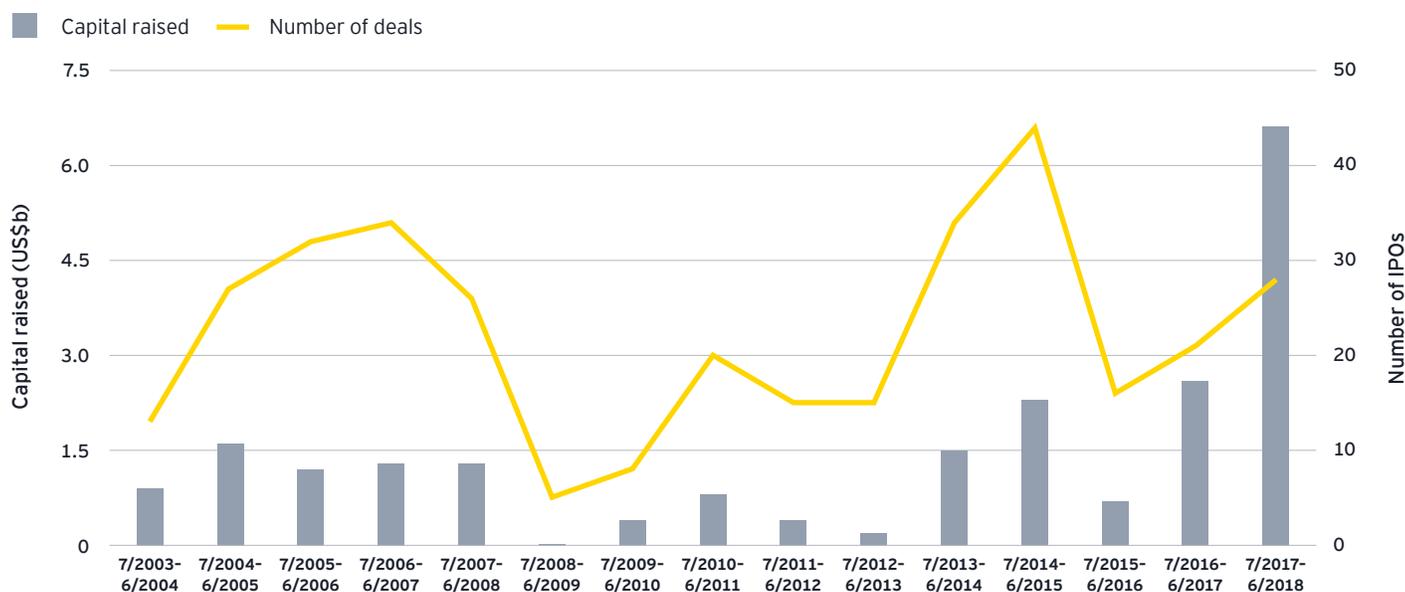
reference the growing importance of big data, AI and deep machine learning. Products such as Siemens' Biograph Vision PET/CT scanner are marketed as precision medicine-enabling technologies built on AI algorithm-driven software.

A number of other companies are also exploring AI's potential in imaging. GE Healthcare, which announced in June 2018 that it would spin off from its parent General Electric, and Philips are both making major investments in this arena.

As Tom McGuinness, President and CEO of GE Healthcare's US\$9b Imaging business notes, GE Healthcare is already using AI to accelerate image acquisition and

processing speed in tens of thousands of imaging devices globally. However, while imaging has been a valuable test case for AI in medtech, its potential is far wider, opening up every area of medical data to systematic analysis. (See the perspective, *"How AI-powered imaging can help build precision health."*)

As McGuinness says, the "mountain of data" already generated by the health care system has traditionally been an underused resource. "Less than 3% of health data is actionable, tagged or analyzed. That equation changes with AI, which can augment human decision-making to scale the delivery of improved outcomes," he says.

**Figure 12.** IPO deal numbers and cumulative value July 2003-June 2018

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

## Algorithms revolutionize diabetic retinopathy diagnosis

An important bellwether signalling the growing importance of AI is the FDA's April 2018 approval of IDx's proprietary algorithm IDx-DR, a new tool to diagnose diabetic retinopathy. IDx's product is the 13th AI-based algorithm to win FDA approval since Arterys' MRI cardiac imaging interpretation became the first in January 2017.

But IDx-DR differs from the previous approved algorithms in that it is the first ever to make screening decisions without the need for any additional human interpretation. Supporting the higher level of evidence required, this is also the first algorithm to be approved based on a prospective clinical trial. In IDx's pivotal trial, the algorithm showed more than 87% sensitivity and 90% specificity, beating pre-specified primary endpoints.<sup>1</sup>

The implications of the IDx product are profound. In the past, physicians would have studied patients' retinal images to detect disease symptoms, requiring screening by ophthalmologists. With IDx-DR, scanning for diabetic retinopathy can now be automated and managed by non-specialists in primary care and retail clinics. Those at greatest risk would be identified for a follow-up consultation with a specialist.

The machine learning capabilities seen in the IDx-DR product are early signals of the impact AI will have in medtech. This technology has potential to improve areas of care delivery ranging from remote monitoring to complex surgery. Next-generation robotic surgical platforms from Verb Surgical and Versius are incorporating AI so that systems can learn to optimize their performance. The relative value of surgical systems in the future

may be determined not by their robotic hardware but by the level of learned surgical expertise in their algorithms.

In order for AI and deep learning capabilities to become mainstream in the medical device industry, however, more flexible regulatory processes that promote the continuous improvements required for software will be critical. (See sidebar, "To augment AI, the industry must focus on regulatory flexibility and security.")

<sup>1</sup> Michael D. Abràmoff, et al. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. *npj Digital Medicine*, volume 1, Article number: 39 (2018). <https://www.nature.com/articles/s41746-018-0040-6>

## Diagnostics drive industry growth as personalized health becomes more important

In the past, diagnostics may have seemed like a peripheral value stream for the medical device industry. Today, however, they hold the potential to transform health care delivery. In the digital era of medtech, wearables that funnel data directly to the cloud decouple the acquisition of medical data from traditional office visits to care providers. Built-in AI analytics, meanwhile, mean these data become highly meaningful and actionable in real-time.

Key metrics from 2017-18 underscore the growing importance of non-imaging diagnostics to the medtech industry's future performance and overall growth. For instance, non-imaging diagnostic companies accumulated 38% of the US\$14.4b venture dollars invested in medtech between 2016 and 2018.

In particular, venture investors see major opportunities in the consumer genomics space. Helix, Counsyl, 23andMe and

Color raised some of the largest US venture rounds observed in 2017-18. (See *"The Pulse of the industry data book,"* page 38.) These companies have the ability to generate unprecedented amounts of personal data while simultaneously empowering consumers in their health care. Though companies must remain vigilant about the security and privacy of personal data, creating the tools to build that data is nevertheless an important advance in the diagnostics field.

Over the course of 2017-18, data-rich, non-imaging diagnostic companies were increasingly important acquisition targets. Twenty-three percent of the 2017-18 total M&A spend was dedicated to the acquisition of diagnostic assets. That is a considerable jump from the 9% 5-year average observed from 2013-17.

At the same time, therapeutic devices' share of medtech's total M&A spend fell from a five-year average of 77% to only 53% in 2017-18. This suggests that even though traditional therapeutic devices are still the mainstay of the market, acquirers

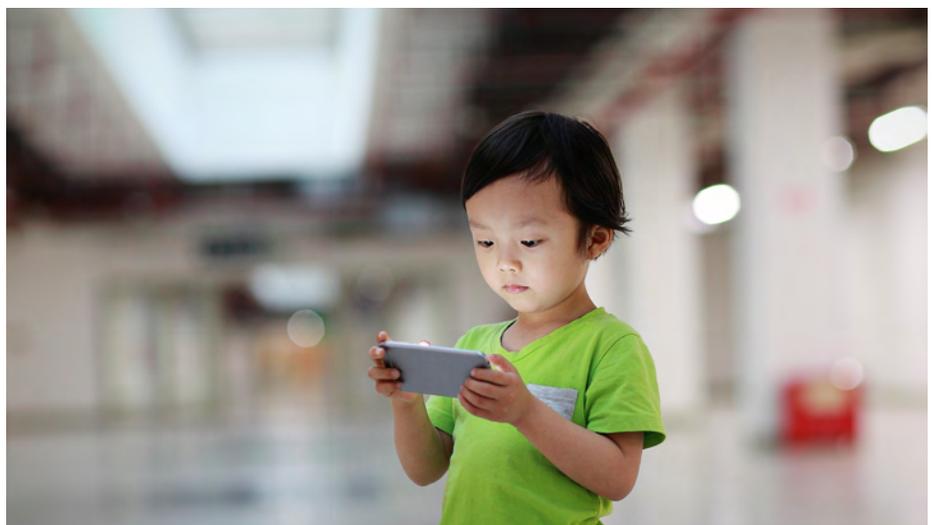
recognize that these products in isolation no longer have the same value-creating potential they once did. To create more value in the future, therapeutic devices will have to continue to focus on building the data capture and analysis capabilities that are already altering medtech's diagnostics and imaging segments.

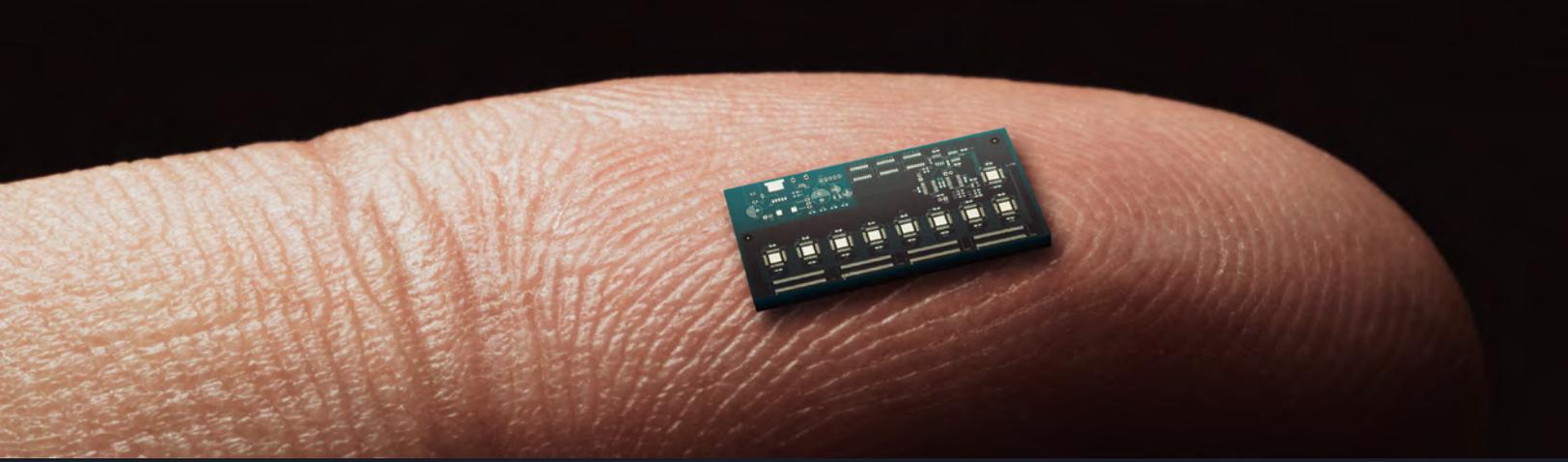
### Questions for medtech companies to consider

- ▶ How will medtechs use diagnostics and AI-driven analytics to achieve better therapeutic outcomes for their customers?
- ▶ How will medtechs use data to deepen their relationships with consumers and providers?
- ▶ As connectivity becomes standard, what steps are medtechs taking to secure their devices – and patient data?

"Less than 3% of health data is actionable, tagged or analyzed. That equation changes with AI, which can augment human decision-making to scale the delivery of improved outcomes."

**Tom McGuinness**  
President and CEO, Imaging  
GE Healthcare





## To augment AI, the industry must focus on regulatory flexibility and security

As Dr. Simon Kos, Chief Health Officer of Microsoft notes in an accompanying perspective, “We are at a point in medical history where we have more data than human beings can process, and at a critical time when technology can help make sense of that data.” (See guest perspective, *“Creating the health infrastructure to massively improve health outcomes.”*) To make sense of the data, AI-driven algorithms will be essential. That need creates regulatory hurdles, too. To work with these new products, regulators need to build flexible and intelligent frameworks that optimize the use of data in health care while minimizing risk.

Traditional regulatory bodies treat devices as unchanging products requiring a single assessment before entering the market. This approach, however, does not capture the reality of how self-learning algorithms work, constantly improving and updating themselves. Given the rate of AI’s evolution, new technologies that rely on the capability have the potential to be reviewed and updated on a continual basis. As Scripps Translational Science Institute’s Jones notes, “The challenge medtechs have now is managing these overlapping business cycles so that hardware advances remain aligned with software developments.”

### The cybersecurity opportunity

Continuous upgrading is not only necessary to maintain software efficacy, but to maintain safety. Indeed, one of the central challenges as AI is embedded in more and more medtech products is creating systems that are robust enough to resist emerging cyber terrorist threats.

“Cybersecurity is one or two headlines away” from becoming the primary focus of the media and consumers, contends Juan-Pablo Mas, a partner

at Action Potential Venture Capital. A steady trickle of negative headlines in 2016 and 2017 linked to the hacking of insulin pumps and vulnerabilities in implantable cardiac devices continues to create anxiety.

As yet, no hacker has attempted to corrupt a medical device to inflict individual harm, but that doesn’t mean medical devices and the data they generate aren’t valuable targets. Microsoft’s Kos notes that health care organizations are “more at risk than many other industries due the age, number and complexity of hospital systems.” Based on Microsoft’s analysis of which data are most valuable to cybercriminals, Kos believes “cybercriminals are aware that health data is considerably more valuable than financial data alone.”

Moreover, as digital technology enables the rise of personalized health care, it also blurs the boundary between medical data and individual personal data, leaving a broad front for medtech to defend against cybersecurity vulnerabilities. What companies have traditionally seen as a distinct IT problem will increasingly become a necessary strategic focus for medtech development.



# Future success requires greater participation in the health ecosystem

The promising developments in the imaging and non-diagnostics segments offer a glimpse of how new thinking and new technology could transform the medtech industry's fortunes. Current high valuations for medtech companies suggest that investors are optimistic for the industry's future. To justify this positive sentiment and position themselves to create future value, medtech companies must embrace digital technologies and increase their data and analytics focus. Above all, medtechs will have to work with their partners in the broader health ecosystem to rebuild health care around the patient-consumer, if they are to achieve better outcomes for all stakeholders.

## Can medtech continue to outperform the broader indices using the usual formula?

In 2017-18, the medtech industry outperformed the broader indices, with valuations across the industry soaring 50%. Medtech's smaller companies, businesses with less than US\$500m

in revenue, and non-imaging diagnostic companies led the valuation surge. Indeed, valuations for these two subgroups increased 92% and 82%, respectively. Investor confidence was partly driven by growing investment in the non-imaging diagnostics space and continued refinement of chronic disease management. A more transparent US regulatory process, including continued evaluation of a digital health software precertification program, removed uncertainties that weighed down investor expectations in previous years.

Yet, as we have noted, there are also warning signs on the horizon. While certain companies have started to embrace digital, data-rich business

models, much of the industry is still focused on "business as usual." That emphasis on the status quo may make it difficult for some companies to continue to justify their high valuations in the future.

## To create future value, medtechs need to embed themselves in the health ecosystem

Success for medtech in the future means abandoning the business as usual approach that has yielded solid if uninspiring growth via bolt-on M&A and consolidation. Medtechs may hold unique expertise in manufacturing devices, but if data and algorithms become the

Medtechs that embed their devices, services and solutions in the health ecosystem's workflows can exploit the power of the network.

primary products, the new leaders will be the companies that can integrate the information and make it usable and accessible to individuals.

To deliver value in the future, medtechs will also need to begin sharing data more broadly within the health care ecosystem. Life sciences companies have traditionally seen data as a proprietary asset. In the future, as medical devices begin to build more intimate and information-rich relationships with individuals, medtechs must be able to safely and securely communicate that data to other partners in the ecosystem.

Payers in particular will need access to this data flow to trust the effectiveness of the devices they reimburse. More broadly, devices – and the data they generate – will need to connect with clinicians and health care systems to improve care decisions.

For medtech companies, moving from selling devices to data may seem risky. However, in the connected future, trying to preserve the current business model may be even riskier. Scripps Translational Science Institute's Jones notes the potential downsides to retaining a product-centric approach, "Companies continue to focus their efforts on products that are siloed solutions. But the reality is, if you're offering a siloed solution it's much easier to be replaced with the next brighter, shinier siloed solution."

In contrast, companies that can form connections with other stakeholders and embed their own devices, services and solutions in the health ecosystem's workflows can exploit the power of the network. The network phenomenon has had a major impact in other sectors. Indeed, examples in the retail and mobility space demonstrate the utility of platforms that bring different stakeholders together.

As the user bases for these platforms grow, the platforms become linchpins for how their ecosystems function, especially the flow of data. As such, they are increasingly difficult to replace with new platforms.

### **Medtechs need to get serious about the customer experience**

To embed themselves more deeply in the health ecosystem, medtechs must also break down the barriers that limit data flow and the creation of more holistic solutions. The rapid advances in digital health have created an array of different solutions that solve specific problems but don't work well together. These disease-specific offerings require patients to adapt to the technology, interfering with the seamless customer experience.

To drive better outcomes, it will be imperative that the technologies are flexible enough to fit naturally into patients' lives. As Propeller Health's Van Sickle says, the ultimate goal is not to create proliferating digital health solutions that work in isolation, but to digitally integrate care management. "Stand-alone digital systems designed to work specifically with a particular therapeutic are counterproductive to a holistic experience and the understanding of a person's disease," he says. Thus, the emphasis should be the creation of a spectrum of solutions that are tailored to individual needs and help coordinate care.

Holistic health care management, in short, is going to become the central measure on which medtech companies stand or fall. They will be judged not by the products they create, but by the user experiences they deliver. To date, the resources put into improving the overall digital medtech customer experience have been modest.

But the emphasis on the customer experience will be critical to the future success of device manufacturers.

### **Conclusion**

The medtechs that seize the opportunities inherent in digital transformation will have to achieve two things. First, they have to accelerate their digital strategies, either through organic investments or partnerships and acquisitions. In the near-term, companies should focus on amassing expertise in areas such as data capture and storage and AI-enabled analytics.

Second, medtech companies will have to focus as never before on the individual. The empowered super consumer will be the final arbiter of future success. As Van Sickle says, "Emphasizing the consumer experience will be central – at least for those medtechs that survive."

### **Questions for medtech companies to consider**

- ▶ How are medtechs embedding the user experience into their innovations?
- ▶ How can medtechs create networks to secure their positions in the health care ecosystem?
- ▶ What organizations should medtechs partner with to acquire the technologies and talent required for business model transformation?



# China's growing importance for medtech

One important trend for medtech companies to watch is the capital flow from China, where diverse investment in medtech, both domestic and international, has the potential to reshape the entire industry.

The influence of China on the global medtech market is multifaceted; long the second-largest medtech market, China is also becoming a major source of innovation and capital investment. (See Figure 13.) Elton Satusky, a partner at the law firm Wilson Sonsini Goodrich & Rosati, notes the huge remaining growth potential for the Chinese medtech sector. "The medtech growth rate is much higher in China given the lower penetration for most devices," says Satusky.

## Chinese firms look to the West for growth

Chinese medtechs themselves are also looking overseas, seeking globalization. In 2017, for instance, China's Weigao Group acquired Texas-based Argon Medical Devices for more than US\$800m in a strategic attempt to diversify its revenue streams into overseas markets. It was the second largest M&A involving an Asia-Pacific buyer. China's CDH Investments claimed the top spot with its acquisition of Sirtex Medical for nearly US\$2b.

## Leapfrogging to mobile solutions

China's expertise in AI and genomics, among other cutting-edge areas, leaves open the possibility that its innovators will overtake the US and European medtech leaders in implementing new digital solutions. The use of ultrasound to detect breast cancer is one area to watch says Satusky.

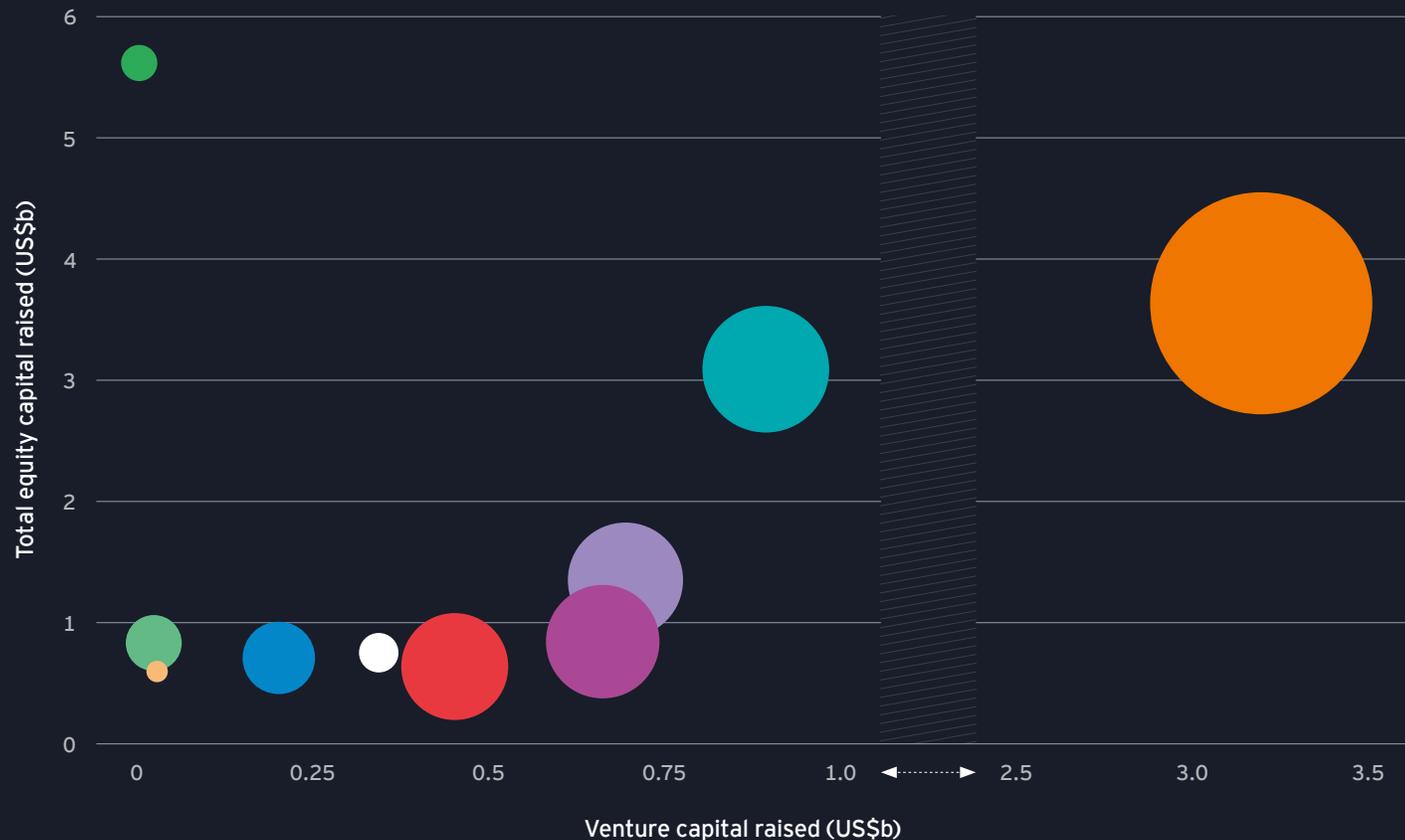
In the US and Europe, mammography is the established standard of care despite the significant capital requirements for the instruments and technological limitations that result in false negatives in up to 20% of individuals with breast cancer. However, in China, where mammography hasn't been as widely adopted, there is now an opportunity for the lighter, handheld procedure to leapfrog traditional practice.





**Figure 13.** Capital raised by leading regions excluding debt, July 2017-June 2018

- China
- France
- Germany
- Israel
- Sweden
- US – Massachusetts
- US – New Jersey
- US – Northern California
- US – Southern California
- UK



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



GUEST PERSPECTIVE

# How AI-powered imaging can help build precision health



## Tom McGuinness

President and CEO, Imaging  
GE Healthcare

The prescription for systemic recovery is as simple as it is challenging. Health care needs to become more personalized, digitally integrated and collaborative.

Improving health care outcomes at the macro-level will require a blend of precision diagnostics, therapeutics and monitoring tailored to each and every patient. We call this “precision health.” Done right and done at scale, precision health delivers on health care’s triple aim: better quality care at a lower cost with increased access for patients around the world. This enables a future where data, analytics and individualized care help accurately diagnose disease,

**Our global health care system is ailing. The symptoms are serious: limited access to care, with a shortage of seven million health care workers globally; unsustainable cost increases, with the US spending nearly 20% of its GDP on health care alone; caregiver fatigue, with half of radiologists worldwide showing signs of burnout; a deluge of medical data, growing nearly 50% per year; and a host of other pain points.<sup>1</sup>**

comprehensively monitor a treatment’s effectiveness and improve the patient experience.

Medicine’s oldest form of diagnostic imaging, the X-ray, is at the heart of a new analytical solution that embodies precision health. X-ray accounts for 60% of all scans today, but of the millions of images taken each year, up to 25% are rejected due to poor image quality.<sup>2</sup> To address this, GE Healthcare developed an app that helps clinicians automate their data collection and pinpoint the root causes of rejected images, which helps shorten exam times and patient discomfort, reduces unnecessary re-scans

and saves costs. Piloted at the University of Washington Medical Center, this app has automated a process that once required more than 230 mouse clicks and nearly seven hours of work.<sup>3</sup>

Solutions like this X-ray app are powered today by digitally integrated tools, and eventually by artificial intelligence (AI), which will help make caregivers’ jobs easier and patients’ experiences smoother. This year alone, more than 100 start-ups are focused solely on health care AI, and that number will only grow. Yet medical AI must be integrated and embedded seamlessly – even “invisibly” – into devices and workflows already in use today. It



**Medical AI must be integrated and embedded seamlessly – even “invisibly” – into devices and workflows already in use today. It cannot and will not be adopted if it disrupts the workflow of the same caregivers it aims to help.**

cannot and will not be adopted if it disrupts the workflow of the same caregivers it aims to help. AI can be a game-changer only if it's not a game-stopper.

### **Accelerating outcomes with AI**

When it is integrated, AI enables incredible outcomes. In partnership with NVIDIA, for example, we're using AI to accelerate image acquisition and processing speed in tens of thousands of imaging devices globally. For computed tomography alone, image processing using NVIDIA's platform is twice as fast as current technology, which reduces delays for patients needing critical medical imaging.<sup>4</sup>

Or look at it from the perspective of health care providers. The average hospital generates 50 petabytes of data annually – roughly the size of 10 million standard iCloud storage accounts combined. This mountain of data includes medical images, clinical and operational charts, financial information and sensor readings. Yet less than 3% of the data are actionable,

tagged or analyzed. That equation changes with AI.

The import of precision health and influx of AI reinforce the fact that health care's future requires a team effort. Doctors, hospitals and health systems are asking for help solving big problems, and they want more than just the latest band-aid solution.

That is why we are partnering with our customers, clinicians on the ground and even other medtech innovators, to address hospitals' and patients' needs across the entire care pathway. Take for instance our recent collaboration with Roche Diagnostics, which is focused initially on acute care and oncology. This first-of-its-kind partnership combines in vivo data from GE Healthcare's advanced analytics, medical imaging and monitoring equipment with the in vitro data from Roche's biomarker, tissue pathology, genomics and sequencing portfolio.

The way forward for health care is equal parts promise and challenge.

We must connect precision diagnostics, therapeutics and monitoring to generate insights for better patient outcomes. We must embrace AI to empower caregivers and improve the patient experience; and we must realize that health care's future requires a team effort.

If we succeed together, the future of health care can be – and will be – more personalized, integrated and collaborative.

### **References**

- <sup>1</sup> [www.ncbi.nlm.nih.gov/pmc/articles/PMC5710014/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5710014/), Kaiser Family Foundation 2016, Peckham C. *Medscape radiology lifestyle report 2015*, NVIDIA Investor Day 2017 Presentation.
- <sup>2</sup> Little, Kevin J., et al. "Unified database for rejected image analysis across multiple vendors in radiography," *Journal of the American College of Radiology* 14.2 (2017): 208-216.
- <sup>3</sup> Kalpana Kanal, PhD in UW Department of Radiology case study for Analytics Viewpoint Newsletter from GE Healthcare.
- <sup>4</sup> GE and NVIDIA Join Forces to Accelerate Artificial Intelligence Adoption in Health-care. [www.businesswire.com/news/home/20171126005051/en/GE-NVIDIA-Join-Forces-Accelerate-Artificial-Intelligence](http://www.businesswire.com/news/home/20171126005051/en/GE-NVIDIA-Join-Forces-Accelerate-Artificial-Intelligence)

GUEST PERSPECTIVE

# Creating value through digital companion experiences



David  
**Van Sickle**

Co-founder and CEO  
Propeller Health

**Twelve years ago, I was working as a disease detective at the CDC when I stumbled upon the story of a mysterious and tragic asthma outbreak. In Barcelona from 1981 to 1987, emergency rooms experienced more than two dozen days when visits for asthma increased significantly. The events sent more than 1,100 people to the hospital and, tragically, resulted in 20 deaths.**

Experts worked for years before they understood the culprit: huge clouds of soybean dust caused by a lack of proper filters on harbor silos. Because soybean dust had never been identified as an allergen, no one considered it.

This mystery gave me an idea. If we could passively monitor medication use, we could help patients and providers better understand respiratory disease and avoid tragedies like this.

Today, Propeller Health does this by connecting patients' inhaled medicines to our platform via sensors that collect data about medication use. The sensors are paired with digital interfaces that guide patients toward better self-management and help them communicate with their physician about their condition.

We've demonstrated that this approach can reduce symptoms and lower the cost of care by making better use of the medicines we already have, which is critical as our industry continues to move toward value-based care. Ultimately, payers don't want to buy medicines; they want to buy the outcomes medicines bring about. To meet these demands, the life sciences business model will evolve away from unit sales and toward services.

## **Therapeutics as a service**

We think about digital medicines as companion experiences coupled to a person's prescribed medicines, generating information that can be put to work in powerful ways. This includes collecting real-world evidence, creating new



---

**We think about these digital medicines as companion experiences tightly coupled to a person's prescribed medicines. They generate information that can be put to work in powerful ways.**

service-oriented business models, and supporting drug discovery.

There are multiple downstream implications once medicines give off information about whether they're taken and how effective they are. We have the opportunity to create more meaningful, therapeutic experiences for every individual with respiratory disease, not just the sickest or most costly.

Adherence is an important example. When you look at why people fail to regularly take their medications, you quickly see how digital experiences can create value, beyond simple medication reminders. Digital tools can make it easier for patients to understand how to use their medication, or identify environmental conditions that contribute to symptoms, helping care teams and consumers mitigate those exposures.

By promoting the ongoing exchange of data between a person with chronic respiratory disease and her care team, digital medicines strengthen patient-physician relationships and create a better experience of chronic disease management.

For this to work, digital medicines must align with the experience of the disease. We've seen a proliferation of stand-alone digital systems designed to work with a particular medication. That approach often assumes that people only use medications from a single company, but people with chronic respiratory disease often use multiple medicines at the same time.

This is why we aimed to make Propeller compatible with a range of respiratory medicines. Our technology works across competing brands, saving individuals from having to use multiple brand-specific interfaces.

### **Looking ahead**

As we continue to build our capabilities, Propeller is expanding into new disease areas where we see a combination of high unmet medical need and low market differentiation. In partnership with Aptar Pharma, we're focused on bringing connectivity to new categories of drug delivery devices, starting with injectables for severe asthma.

We are also growing our scope of coverage. We've partnered with around 60 different payer and provider organizations across the US, and we're now working in 16 countries.

We are on the cusp of an age when providers will have the choice to prescribe analog medicines or their new digital versions, which offer companion therapeutic interfaces and connectivity and monitoring. We have a lot of work to do, but believe digital innovation is changing the experience of chronic disease.

---

**60**

Propeller Health has already partnered with around 60 US-based payer and provider groups and is working in 16 other countries.

GUEST PERSPECTIVE

# Creating the infrastructure to massively improve health outcomes



Dr. Simon  
**Kos**

Chief Medical Officer  
Microsoft

**Q: What role does Microsoft want to play as health systems globally are reimagined?**

**A:** There is an opportunity to modernize and reinvent the experience for people in healthcare, especially the clinician. In our daily lives we expect apps to interface seamlessly with our personal devices in ways that are intuitive. That isn't the case in the care delivery setting, where cumbersome workflow systems make life harder for providers. To improve the clinical user experience, one of the critical infrastructure upgrades required is the creation of a secure cloud that improves interoperability and enables greater, more transparent data exchange.

Microsoft has a clear role to play in building this secure health cloud. We want it to be a trusted place to store and use health information. But it isn't ours. Nor do we have aspirations of mining the data to create algorithms that can be monetized. We see ourselves as a data steward, helping various organizations aggregate and effectively use a variety of health information to create a more personal, proactive care system.

By eliminating frictions associated with data sharing and use, Microsoft can enable treatment and diagnostic decisions that are individually tailored and more effective from the start.

**Q: What technologies are most important as we evolve from aggregating information to using it to make health decisions?**

**A:** We have gone from dumb devices to smart devices that can capture and send or save information to data lakes. The next step is to make use of that information, and we're at the early stages in terms of our capabilities. We are at a point in medical history where we have more data than human beings can process, and at a critical time when technology can help make sense of that data. Clinicians complain that despite drowning in data, they are information poor. We believe artificial intelligence (AI) will have a dramatic role to play in health, especially the analysis of massive data sets. AI will also reduce the time physicians spend on routine administration, allowing them to spend more time with patients.



**As we combine health data in new ways, we have started to identify proxy indicators that are cheap, ubiquitous and effective. In some cases, we can use these digital biomarkers to diagnose genetic diseases without sequencing.**

AI's impact is likely to be felt first in the realms of diagnostic imaging and complex-care decision-making. Disciplines such as radiology and pathology are already leveraging AI to assist and improve diagnosis, and therapeutic areas such as dermatology and ophthalmology appear ready for similar advances. In April 2018, the U.S. Food & Drug Administration cleared the first retinal diagnostic algorithm which can screen out cases which need to be referred to an eye care professional from those where no such referral is necessary.

**Q: We are hearing a lot about digital biomarkers. How can the aggregation of data create new, cheaper mechanisms for disease diagnosis?**

**A:** We might be able to use smart devices to create alternatives to expensive restricted medical tests. A research team in Australia, for instance, has shown it is possible to reliably diagnose anemia from selfies that measure the relative pallor of the eyelid. In environments where mobile is pervasive but access to routine diagnostics such as blood tests are not, these digital tools are important. For now,

the gold standard for the diagnosis of genetic diseases is genome sequencing. But such tests are expensive, and often must be run multiple times to ensure accuracy. Moreover, they require specially trained personnel to interpret the results. As we combine health data in new ways, we have started to identify proxy indicators that are cheap, ubiquitous and effective. In some cases, we can use these digital biomarkers as effective screening tools, or even to diagnose genetic diseases without sequencing.

**Q: Globally, where are the hot spots for innovations that improve health care delivery?**

**A:** We're seeing fantastic work being done in African nations such as Rwanda and Kenya. Both countries have extreme workforce shortages and need to deliver services via virtual care. They are taking advantage of the widespread ubiquity of broadband internet and mobile phones to deploy digital services in a range of areas, not just in health.

Southeast Asia and India are also innovating on the health delivery side.

In terms of innovations in cloud computing, one key area of interest is using mixed reality in health care. In some of the less regulated markets like Latin America, physicians are using mixed reality in surgery in ways that regulation simply doesn't permit in the US or Europe.

**Q: How do regulatory and data policies need to change to support the greater use of health data?**

**A:** While there are some brave new steps with GDPR [General Data Protection Regulation], there is a lot of evolution we still need to go through as an industry, specifically with respect to the patient/doctor consent model and secondary use of information. In an ideal world, patients should get a copy of every bit of data collected about them, have autonomy to say who sees what and even monetize their data.

That information, when aggregated at scale, is valuable to companies. At the moment, the aggregators of patient data are health care organizations, but certain technology companies are also beginning to move into this space.



GUEST PERSPECTIVE

# Seizing the opportunities powered by connected devices



---

## Donald Jones

Chief Digital Officer  
Scripps Translational  
Science Institute

Chairman  
Cardiff Ocean Group

**It's time for traditional medtech companies to take stock of their business models. Like the taxi companies ignoring Uber, many are ignoring the digital opportunities to their own peril. The reality is many new devices are designed to be connected to generate value via predictive analytics and improved clinical decision-making. There exists a network effect opportunity that naturally leads to growth that companies across the health ecosystem often just don't understand.**

Companies continue to focus their efforts on products that are siloed solutions. But the reality is, if you're offering a siloed solution it's much easier to be replaced with the next brighter, shinier solution. The cost and difficulty of switching is relatively low.

Participating in a networked solution can protect from this kind of commoditization. If a solution is a node in a network and the network components work well together, customers have a disincentive to switch to another solution. As health care embraces this network mentality, there will be

opportunities for medtech to create and participate in these networked solutions, often in conjunction with other device and software solutions.

At the moment, many medical device companies are still locked into 10-year product cycles at a time when evidence suggests these cycles are being compressed. Indeed, as medical device companies move closer to their end customers (the patient), the business cycle will start to look more like a consumer electronics cycle, with some medtechs spending one year in the

---

## To create future value, device companies will need to own the algorithms and user interfaces that derive usable information from these data streams for the clinician.

research lab, one year in development and one year in the market, resulting in a two year product life cycle.

This time compression requires greater agility and medtechs must be prepared to submit products to regulatory authorities every two years. And sooner than medtechs think, they will need to be able to complete regulatory cycles like software developers, who now often operate on a 24-hour product update cycle. The challenge medtechs have now is managing these overlapping business cycles so that hardware advances remain aligned with software developments and with regulatory filing requirements.

### **Disruption in action**

We know that existing brick-and-mortar healthcare systems can't manage patients the 99% of the time that they are outside of the care site. This is especially true for chronic diseases, where costs are skyrocketing because the conditions aren't managed well. But new technologies that

capture data in real, or near real, time allow physicians to make more informed and timely decisions about the care of their patients and the therapy interventions required. It used to be that physicians required patients to come in for an office visit because that was the only way to obtain the data to make a proper care decision. Miniaturized devices and wearables that funnel data to the cloud now mean it is possible to acquire data independent of that bricks-and-mortar office visit.

If I operated a medtech company building boxes, I would not be looking at a 3-5 year business plan continuing to build boxes. My business plan would be to build wireless sensors and to run the medical device in the cloud as a service, using available screens (mobile, tablets, wall, TVs, etc. – yes the FDA precedent has been set) as user interfaces. The opportunity shifts health system capital spend dollars to operating dollars, while creating a recurring revenue model for the medtech company. The disposable component of medtech revenue remains in place.

Near-term, one of the largest opportunities for device makers is the creation of sophisticated but disposable smart patches that passively collect streams of data, analyze and store them in the cloud, while outputting actionable clinical information. In this environment, the value is in the clinical insights and trend analysis that the devices spit out, rather than in the med device itself.

To create future value, device companies will need to own the algorithms and user interfaces that derive usable information from these data streams for the clinician. If they don't own these, the companies will lose value over time. For now, smaller startups, not medtech's mainstays, are driving the innovations critical to creating this evolving cloud based smart patch and wearables industry.

GUEST PERSPECTIVE

# Scientific rigor will drive digital health success



Anand  
Iyer

Chief Strategy Officer  
WellDoc

**There's a lot of hype about digital health today. And even a lot of names. mHealth. eHealth. dHealth. We believe that in the future, it may just be health, and if there isn't a digital component to it, well, it won't be mainstream.**

At WellDoc, we believe there is an opportunity to leverage the ubiquity, accessibility and affordability of mobile technology to empower people with chronic conditions to better self-manage their diseases, bringing them closer to their care teams and helping them to achieve better health outcomes. To accomplish these goals, our digital health solutions have to fit naturally into patients' daily routines and the clinical workflows of health care providers.

We believe that to build trust with different customers, digital health solutions need to meet the same standards as traditional drugs and medical devices. That means running clinical trials to demonstrate outcomes and efficacy in statistically validated ways, achieving regulatory approvals to demonstrate patient safety and ensuring that data – especially

protected health information (PHI) – is properly secured using the latest cybersecurity leading practices and guidelines. In addition, such rigor is not limited to the solution itself – it must also be applied to the processes that support the solution's delivery.

Taking such a scientifically rigorous approach is one of the primary ways we've differentiated our BlueStar digital health solution for diabetes. We've conducted multiple randomized controlled trials demonstrating our application helps patients reduce their A1C levels by an average of two points within the first three to six months of use. Those data paved the way for a U.S. Food & Drug Administration Class II medical device approval.



---

**Interoperability has been critical to advances observed in the telecom, financial services and manufacturing industries. In health care, interoperability is primarily seen as a data issue. To achieve sustainable outcomes, however, we need to think about interoperability more broadly.**

### **Creating the case for economic savings and reimbursement**

With help from Truven Health Analytics, an IBM Watson Health Company, we've quantified the economic value of our A1C shifts, too: in the US, it's an annual average savings of roughly US\$3,150 per patient with poor diabetes control as measured by elevated A1C values. The improvements in outcomes and economics savings have been critical to driving adoption by, and reimbursement from, health insurance companies, large hospital systems and self-insured employers.

Since commercializing BlueStar, we've learned a lot about the use of digital therapeutics – and how to innovate. When solutions are intuitive and fit into clinical workflows and daily life, higher user engagement can result. And we've been able to dispel some critical myths. Many believe that the elderly can't adopt a "digital only" solution like BlueStar, but prefer, and perhaps even require, human coaching. But our data have consistently shown our elderly patients to be our highest users.

We continue to improve both the user experience and BlueStar's functionality. We recently launched hypertension and weight management tools inside the BlueStar experience, so that patients who suffer from these co-morbid conditions can manage their health – not just their diabetes – within a single, clinically validated experience. We've also built a BlueStar "light" platform aimed at patients who need only a maintenance solution.

### **Winning in a crowded market**

One of the challenges with today's digital health market is the fragmentation by condition, experience, and integration into the clinical workflow. As a patient myself, I know that others with multiple conditions don't want X for a diabetes solution, Y for a hypertension solution and possibly Z for a congestive heart failure solution. People want one experience that holistically manages various conditions specific to them.

Creating these integrated services requires partnering judiciously with organizations that bring expertise from different domains. It's likely we will witness

a number of collaborative efforts during the remainder of 2018 and throughout 2019 as digital health solutions take their legitimate position alongside other proven therapeutic solutions and pathways.

For Welldoc, collaboration is a natural part of our future – and for the digital health industry at large. We don't have to – and likely may not – build everything in-house. Instead, we will map out a logical structure for expansion in which we create scale by adding new capabilities over time on a case-by-case basis.

Interoperability has been critical to advances observed in the telecom, financial services and manufacturing industries. In health care, interoperability is primarily seen as a data issue, with a focus on data sharing standards. To achieve sustainable improvements in health outcomes, however, we need to think about interoperability more broadly, applying its principles to the systems, processes, workflows and experiences of patients and providers. In doing so, we will come full circle – to health, not digital health – in our never-ending endeavor to help people live better lives.

# data

# book

FINANCIAL PERFORMANCE

## Medical technology at a glance

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

Public company data	2017	2016	Change	% change
Revenues	\$ 379.1	\$ 363.5	\$ 15.6	4.3%
Conglomerates	\$ 163.0	\$ 152.7	\$ 10.2	6.7%
Pure-play companies	\$ 216.1	\$ 210.8	\$ 5.3	2.5%
Commercial leaders	\$ 199.0	\$ 192.3	\$ 6.6	3.4%
Non-commercial leaders	\$ 17.2	\$ 18.4	\$ (1.3)	-6.9%
R&D expense	\$ 15.9	\$ 16.0	\$ (0.1)	-0.4%
SG&A expense	\$ 72.6	\$ 70.3	\$ 2.3	3.3%
Net income	\$ 14.9	\$ 16.1	\$ (1.2)	-7.2%
Market capitalization	\$ 927.5	\$ 752.8	\$ 174.7	23.2%
Number of employees	809,800	807,400	2,400	0.3%
Number of public companies	427	432	-5	-1.2%

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 2017 and 31 December 2018.

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

### Slow and steady growth

- ▶ 2017's revenue growth rate was the second highest in the last five years, but still well below the pre-financial crisis average of nearly 15%.
- ▶ The Abbott/St. Jude Medical acquisition negatively affected the R&D investment and net income of pure-play medtechs. Normalizing for the conglomerate's acquisition, R&D investment increased 4.4%, while net income fell 2.7%.
- ▶ Two large, one-time charges by Dentsply and Medtronic also biased the net income results. Accounting for these charges, net income would have increased nearly 30%.

FINANCIAL PERFORMANCE

# US and EU medtech public company revenues



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

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

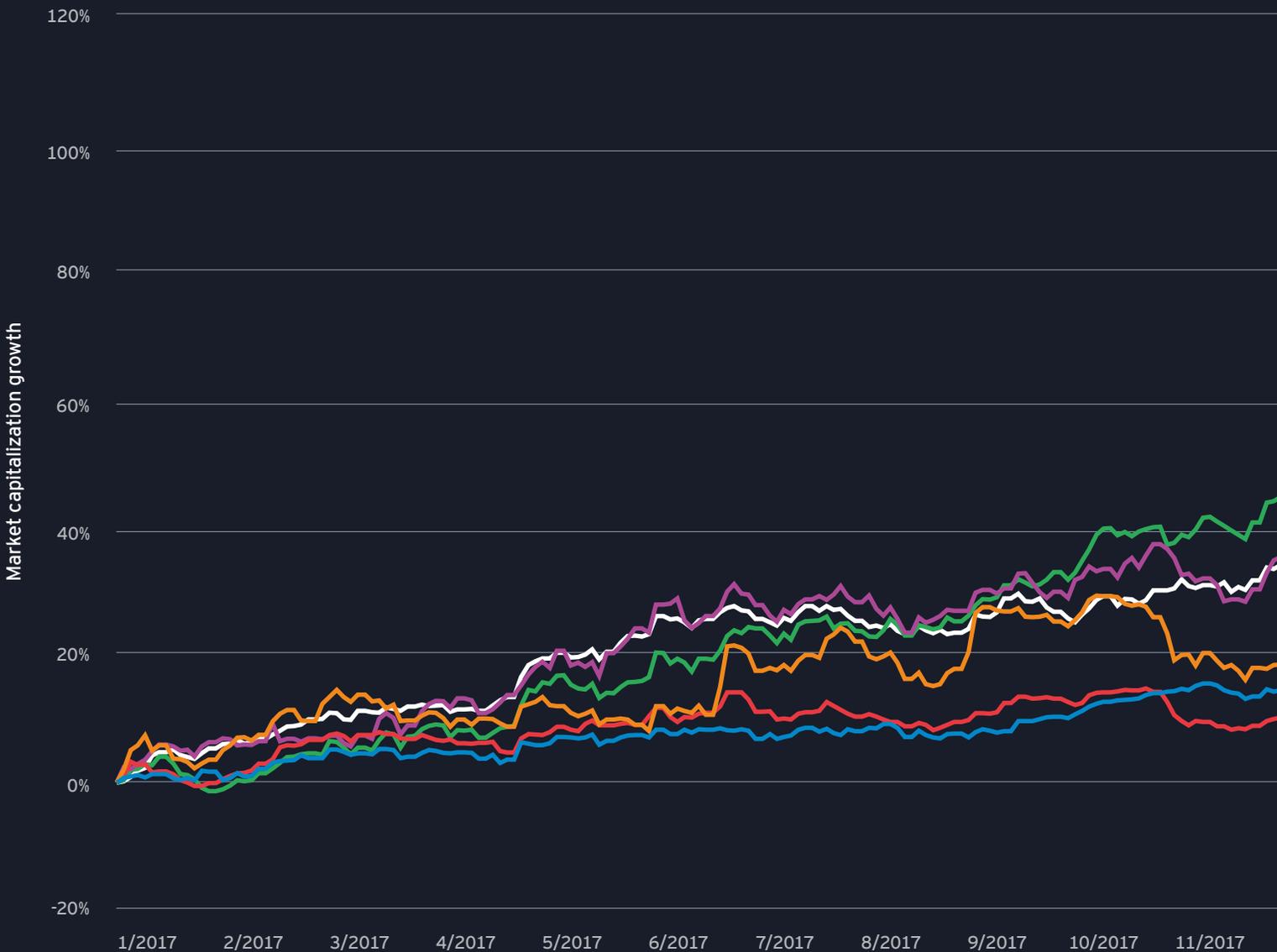
## Commercial leaders setting the pace

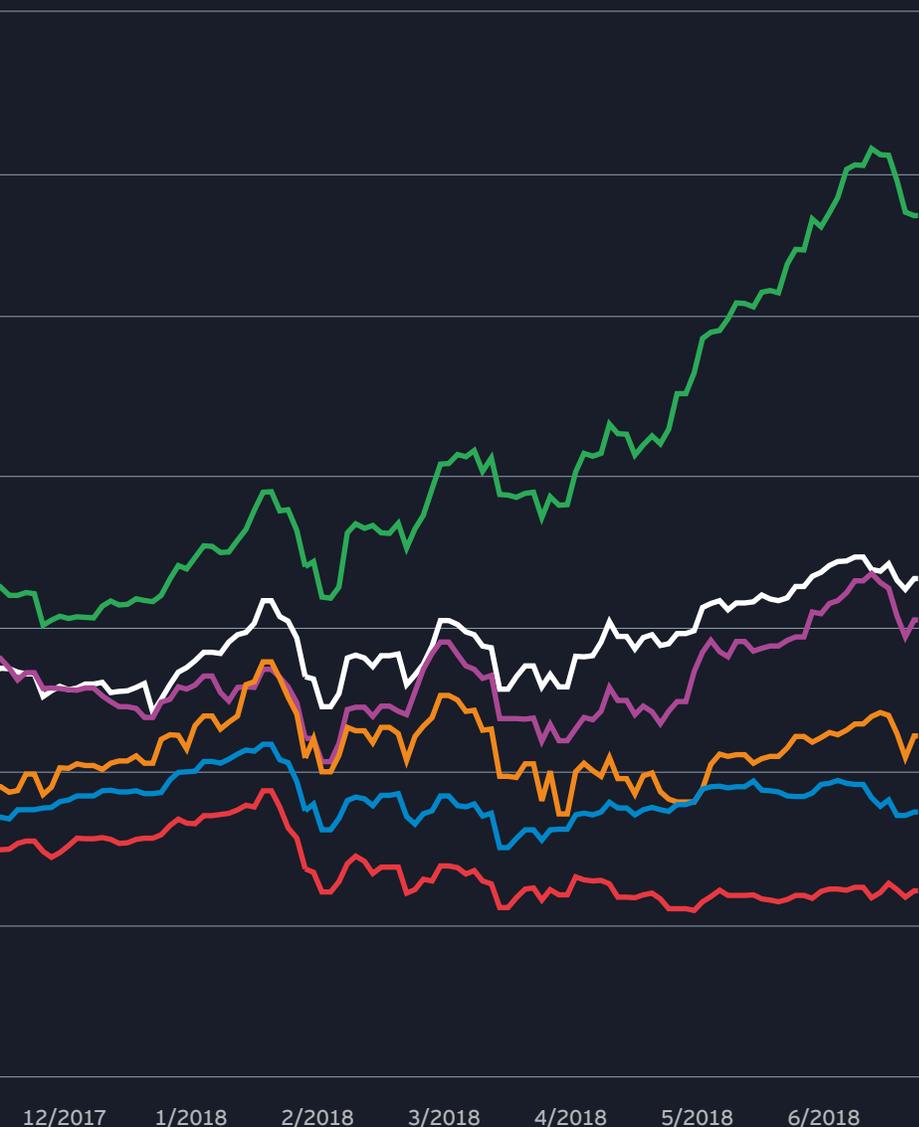
- ▶ Pure-play revenues ticked up 17% from 2012 to 2017, with a compound annual growth rate (CAGR) of 3.2%.
- ▶ Revenue increases at commercial leaders drove the growth: the CAGR for commercial leaders' revenue was 5%; it was 1.4% for non-commercial leaders.
- ▶ Medtronic (+1% to US\$29.9b), Johnson & Johnson (+6% to US\$26.6b) and Thermo Fisher Scientific (+14% to US\$20.9b) were the top-three revenue generators.

FINANCIAL PERFORMANCE

# US and European medtech market capitalization relative to leading indices

- EY medtech commercial leaders
- EY medtech non-commercial leaders
- Rock Health Digital Health Public Company Index
- Big pharma
- NASDAQ biotech
- Composite broader indices\*





### Investors reward innovative medtechs

- ▶ Investors flocked to medtech as the industry's cumulative public valuation surged 57% during the 18-month period ending 30 June 2018, outpacing the broader industries.
- ▶ Non-commercial leaders (+92%) and non-imaging diagnostic companies (+82%) captured investors' attention.
- ▶ The 124% uptick in value for earlier stage, non-imaging diagnostic companies is a signpost of the growing importance of deep, personalized data as health care customers demand more tailored products and services.

Chart includes companies that were active on 30 June 2018.

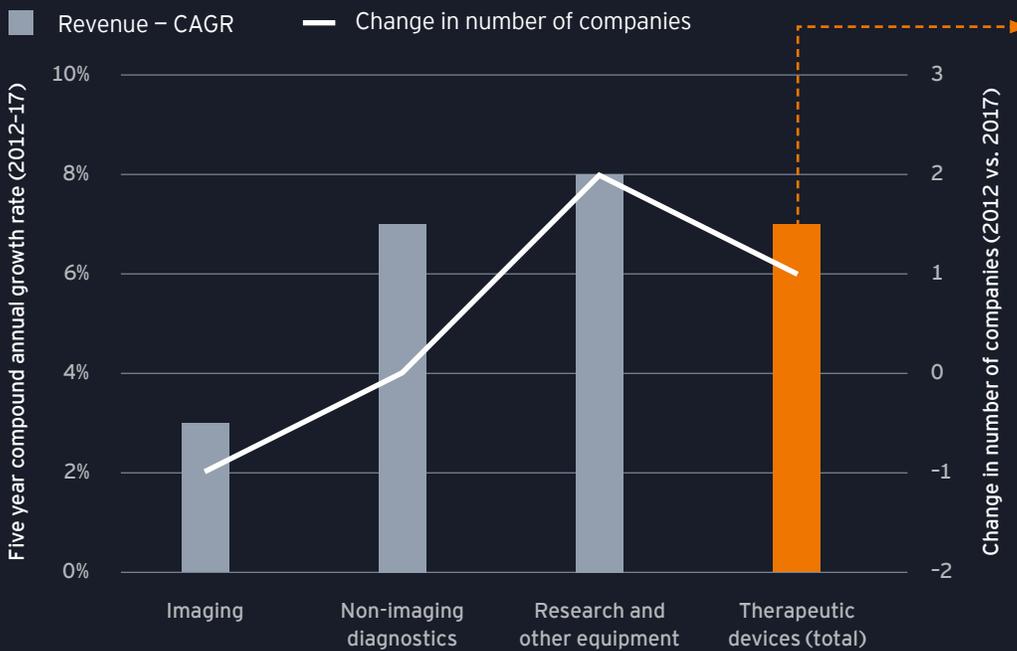
Commercial leaders are companies with revenues  $\geq$  US\$500m. Other companies include figures for conglomerates.

\*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.

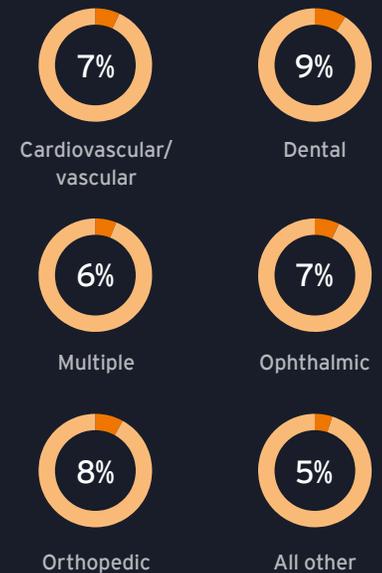
Sources: EY and Capital IQ.

FINANCIAL PERFORMANCE

US and European revenue growth by product group: pure-plays, 2012-17



Changes in revenue by disease category: therapeutic devices, 2012-17



Medtechs in the Research and other equipment (ROE) subsector powered the industry's revenue growth

- ▶ Over the past five years, ROE companies grew, on average, 8% annually; during the same period, therapeutic device and non-imaging diagnostic companies averaged annual yearly growth of 7% and imaging companies grew 3%.
- ▶ In 2017, medtechs in the ROE category delivered the highest revenue growth (12% compound annual growth rate) of the different medtech product categories, driven by the performance of industry leaders Thermo Fisher Scientific and Illumina.
- ▶ In 2017, therapeutic devices represented 68% (US\$146b) of the total revenue for pure-play medtech. However, this group only grew 1% year-over-year. Essilor posted the largest single increase in revenue (+20% or US\$1.5b), making ophthalmology the therapeutic area with the largest revenue growth in 2017.
- ▶ Companies in the "Cardiovascular," "Dental," "Ophthalmic" and "Orthopedic" disease categories delivered positive revenue growth in 2017. Revenue growth in the "Multiple" category decreased and was influenced by Abbott's acquisition of St. Jude Medical.

Data shown for pure-play companies only.

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

A young woman with a joyful expression is shown in profile, looking down at a white medical device. She is wearing traditional African attire, including a vibrant, multi-colored patterned wrap and a thick, multi-strand red beaded necklace. Her left wrist is adorned with several colorful beaded bangles. The background is a blurred outdoor setting with natural elements. The text is overlaid on the right side of the image, separated from the main content by a thin yellow horizontal line.

In 2017, therapeutic devices represented 68% (US\$146b) of the total revenue for pure-play medtech. However, this group only grew 1% year-over-year.

FINANCIAL PERFORMANCE

## Top 10 changes in US and European market capitalizations

H2 2013 through H1 2018 (US\$b)

Company	Market cap 30 June 2018	Market cap 1 July 2013	Market cap change	CAGR
Medtronic	115,720	52,436	63,284	17%
Thermo Fisher Scientific	83,337	31,097	52,240	22%
BD	64,011	19,279	44,731	27%
Stryker	63,105	24,358	38,747	21%
Intuitive Surgical	54,209	20,143	34,067	22%
Boston Scientific	45,120	12,655	32,465	29%
Illumina	41,056	9,486	31,569	34%
Align Technology	27,422	3,082	24,340	55%
Edwards Lifesciences	30,683	7,575	23,108	32%
Abiomed	18,261	863	17,398	84%
<b>Total</b>	<b>542,924</b>	<b>180,975</b>	<b>361,949</b>	<b>25%</b>

CAGR = compound annual growth rate

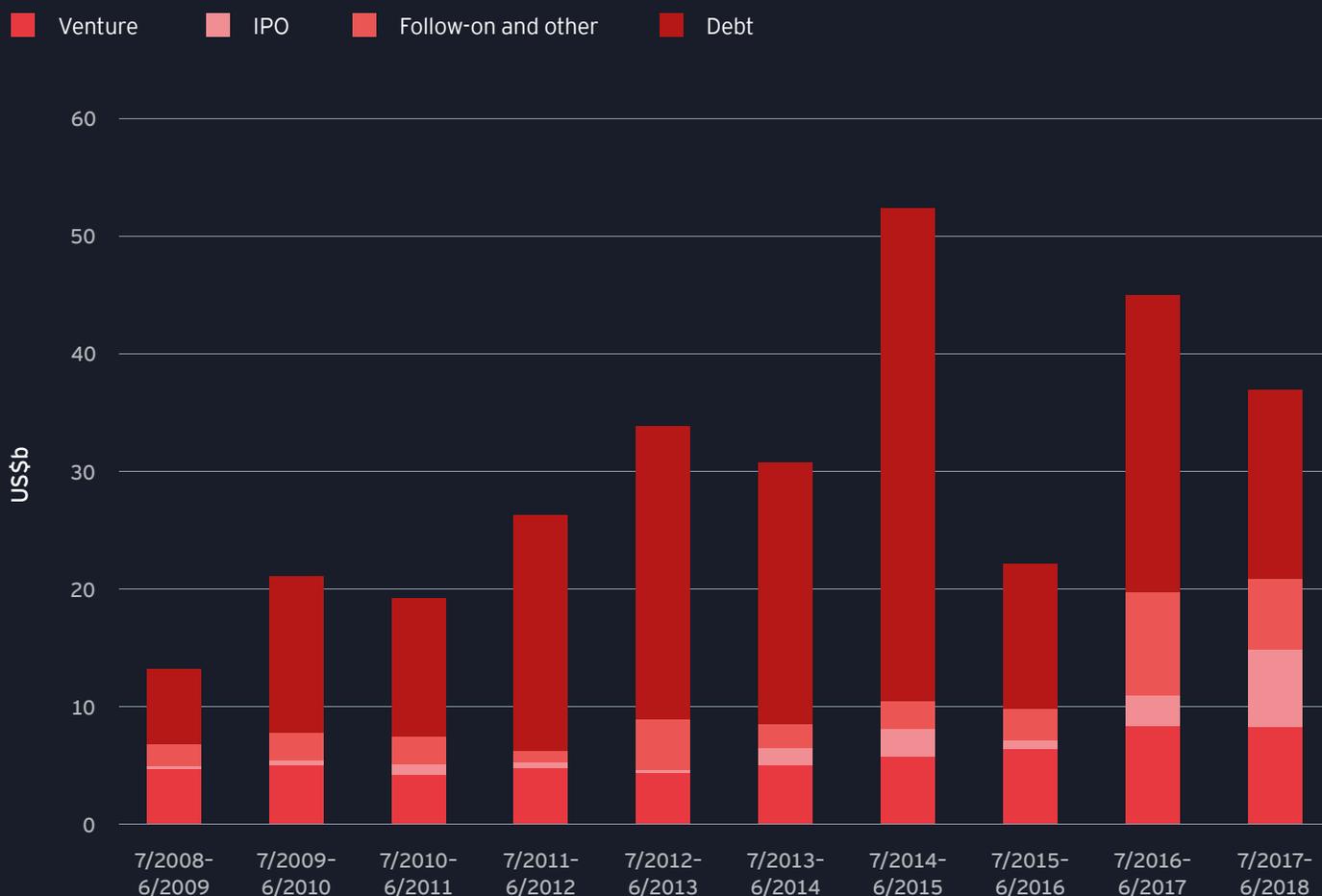
Sources: EY, Capital IQ and company financial statement data.

### Commercial leaders have used different strategies to entice investors

- ▶ Three of the fastest growing medtechs since 2013 – Medtronic, Thermo Fisher Scientific and BD – boosted their market valuations via megadeals (deals valued at more than US\$10b).
- ▶ Organic growth boosted Abiomed, Align Technology, Illumina and Intuitive Surgical, while Boston Scientific, Edwards Lifesciences and Stryker took advantage of bolt-on transactions to help improve their valuations.

FINANCING

# Capital raised in the US and Europe by year



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

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

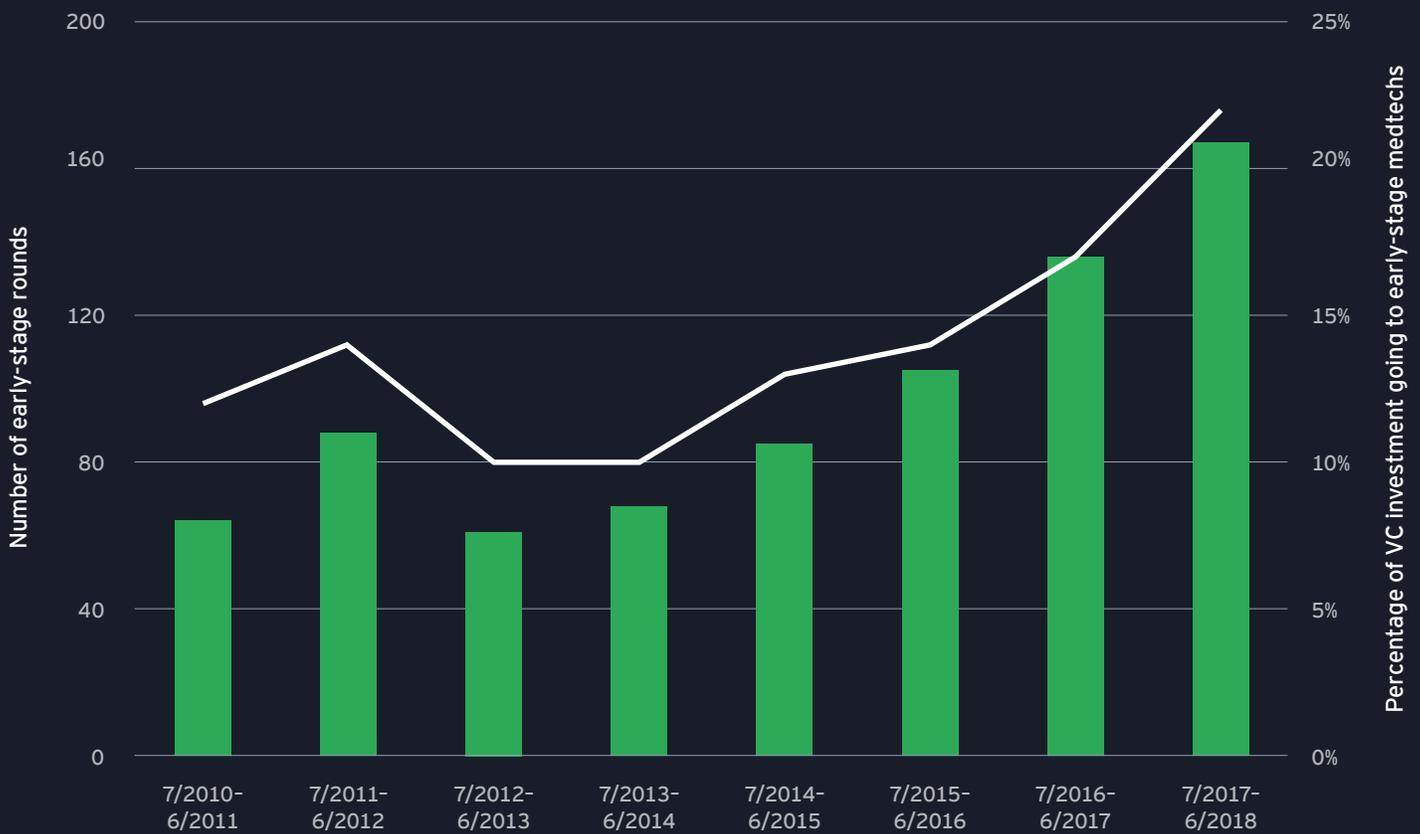
## A year of superlatives

- ▶ Total industry financing reached US\$36.9b, the third highest total ever.
- ▶ Innovation capital, capital raised by companies with less than US\$500m in sales, reached an all-time high of US\$21.7b, and made up 59% of the 2017-18 total financing.
- ▶ US medtechs raised 73% of the total financing; that is the lowest figure in more than a decade.

FINANCING

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

■ Number of early-stage VC rounds (>US\$5m) — Percentage of VC investment going to early-stage medtechs



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

Sources: EY, Dow Jones VentureSource and Capital IQ.

### Early-stage medtechs raised US\$3.3b from venture investors, a positive sign for the long-term health of the industry

- ▶ Privately held medtechs raised US\$8.2b in 2017-18, 64% greater than the previous five-year average.
- ▶ Early-stage deals accounted for 22% of the 2017-18 financing rounds, a new high.

---

**Total industry financing  
reached US\$36.9b, the  
third highest total ever.**



FINANCING

## Top US and European venture rounds

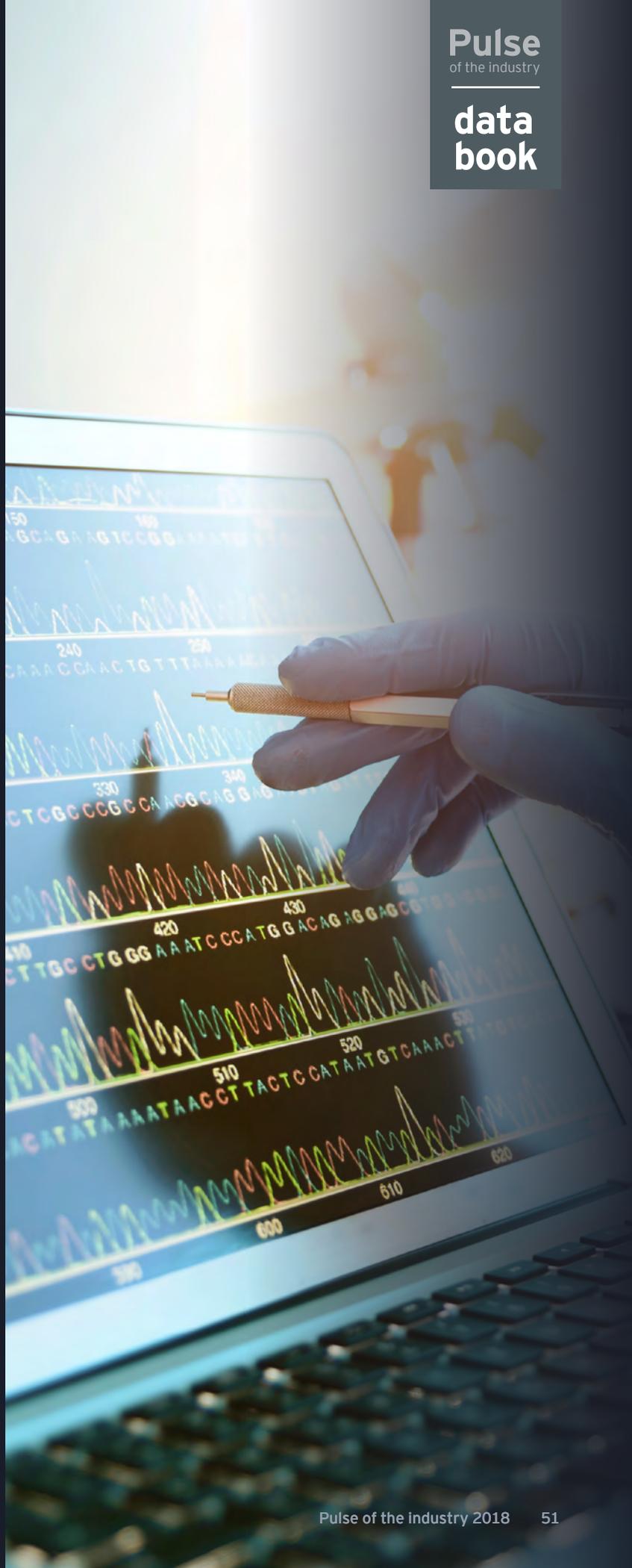
July 2017-June 2018

Company	Product type (disease)	Gross amount raised (US\$m)	Quarter	Round type
GRAIL US (Northern California)	Non-imaging diagnostics	300	Q2 2018	Late stage
Auris Health US (Northern California)	Therapeutic devices (oncology)	280	Q3 2017	Late stage
23andMe US (Northern California)	Non-imaging diagnostics	250	Q3 2017	Late stage
HeartFlow US (Northern California)	Other	240	Q1 2018	Late stage
Helix US (Southern California)	Non-imaging diagnostics	200	Q1 2018	Early stage
INSIGHTEC Israel	Imaging	150	Q4 2017	Late stage
Mevion Medical Systems US (Massachusetts)	Therapeutic devices (oncology)	150	Q2 2018	Late stage
Oxford Nanopore Technologies UK	Research and other equipment	139	Q1 2018	Late stage
Centinel Spine US (New York)	Therapeutic devices (orthopedic)	132	Q1 2018	Early stage
PROCEPT BioRobotics US (Northern California)	Therapeutic devices (urology/pelvic)	118	Q1 2018	Early stage
Livongo US (Northern California)	Other	105	Q2 2018	Late stage
CMR Surgical UK	Therapeutic devices (non-disease-specific)	100	Q2 2018	Early stage
RefleXion Medical US (Northern California)	Therapeutic devices (oncology)	100	Q2 2018	Late stage
Theranos US (Northern California)	Non-imaging diagnostics	100	Q4 2017	Late stage
Millipede US (Northern California)	Therapeutic devices (cardiovascular/vascular)	90	Q1 2018	Early stage
Biocare Medical US (North Carolina)	Research and other equipment	85	Q3 2017	Early stage
Counsyl US (Northern California)	Non-imaging diagnostics	80	Q4 2017	Late stage
Color US (Northern California)	Non-imaging diagnostics	80	Q3 2017	Late stage

**Big rounds for diagnostics and digital health companies showcase the growing opportunities linked to data and an improved consumer experience**

- ▶ Three of the top five largest venture financings in 2017-18 funded consumer diagnostics and digital health companies.
- ▶ Digital health companies have raised more than US\$5.7b in venture financing in the past three years.
- ▶ GRAIL, a developer of DNA-based blood tests for the early detection of cancer, alone has raised US\$1.5b since 2016.
- ▶ Corporate investors participated in medtech financings worth US\$1.3b, the second highest total ever.

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



M&A

## M&A in the US and Europe by year

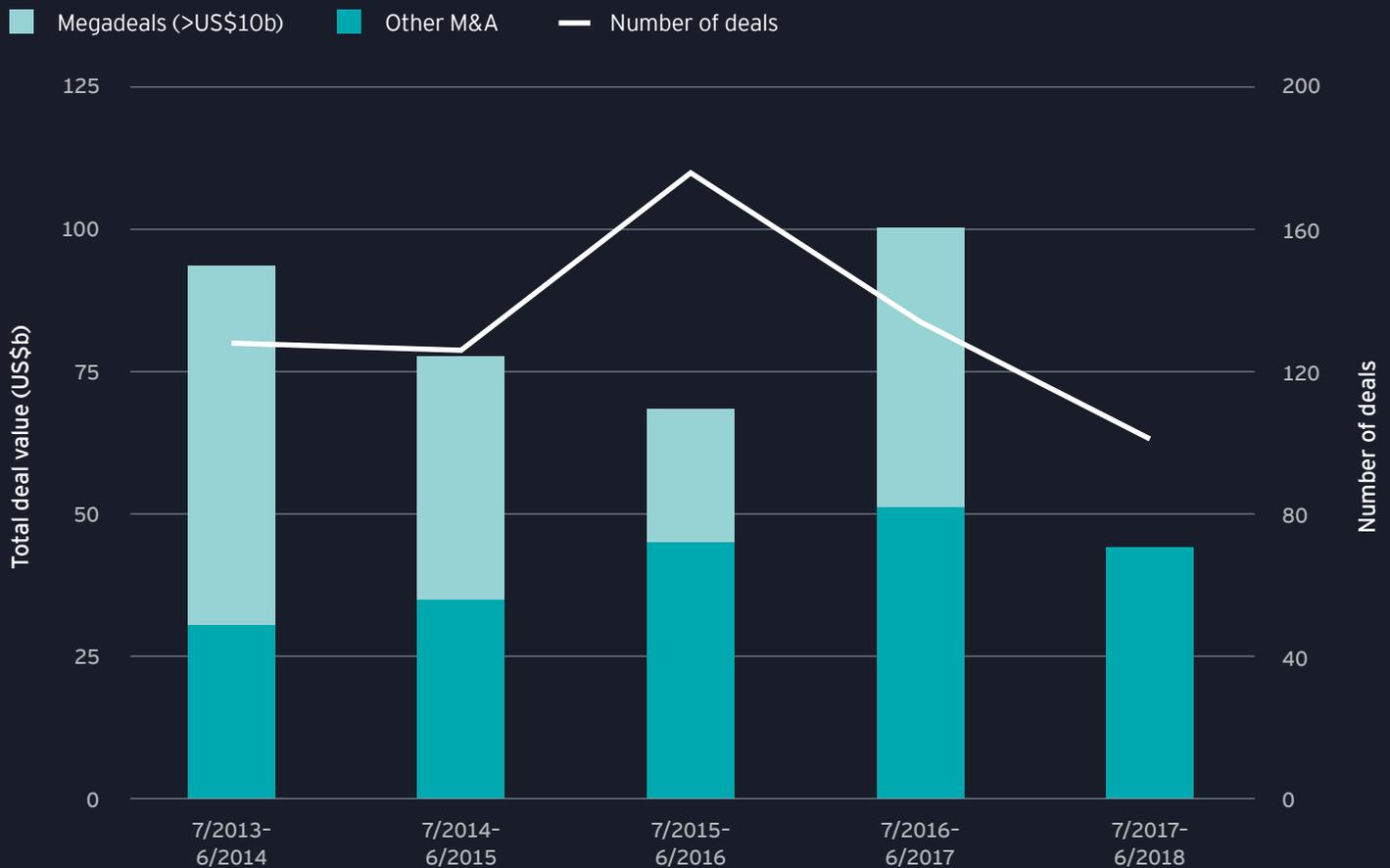


Chart includes deals ≥US\$5m (medtech deal where either acquirer or target is located in the US or Europe).

Sources: EY, Capital IQ and Thomson ONE.

### Medtechs focused on tuck-in acquisitions in 2017-18

- ▶ Medtechs in 2017-18 focused on bolt-on acquisitions to create category leadership and integration of previous deals.
- ▶ Thirteen acquisitions valued between US\$1b and US\$10b drove the total M&A value to US\$44.1b.
- ▶ The absence of megadeals reduced total M&A value by 56%, but a comparison of non-megadeals shows the yearly total was only down 14% from 2016-17. The 2017-18 total was higher than the previous three-year average of US\$36.7b.
- ▶ Deal volume also dwindled, potentially driven by high market valuations for earlier stage companies. The number of medtech acquisitions (101) was well below the previous four-year average of 141.

M&A

## Milestone share in US and European medtech M&A

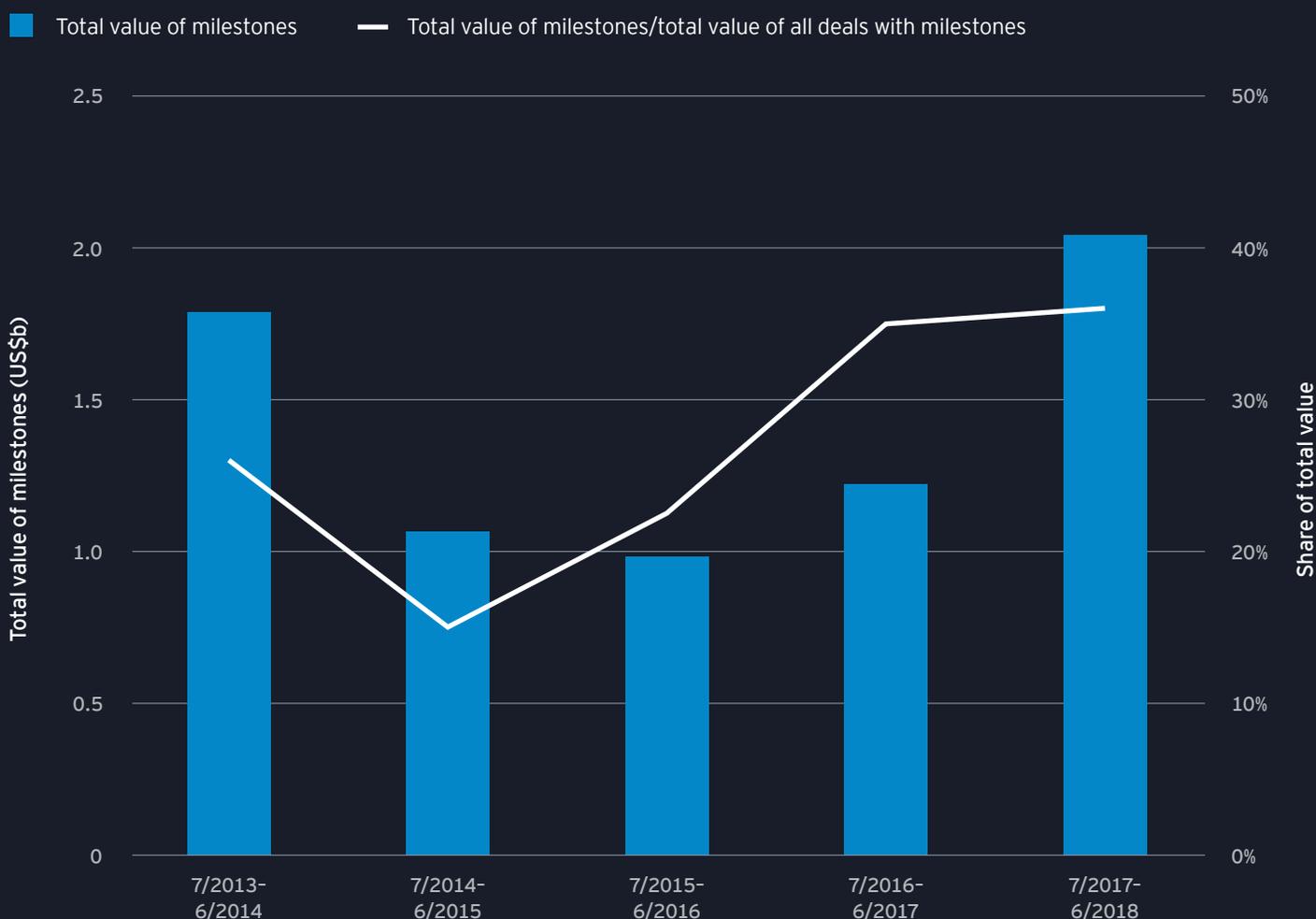


Chart includes deals >US\$5m.

Sources: EY, Capital IQ and Thomson ONE.

### Milestones become more prevalent

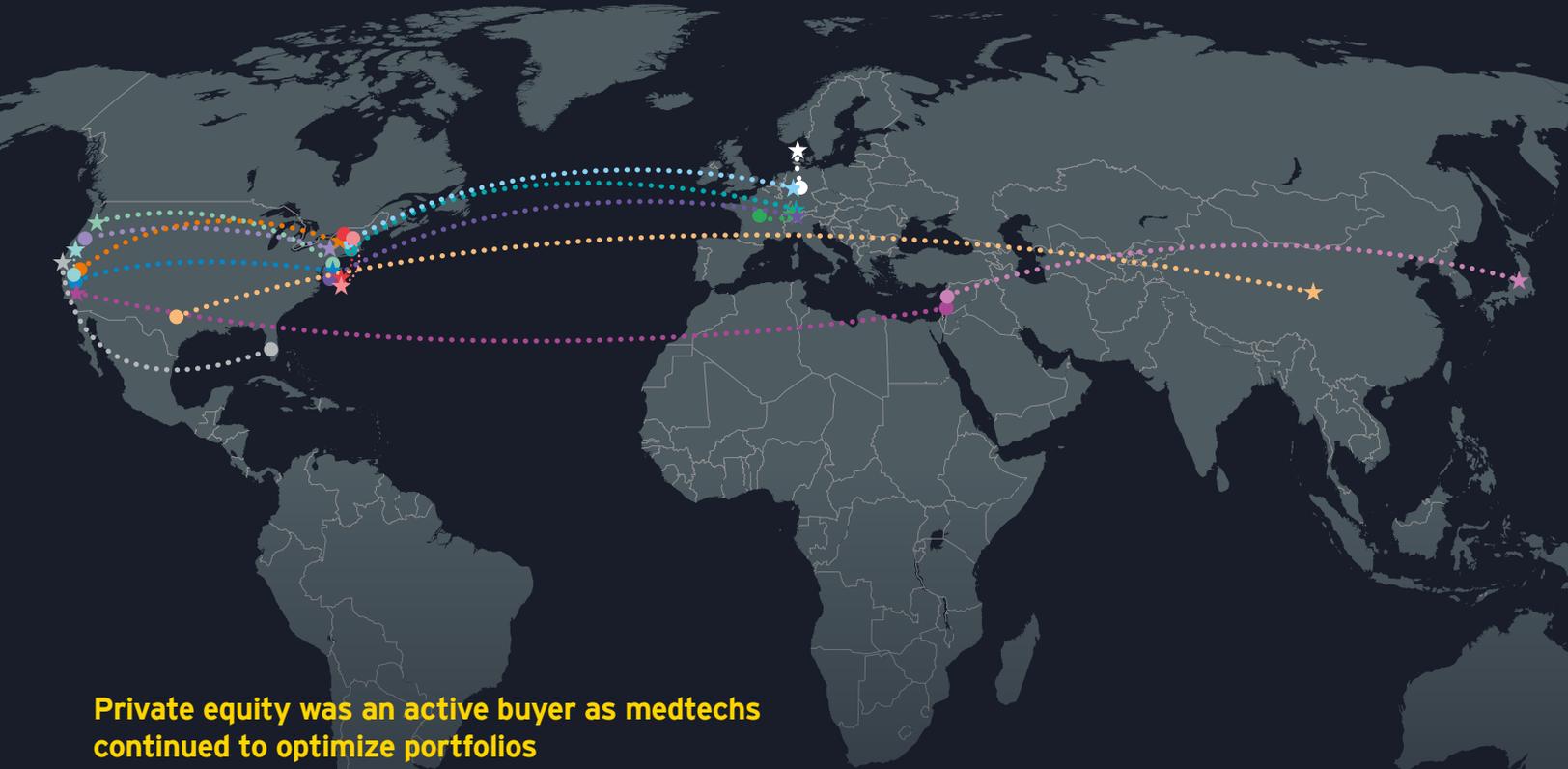
- ▶ Despite a strong year for market valuations, medtech buyers convinced more sellers to agree to structured acquisitions than in prior years.
- ▶ The total value of potential milestones increased 67% to more than US\$2b, the largest dollar value in at least five years. The percentage of milestone-containing deals reached a four-year high (22%).
- ▶ Average milestones were essentially flat (US\$94m to US\$93m) while average total potential deal value was down 3% to US\$260m.

M&A

## Selected US and European M&As

July 2017-June 2018

★ Buyer ● Seller



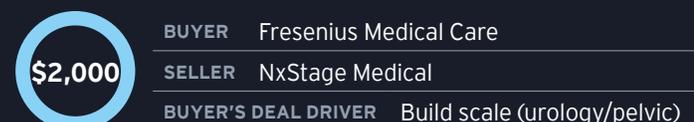
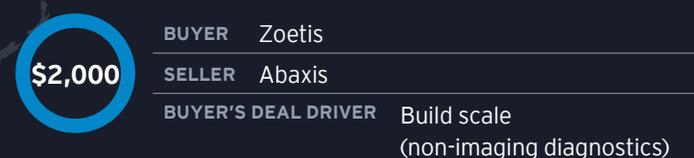
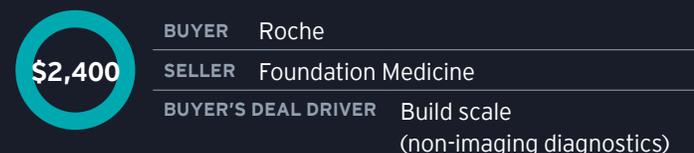
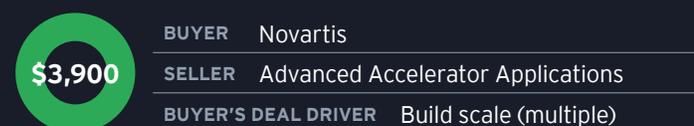
### Private equity was an active buyer as medtechs continued to optimize portfolios

- ▶ Private equity participated in M&A deals worth US\$14b in 2017-18, accounting for roughly a third of the year's total M&A value.
- ▶ Two of the top five deals of the year (Widex/Sivantos and Platinum/Johnson & Johnson) involved private equity.
- ▶ Six of the year's largest deals were divestitures as medtechs continue to shed non-core assets. Johnson & Johnson's sales of its Advanced Sterilization Products and LifeScan business units are the conglomerate's fourth and fifth medtech billion-dollar-plus divestments since 2014.
- ▶ Therapeutic device targets brought in 53% of the total M&A value (down from a 77% five-year average), while non-imaging diagnostic companies attracted 23% of the total (up from 9%).
- ▶ Roche paid US\$4.3b to acquire two data-centric businesses that have the potential to revamp care delivery and cancer drug and diagnostic development: Flatiron Health and full control of Foundation Medicine.

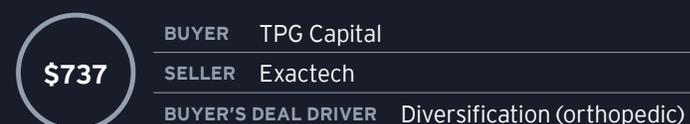
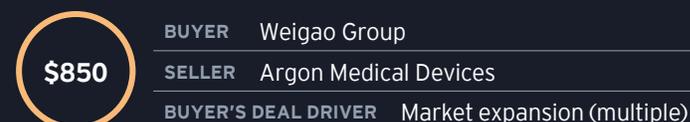
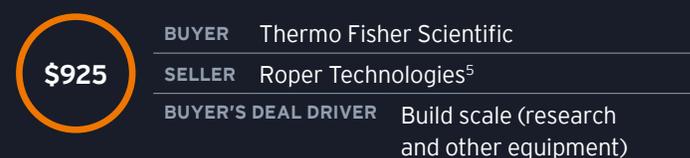
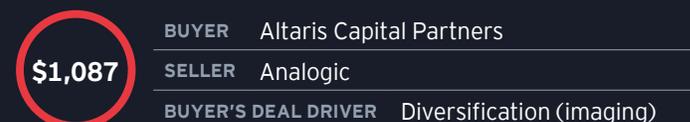
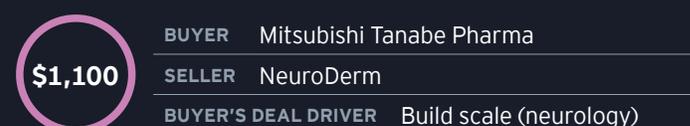
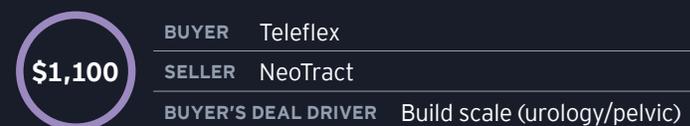
There were three types of buyer deal drivers: build scale, market expansion and diversification. Where possible, deals were classified by therapeutic area or product segment, shown in parentheses. If an acquisition involved multiple therapy areas, the "multiple" designation was used.

Sources: EY, Capital IQ and Thomson ONE.

VALUE (\$USm)



VALUE (\$USm)



<sup>1</sup> Advanced Sterilization Products <sup>2</sup>LifeScan <sup>3</sup>PARAGARD IUD <sup>4</sup>Ambulatory care and workforce management software unit <sup>5</sup>Gatan

M&A

## Medtech M&As with Asia-Pacific buyers

■ Total value of M&As — Number of M&As

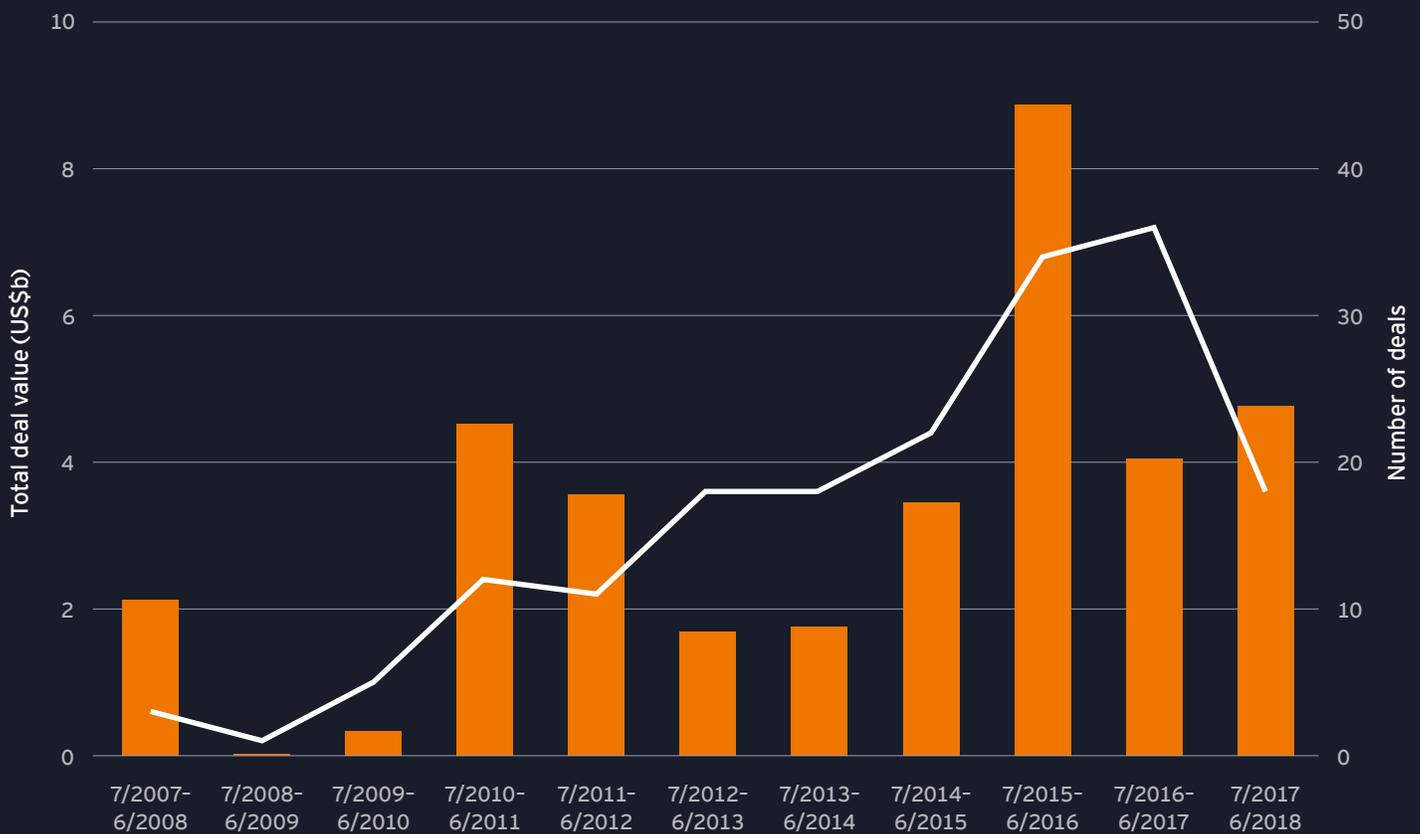


Chart includes deals greater than US\$5m where buyer is from Asia-Pacific region, and either the buyer or seller company is a medtech company.

Sources: EY, Capital IQ and Thomson ONE.

### Capital continues to flow from East-to-West

- ▶ The number of M&A deals by Asia-Pacific buyers fell 50% in 2017-18, but the deals that were done were more substantial.
- ▶ Total value of M&As by Asia-Pacific buyers surged 18% to US\$4.8b in 2017-18, the second highest level in at least the past decade.
- ▶ Three deals accounted for roughly 80% of the entire total: China's CDH Investments and Weigao International Medical acquired SIRTex Medical (US\$1.9b) and Argon Medical Devices (US\$850m), respectively; Mitsubishi Tanabe Pharma, of Japan, purchased NeuroDerm (US\$1.1b).

# 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 tool 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: Diagnostics and Vascular Products
- Agilent Technologies: Life Sciences & Applied Markets
- Baxter International: Fluid Systems, Renal and Surgical Care
- Corning: Life Sciences
- Danaher: Life Sciences, Diagnostics and Dental
- General Electric: GE Healthcare
- IDEX: Health & Science Technologies
- 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: GN 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

# Contact us

<b>EY Global Life Sciences Industry Leader</b>	Pamela Spence	pspence2@uk.ey.com	+44 207 951 3523
<b>EY Global Life Sciences Assurance Leader</b>	Tobias Schlebusch	tobias.schlebusch@de.ey.com	+49 211 9352 10351
<b>EY Global Life Sciences Advisory Leader</b>	Nick Cernese	nick.cernese@ey.com	+1 201 551 5006
<b>EY Global Life Sciences Tax Leader</b>	Mitch Cohen	mittchell.cohen@ey.com	+1 203 674 3244
<b>EY Global Life Sciences Transaction Advisory Services Leader</b>	Peter Behner	peter.behner@de.ey.com	+49 30 25471 12467

<b>Australia</b>	<b>Melbourne</b>	Denise Brotherton	denise.brotherton@au.ey.com	+61 3 9288 8758
	<b>Sydney</b>	Gamini Martinus	gamini.martinus@au.ey.com	+61 2 9248 4702
<b>Austria</b>	<b>Vienna</b>	Erich Lehner	erich.lehner@at.ey.com	+43 1 21170 1152
<b>Belgium</b>	<b>Brussels</b>	Lucien De Busscher	lucien.de.busscher@be.ey.com	+32 2 774 6441
<b>Brazil</b>	<b>São Paulo</b>	Frank de Meijer	frank-de.meijer@br.ey.com	+55 11 2573 3383
<b>Canada</b>	<b>Montréal</b>	Sylvain Boucher	sylvain.boucher@ca.ey.com	+1 514 874 4393
		Lara Iob	lara.iob@ca.ey.com	+1 514 879 6514
	<b>Toronto</b>	Mario Piccinin	mario.piccinin@ca.ey.com	+1 416 932 6231
	<b>Vancouver</b>	Nicole Poirier	nicole.poirier@ca.ey.com	+1 604 891 8342
<b>Czech Republic</b>	<b>Prague</b>	Petr Knap	petr.knap@cz.ey.com	+420 225 335 582
<b>Denmark</b>	<b>Copenhagen</b>	Christian Johansen	christian-s.johansen@dk.ey.com	+45 5158 2548
<b>Finland</b>	<b>Helsinki</b>	Sakari Helminen	sakari.helminen@fi.ey.com	+358 405 454 683
<b>France</b>	<b>Paris</b>	Virginie Lefebvre-Dutilleul	virginie.lefebvre-dutilleul@ey-avocats.com	+33 1 55 61 10 62
		George Fife	george.fife@fr.ey.com	+33 6 7599 7571
<b>Germany</b>	<b>Cologne</b>	Gerd Stürz	gerd.w.stuerz@de.ey.com	+49 211 9352 18622
	<b>Mannheim</b>	Siegfried Bialojan	siegfried.bialojan@de.ey.com	+49 621 4208 11405
<b>Greater China</b>	<b>Shanghai</b>	Titus Bongart	titus.bongart@cn.ey.com	+86 21 22282884
		Felix Fei	felix.fei@cn.ey.com	+86 21 22282586
<b>India</b>	<b>Mumbai</b>	V. Krishnakumar	krishnakumar.v@in.ey.com	+91 22 6192 0950
		Hitesh Sharma	hitesh.sharma@in.ey.com	+91 22 6192 0950
		Sriram Shrinivasan	sriram.shrinivasan@in.ey.com	+91 22 6192 0000
<b>Ireland</b>	<b>Cork</b>	Michelle Cuddigan	michelle.cuddigan@ie.ey.com	+353 21 480 2827
<b>Israel</b>	<b>Tel Aviv</b>	Eyal Ben-Yaakov	eyal.benyaakov@il.ey.com	+972 3 623 2512
<b>Italy</b>	<b>Milan</b>	Luca Minotti	mailto:luca.minotti@it.ey.com	+39 028 0669 3500
<b>Japan</b>	<b>Tokyo</b>	Hironao Yazaki	yazaki-hrn@shinnihon.or.jp	+81 3 3503 2165
		Patrick Flochel	patrick.flochel@jp.ey.com	+81 3 3503 1542
<b>Netherlands</b>	<b>Amsterdam</b>	Dick Hoogenberg	dick.hoogenberg@nl.ey.com	+31 88 40 71419
<b>New Zealand</b>	<b>Auckland</b>	Jon Hooper	jon.hooper@nz.ey.com	+64 9 300 8124
<b>Norway</b>	<b>Trondheim/Oslo</b>	Willy Eidissen	willy.eidissen@no.ey.com	+47 918 63 845

Historically, the medical device industry has created tremendous value via the creation of therapeutic devices. It is now time for the industry to invest more effort in analytics-based solutions that enable seamless, real-time care management.

<b>Poland</b>	<b>Warsaw</b>	Mariusz Witalis	mariusz.witalis@pl.ey.com	+48 225 577950
<b>Russia</b>	<b>Moscow</b>	Dmitry Khalilov	dmitry.khalilov@ru.ey.com	+7 495 755 9757
<b>Singapore</b>	<b>Singapore</b>	Hugo Walkinshaw	hugo.walkinshaw@sg.ey.com	+65 6309 8098
<b>South Africa</b>	<b>Johannesburg</b>	Warren Kinnear	warren.kinnear@za.ey.com	+27 11 772 3576
<b>Sweden</b>	<b>Göteborg</b>	Jan Koch	jan.koch@se.ey.com	+46 7 3021 1301
<b>Switzerland</b>	<b>Basel</b>	Jürg Zürcher	juerg.zuercher@ch.ey.com	+41 58 286 84 03
<b>United Kingdom</b>	<b>Bristol</b>	John Howarth	jhowarth@uk.ey.com	+44 11 7917 8653
		James Turner	jturner1@uk.ey.com	+44 12 2339 4514
	<b>Cambridge</b>	Rachel Wilden	rwilden@uk.ey.com	+44 12 2355 7096
		Mark Harvey	mharvey2@uk.ey.com	+44 13 1777 2294
		Jonathan Lloyd-Hirst	jlloydhirst@uk.ey.com	+44 13 1777 2475
	<b>London/Reading</b>	Leo Gribben	lgribben@uk.ey.com	+44 20 7951 4213
		Daniel Mathews	dmathews1@uk.ey.com	+44 20 7197 9375
		Andrew Monro	amonro@uk.ey.com	+44 20 7951 2125
	<b>United States</b>	<b>Boston</b>	Kevin Casey	kevin.casey1@ey.com
Michael Donovan			michael.donovan1@ey.com	+1 617 585 1957
<b>Chicago</b>		James Welch	james.welch@ey.com	+1 312 879 3827
<b>Houston</b>		Carole Faig	carole.faig@ey.com	+1 713 750 1535
<b>Minneapolis</b>		William Miller	william.miller@ey.com	+1 612 371 6984
		Stephen Stenbeck	stephen.stenbeck@ey.com	+1 612 371 6994
<b>New York/New Jersey</b>		John Babitt	john.babitt@ey.com	+1 212 773 0912
		Orlan Boston	orlan.boston@ey.com	+1 212 773 2269
		David Womelsdorf	david.womelsdorf@ey.com	+1 732 516 4292
<b>Orange County</b>		Kim Letch	kim.letch@ey.com	+1 949 437 0244
<b>Philadelphia</b>		Howard Brooks	howard.brooks@ey.com	+1 215 448 5115
		Steve Simpson	stephen.simpson@ey.com	+1 215 448 5309
<b>Raleigh</b>		Mark Baxter	mark.baxter@ey.com	+1 919 981 2966
<b>Redwood Shores</b>		Chris Nolet	chris.nolet@ey.com	+1 650 802 4504
		Rich Ramko	richard.ramko@ey.com	+1 650 802 4518
<b>San Diego</b>		Dan Kleeberg	daniel.kleeberg@ey.com	+1 858 535 7209

# Acknowledgments

## Project leadership

**Ellen Licking**, EY Life Sciences Senior Analyst, was the managing editor, responsible for content development, including the co-creation of the articles and data analysis.

**James Evans**, EY Life Sciences Senior Analyst, was the report's lead author. He was responsible for writing the main article and the guest perspectives.

**Jason Hillenbach**, EY Life Sciences Knowledge Leader, led the analysis of the industry trends, developed the data book and provided project management.

Ellen, James and Jason would like to recognize **Pamela Spence**, EY Global Life Sciences Leader, for her strategic guidance and editorial contributions.

## Editing assistance

**Scott Chapski** was the publication's copy editor. His patience, hard work and attention to detail were unparalleled.

## Data analysis

**Tanya Mehra** collected, organized and analyzed the research included in this year's report. She was assisted by **Arushi Agarwal**.

**Jason Hillenbach**, **Kim Medland** and **Rajni Sadana** conducted fact-checking and quality review of the numbers presented in the publication.

## Design

**Mike Fine** was the art director and designer for this project. This publication would not look the way it does without his creativity.

## PR and marketing

**Laura Powers**, **Katie Costello** and **Cecile Guiot** led the marketing and public relations efforts.



#### About EY

EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit [ey.com](http://ey.com).

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

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

Our Global Life Sciences Sector brings together a worldwide network of 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.

© 2018 EYGM Limited.  
All Rights Reserved.

EYG no. 011301-18Gbl  
1807-2802571 US CSG  
ED none

#### [ey.com/lifesciences](http://ey.com/lifesciences)

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax or other professional advice. Please refer to your advisors for specific advice.

The views of third parties set out in this publication are not necessarily the views of the global EY organization or its member firms. Moreover, they should be seen in the context of the time they were made.