
As change accelerates, how can medtechs move ahead and stay there?
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Medical technology report 2017

As the pace of change accelerates, how can medtechs move ahead and stay there? Answering this question is a strategic imperative for medical technology companies no matter their size. In 2017, the velocity and scope of technological innovation are blurring the lines between medicine and technology, redefining traditional medtech and fundamentally altering business models.

Decision-making power continues to shift away from device companies to other stakeholders even as technology companies and digital entrants encroach on traditional medtech territory. As a result, the supply and demand sides of medtech businesses are being disrupted. To remain competitive in this new health care economy, device makers must embrace customer-centric, data-driven strategies. Platforms that combine individual medtech products and services into holistic care solutions underpin this transformation, which EY terms the Life Sciences 4.0 business model.

In EY's 11th annual *Pulse of the industry* report, we document the dynamic and competitive medtech playing field and discuss the strategies that companies can employ as they seek an inside track to growth. The good news is medical technology companies appear well-placed to play a central role in the digital, customer-focused health care ecosystem that is emerging.

Emphasis in prior years on capital efficiency, therapeutic focus and delivering better health outcomes means many of the industry's commercial leaders are now delivering strong top-line and bottom-line growth. Meanwhile, smaller companies, and their increasingly savvy investors, have enjoyed several years of robust public and private financing. As a result, they have — for now — sufficient funds to develop tomorrow's new medtech innovations. Importantly, the globalization of capital means new sources of financing are emerging, particularly in Asia, which medtechs can also tap for future needs.

For continued success, medtechs will need to forge partnerships with a range of stakeholders, including payers and providers. Device companies will also need to invest in new technologies such as additive manufacturing and artificial intelligence, as well as new capabilities such as behavioral science and data analytics. But if they make the right technological investments and strike the right partnerships, medtechs will find new ways to build sustainable businesses that create value for themselves and other members of the health care ecosystem.

Identifying strategies to move forward — and stay there — is never easy. As medtechs continue to adapt their business strategies, EY continues to track the pulse of the industry. Connect with us at our digital home, Vital Signs (ey.com/VitalSigns) and via social media through our Twitter feed (@EY_LifeSciences).

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Year in review

Medtechs seek the inside track

In our 2016 *Pulse of the industry* report, we highlighted a medtech industry in transition. In 2017, the industry demonstrates resilience and agility even as the pace of change accelerates on technological, reimbursement and regulatory fronts and new digitally based operating models shift power to consumers.

As Klaus Schwab, Founder and Executive Chairman of the World Economic Forum, describes in the book *The Fourth Industrial Revolution*, the velocity and scope of innovation is "blurring the lines between the physical, digital and biological spheres."

For medtech companies, this convergence fundamentally alters business models, as decision-making power shifts away from manufacturers to other health care stakeholders. To remain competitive when both the supply and demand sides of their businesses are being disrupted, device makers need to evolve from being product-centric to customer-centric, with an emphasis on the seamless capture and communication of real-world data. Platforms that combine individual medtech products and services into holistic care solutions underpin this transformation, which EY terms the Life Sciences 4.0 business model.

As we write in this year's report, the shift to platforms and Life Sciences 4.0 is already underway. Many medtechs have already embraced digital strategies and are in the process of aligning their commercial organizations to deliver meaningful outcomes and system improvements to end users.

In the coming pages, we also review the medical device industry's financial performance in 2016–17. In our analysis, we highlight the top trends and issues and put the financial metrics in context as traditional medtech innovation and business models continue their transformations.

Strong results
The medtech industry delivered strong results even as it continued to adapt to rapid technological change, rising reimbursement, regulatory and legislative uncertainty, and increasing customer expectations.

Shifting models
Business models continue to shift, as product-centric innovations and services are combined to create holistic platforms that increase shareholder value by enhancing the customer experience.

Collaboration mandate
To access the necessary skills to create relevant care platforms, medtechs must collaborate with a range of stakeholders, including digital entrants, technology companies, payers and providers.

Understanding the key financial indicators

What strategies should medtechs adopt for peak performance as the pace of change accelerates?

After a disappointing 2015, when revenue contracted 3% and net income dropped 15%, the overall medtech industry generated US$364.4 billion in revenue and its best year-on-year growth since the global financial crisis of 2008. In aggregate, medtechs in the US and Europe expanded their top line 5% in 2016 and grew their total bottom line 17%.

It's too soon to say if these data points suggest a lasting turnaround or are simply a one-year anomaly. Regardless, the positive results suggest that the medtech industry's long-term growth strategies are finally starting to deliver results – at least for some companies.

Importantly, the 2016 uptick in revenue growth was driven almost entirely by acquisitions designed to provide therapeutic focus as well as commercial scale. For the past several years, device makers have been under pressure to deploy capital more efficiently. That pressure continued in 2016–17, as medtechs continued to seek new solutions to address their productivity challenges and a tightening reimbursement climate. In the near term, this focus has translated into increased inorganic activity as medtechs recognize that acquisitions that build end-to-end capabilities in a particular therapeutic area or expand the company's geographic or technological reach are one of the fastest paths to growth.

The positive results suggest that the medtech industry's long-term growth strategies are finally starting to deliver results – at least for some companies.

Notably, 8 of the industry's 61 pure play commercial leaders each bolstered its top line by more than US$500 million, and 6 of those 8 did so via M&A. Absent those deals, revenue growth at many of these top companies would have been in the pedestrian single digits. That's not to say organic growth didn't contribute to medtech revenue growth. Stryker, Boston Scientific, Medtronic and Edwards Lifesciences were among the companies demonstrating that focused R&D investment could not only extend product franchises but also result in positive financial metrics.

After a prolonged period of medtech dealmaking, we also see a continued emphasis on portfolio optimization. Divestitures and spin-outs allow medtechs to capture additional value by improving capital efficiency, reducing operational complexity and reallocating capital to higher-growth businesses as the industry invests more R&D dollars in the development of innovative products that demonstrate value in an era of price pressures.

Indeed, Abbott's sale of its ophthalmic business to Johnson & Johnson, Medtronic's sale of its medical supplies business to Cardinal Health and Johnson & Johnson's divestiture of Codman Neurosurgery to Integra LifeSciences suggest capital efficiency and portfolio optimization will be an ongoing trend in 2018.

Haves and have nots

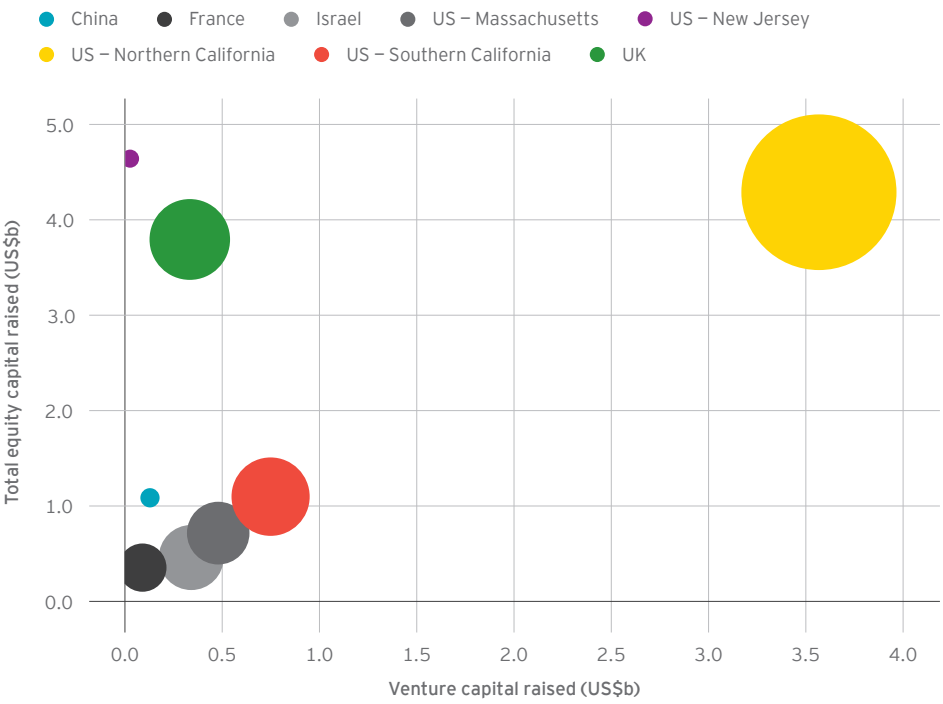
The medtech industry continues to be an industry of "haves" and "have nots," especially in terms of access to capital. In both the US and Europe, the number of public medtechs with less than two years of cash continues to swell. Meanwhile, the market for initial public offerings wasn't exactly robust. Excluding ConvaTec's massive debut, medtech IPO financing in 2016–17 was much more like the pre-boom years of 2009–12 than the recent 2013–15 heyday. While it's still possible for medtechs to go public, general investor participation now requires strong management teams and products that are not only on the market but demonstrating revenue growth. That's a difficult bar to clear. It remains to be seen whether these investors will lower their expectations, creating an opportunity for IPOs to reach the heights achieved in recent years.

The uneven capital distribution also played out on the private side. Privately held medtechs raised nearly US$8 billion in venture capital in 2016–17, a new record and an important catalyst for future innovation. However, more than 25% of that total went to just three medtechs: Grail; Guardant Health; and Verily Life Sciences, the life sciences- and health-focused Alphabet subsidiary. Moving forward, if the public markets grow even tougher and US and European venture capitalists (VCs) become more conservative in their bets, many more early-stage medtechs may be competing to access the same pool of capital.

The good news is that this capital pool is expanding globally. As noted in "Medtech financing clears new heights" on page 52, capital continues to flow from East to West as Asia-based investors look to finance US and European medtechs, as well as innovative companies in their home markets. A recent decision by the Chinese government to preserve liquidity in China may restrict capital outflow in the future. For now, however, these backers represent an important source of additional funding for medtechs regardless of where they are headquartered. The capital they provide allows medtechs to advance strategic priorities, especially at a time when the public markets are more difficult to tap.

In some ways, 2016–17 was business as usual for the medtech industry. Conglomerates and pure play companies navigated a growing array of regulatory, reimbursement and geopolitical uncertainties using their usual capital allocation levers: dealmaking, R&D investment and cash returned to shareholders. Medtechs are faced with the question of what steps to take now to reach, or maintain, peak financial performance.

Capital raised by leading regions excluding debt, July 2016–June 2017



Bubble size shows relative number of financings per region.

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

Enabling innovation

As technology transforms medtech, which innovations provide a lasting edge?

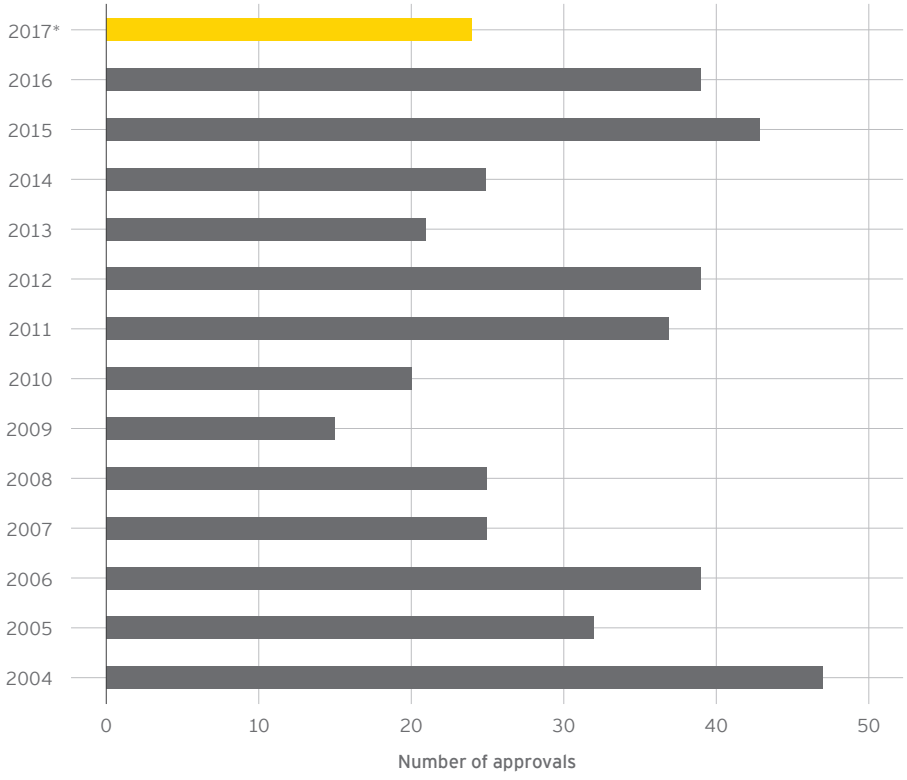
New innovations will continue to drive the medtech industry's growth. In 2016, the U.S. Food & Drug Administration approved 39 new class III medical devices via its pre-market approval (PMA) pathway.

As of 31 July 2017, there were 26 PMA approvals, putting the industry on track to nearly rival the approval numbers last achieved in 2004. The uptick in approvals that began in 2015 suggests that medtechs are beginning to adapt to higher regulatory and reimbursement thresholds and are investing proactively in safety and efficacy studies to better demonstrate the utility of their devices.

Recently approved medtech products already tackle some of today's most difficult health care challenges. For instance, closed-loop systems automatically deliver insulin based on continuous monitoring of blood sugar, and new devices use catheters to repair or replace defective heart valves, limiting the need for invasive open heart surgeries. Meantime, robotic systems are changing how surgical procedures are performed, improving the operating experience for both physicians and patients.

Enabling technologies such as augmented reality (AR) and additive manufacturing (AM), also known as

PMA approvals for medical devices, 2004–17



* Through 31 July 2017

Source: FDA website, includes only originals.

3-D printing, are further expanding the art of the possible. AM, for instance, has an important role to play in the development of specific anatomical models that allow surgeons to practice complicated procedures prior to operating on patients. And the technology is already being used to make more complex orthopedic devices that offer some degree of customization for patient anatomy. Among traditional medtechs, Stryker has invested heavily in AM, building a dedicated facility in Ireland to create components for several spine and joint replacement products.

Meanwhile, Stryker, B. Braun and other medtechs are interested in using AR to improve the precision and outcomes of surgeries. Over the next two years, one major trend will be "smart" operating rooms that juxtapose real-time anatomical information with a variety of other types of data. (See "The operating room of the future" by Jens von Lackum and Boris Hofmann.)

What constitutes medtech innovation continues to evolve. Technological advances in sensors, coupled with advances in artificial intelligence (AI), are broadening the definition of medtech to include digital products and data-driven services. Given this continued march of technology, industry convergence will continue to accelerate, lowering barriers to entry for new entrants, especially those that specialize in software-based or other customer-focused services.

To thrive in this era of rapid and continual change, medtechs must build flexible business models that balance investments in internal R&D and external innovation. As they set their business priorities, medtech senior executives should ask themselves which R&D bets will yield a lasting edge.

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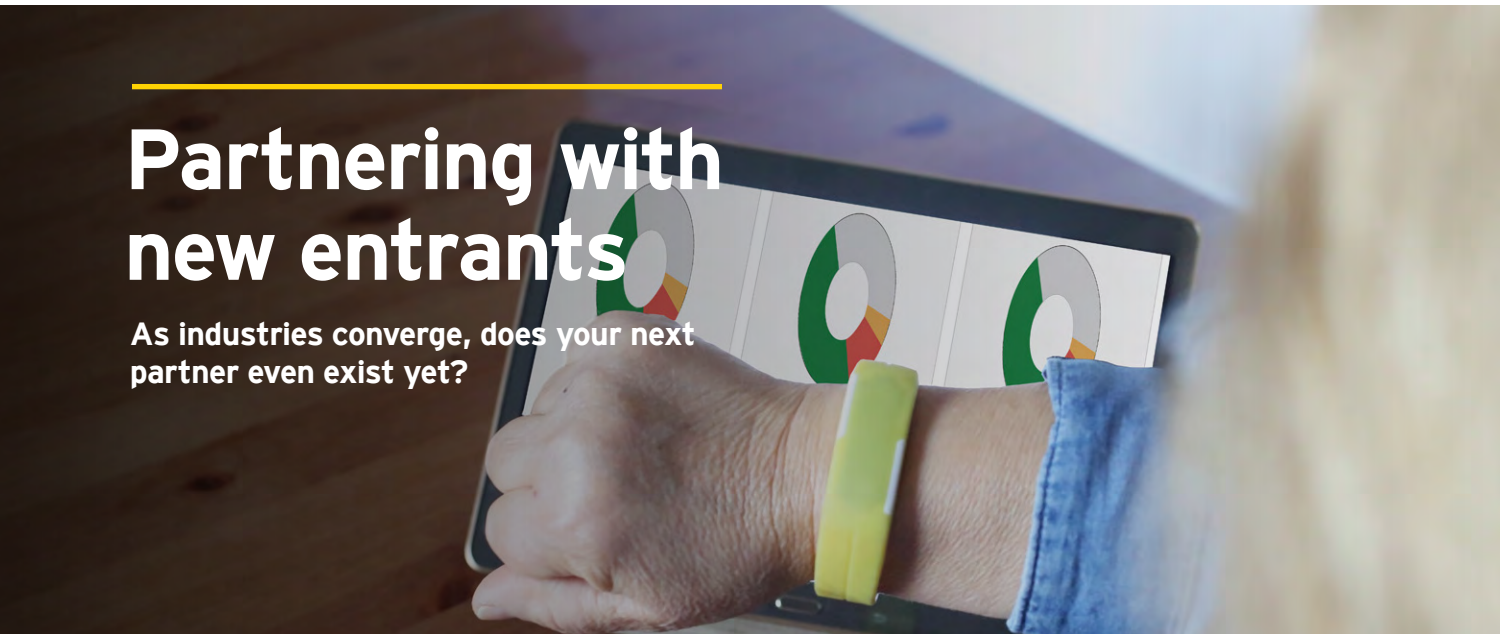


Partnering with new entrants

As industries converge, does your next partner even exist yet?

More and more, product-centric medtech innovations will be bundled with services and solutions, enabling real-time patient engagement, remote monitoring and more targeted care delivery to create new commercial models.

This product-to-services shift and the evolution toward "smart" devices will be further amplified by other shifts happening in the health care economy. These include the continued push to reward value instead of volume and meet increasing customer expectations, whether those customers are payers, providers, or patients and their caregivers.

In the future, medtechs may look to create holistic care platforms that evolve from a disease- or technology-specific focus to managing complicated patients across the care continuum. Such platforms of care could assist providers and payers with one of their most pressing issues.

To create beyond-the-product solutions, medtechs must access new capabilities. That requires collaboration with other organizations, particularly digital health players and new technology entrants, which are well-capitalized. (Based on data from the venture capital firm Rock Health, digital health companies raised an estimated US$3.5 billion in 188 deals in the first six months of 2017.)

In 2016–17, signs of the medtech industry's growing interest in collaborations with tech and digital players continued despite little direct evidence that these alliances have generated additional medtech revenue. In the diabetes space, for instance, Medtronic has partnered with IBM Watson, Qualcomm and Glooko to create an integrated diabetes management program that allows patients to track their blood sugar levels and automatically receive appropriate therapeutic doses of insulin. Verily Life Sciences has formed important joint ventures with Johnson & Johnson, Sanofi and GlaxoSmithKline in the areas of digital surgery (Verb Surgical), diabetes management (Onduo) and bioelectronic treatments (Galvani).

In the future, medtechs may look to create holistic care platforms that evolve from a disease- or technology-specific focus to managing complicated patients across the care continuum. Such platforms of care could assist providers and payers with one of their most pressing issues: the efficient delivery of high-quality, high-touch care across populations with multiple co-morbidities.

As populations around the globe age, the need for such consumer-focused platforms is only growing more acute. By 2050, the world's population over 65 is expected to triple, and the costs of treating chronic diseases will reach an estimated US$47 trillion. As Steven Collens of MATTER notes in an accompanying perspective, "We have democratized old age. There are numerous opportunities for technologies to help people live healthier, even as they live longer." (See "Medtech innovation in an aging world.")

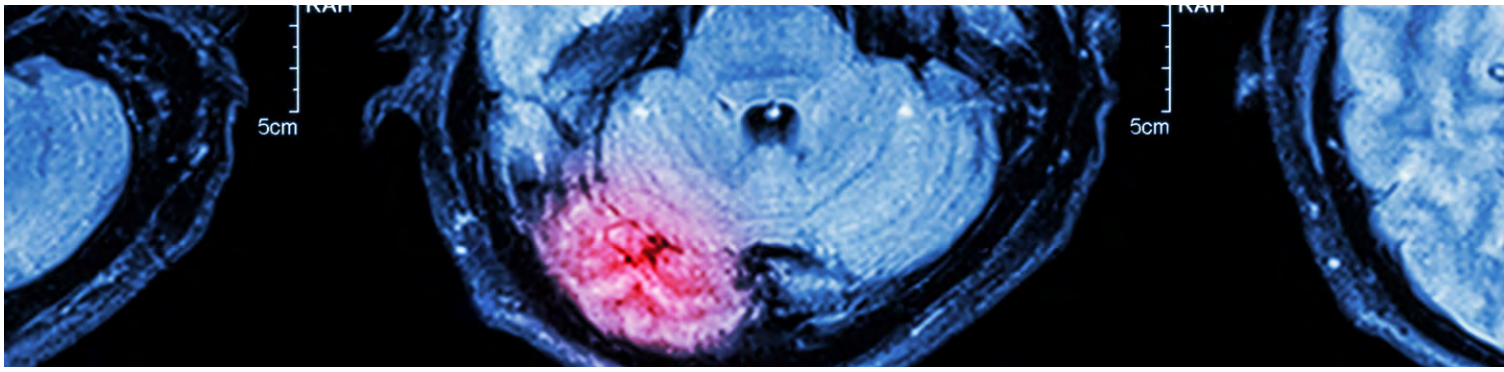
If structured correctly, these emerging platforms will enhance the patient experience and create new revenue opportunities for medtech. For instance, by linking big data capabilities with new knowledge from precision medicine, it will be possible to create precision health offerings that promote preventive interventions before symptoms of disease manifest. The goal is to use digital tools and smart devices to nudge individuals with the right piece of information, cue or intervention at the exact right moment in time to maintain health. Such responsive platforms will not only be valuable to individual patient consumers. They will also be valuable to providers and health systems that are reimbursed according to the value and quality of the care they deliver.

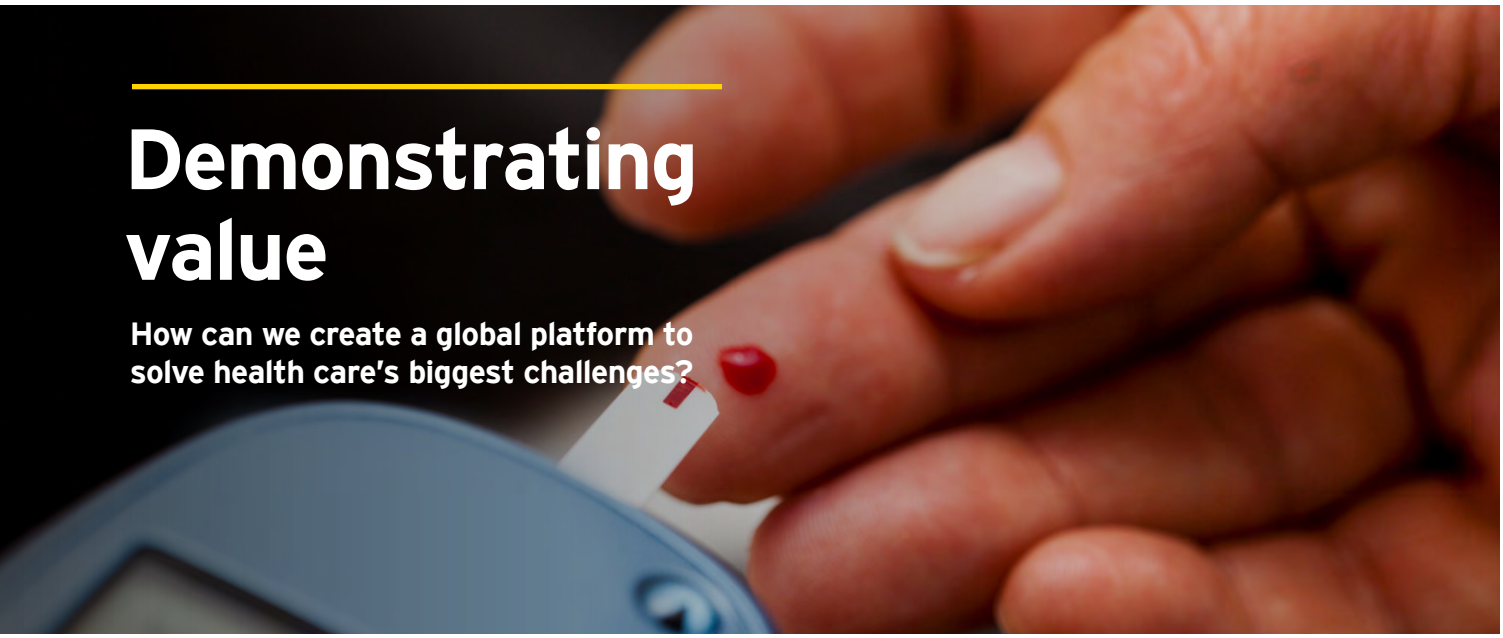
As medtechs continue to transform their business models to increase customer-centricity, the types of partners they need to engage will only expand. In a swiftly moving market, keeping abreast of these potential collaborators is critical and begs the question: for future growth, do the best partners even yet exist?

Selected examples of digital deals, 2016–17

Partners involved	Analysis
Royal Philips and **PathAI**	Solution improves the precision and accuracy of routine diagnosis of breast cancer and other diseases using artificial intelligence.
Stryker and **Microsoft**	Augmented reality-based system integrates multiple types of data to create the operating room of the future.
Medtronic and **IBM Watson Health**	Next-generation predictive diabetes app that proactively alerts patients at risk of hypoglycemia of an attack hours before it actually happens.
Agfa Healthcare and **IBM Watson Health**	Cognitive technologies to improve the accuracy of imaging in multiple disease areas.
Johnson & Johnson (Ethicon) and **Touch Surgery**	Simulated surgical training program distributed via an app for doctors in remote areas of the world.
Sanofi and **Verily**	Launch of Onduo, a joint venture to develop a comprehensive diabetes management platform.
Johnson & Johnson and **Verily**	Joint venture Verb Surgical combines robotics, visualization, data analytics and connectivity to create a digital surgery prototype.

Source: EY and company reports.





Demonstrating value

How can we create a global platform to solve health care's biggest challenges?

As Frans van Houten, CEO of Royal Philips, writes in an accompanying guest perspective, "Current incentive systems reward the old ways of working." However, as pressure grows to contain health care costs, payers and providers are embracing value-based care that prioritizes outcomes over throughput.

That shift to value, much like the technological shifts described earlier, is directly affecting medtech business models. Not only do medtechs need to demonstrate the value of their products to a diverse group of stakeholders, they must also satisfy very different — and sometimes conflicting — definitions of worth.

Enter value frameworks, tools that are designed to objectively compare the efficacy, side effects and costs of different products. Until 2017, such tools were used primarily to evaluate pricing and market access decisions related to biopharmaceutical products. In May 2017, the industry group AdvaMed launched its own value frameworks, one for medical devices and another for diagnostics.

According to Nadim Yared, current chair of AdvaMed and CEO of CVRx, the two different assessment tools are designed to enable flexible, comprehensive determinations of value based on data related to clinical efficacy, cost and care delivery. Intended to be used from the very beginning of the product development process, these value frameworks are "blueprints that will guide companies' data collection and funding strategies," says Yared. (For more of Yared's insights, see his perspective "Creating a framework for future medtech innovation.")

Even with value frameworks, defining the value of medical products is no easy task, requiring relevant, real-world data. To capture such data, medtechs need to collaborate with payers and providers. Thus, just as we have seen anecdotal evidence of increased partnering between medtechs and digital or tech entrants, in 2016–17 we have also witnessed dynamic partnering between medtechs and other health care stakeholders.

These collaborations come in several varieties. Some are broad, multi-year partnerships designed to help providers and payers solve fundamental challenges. This includes creating cloud-based services that aggregate disparate medical and clinical data for real-time access or management systems that support treatment of complicated high-risk patients. Others are more product-centric but significantly alter how medtechs get paid, linking reimbursement to demonstrated outcomes.

Whether broad or narrow in scope, these partnerships are fundamentally different from the transaction-based contracts medtechs have constructed with payers or providers in the past. These new partnerships require medtechs to make up-front investments and share risk as members of a health care ecosystem.

For now, these partnerships are generally one to one, but as successes mount — either in improvements in care delivery or reductions in cost — medtechs must be prepared to partner with other players to create consortia that help answer this vital question: how can different stakeholders combine forces to create platforms to solve the challenges payers and providers most care about?

Selected medtech-payer collaborations, 2016–17		
Medtech company	**Payer**	**Summary**
Johnson & Johnson (Animas division)	Aetna	Value-based agreement for the OneTouch Vibe and Ping insulin pumps that ties payments to A1c outcomes.
Medtronic	Aetna	Value-based agreement partially ties Medtronic's reimbursement to successfully meeting clinical improvement thresholds.
Myriad Genetics	UnitedHealthcare	Collaboration establishes pricing for diagnostic tests in multiple therapeutic areas including breast cancer, prostate cancer, rheumatoid arthritis and neuropsychiatry.

Source: EY and company reports.

The partnerships medtechs must now forge with payers and providers are fundamentally different from the transaction-based contracts that were constructed in the past. These new partnerships require medtechs to make up-front investments and share risk as members of a health care ecosystem.

Managing risks

As regulatory burdens increase, how can you stay compliant and outperform?

Medtechs face many risks in the current environment beyond how to shift successfully from product-centric business models to ones built on customer-centricity and value.

Three other business risks represent ongoing challenges for medtech management teams: the new European medical device regulations, a topic discussed in perspectives on pages 28 and 30; increasing cybersecurity threats; and the potential reinstatement of the US Medical Device Excise Tax.

The 2.3% Medical Device Excise Tax (MDET) has faced widespread criticism and calls for repeal since its creation as part of the Affordable Care Act. As part of a legislative compromise in December 2015, the U.S. Congress suspended the tax for two years. Unless legislators take up the issue in the waning months of 2017, the tax will be automatically reinstated 1 January 2018.

> Although medtech devices have not yet been targets of malicious cyber attacks, the potential damage to patients — and companies' reputations — means medtechs are spending more time and money monitoring potential threats.

Although reinstatement appears unlikely — ongoing discussions mean MDET repeal could be bundled with larger tax reform legislation, for instance — medtech companies need to make sure they are adequately prepared for its return. Steps medtechs should take include continuing to monitor possible legislative changes; evaluating IT infrastructure to make sure it's robust enough to track owed — and estimated — taxes; and dedicating sufficient financial resources to MDET expenditures.

Cybersecurity now a top priority

The 2017 worldwide WannaCry ransomware attack was a stark reminder that while smart devices provide significant benefits to patient care, their connectivity exposes manufacturers, health care providers and consumers to new, hard-to-anticipate cyber threats. Identified security flaws in devices such as defibrillators, pacemakers and insulin pumps, for instance, make it possible — theoretically — for hackers to take control of these products and alter their function, a scenario that could result in serious patient harm. Although no devices have yet suffered this kind of malicious attack, the potential damage to patients — and companies' reputations — means medtechs are spending more time and money monitoring potential threats.

Regulators and policymakers are also increasingly focused on the issue as well. In May 2017, the U.S. Department of Health and Human Services said health cybersecurity was in "critical condition." The FDA, meanwhile, has called cybersecurity a "shared responsibility" and has released several guidance documents on the steps that medtechs can take to manage the cybersecurity vulnerabilities. It continues to actively monitor threats and issue warning letters, as well. In January 2017, for instance, the FDA warned Abbot about

its failure to investigate and resolve risks related to implanted heart devices that were acquired as part of its St. Jude purchase. In August 2017, Abbott announced software updates that provide additional security protections.

Nadim Yared, Chairman of dvaMed and President & CEO of CVRx, believes current regulations strike the right balance of safeguarding device integrity but not stifling innovation. "I think the best thing we can do moving forward is to keep the lines of communication and collaboration open," he said in an interview.

Yared's advice applies whether the risk is tied to changing regulations, cyber threats or building trust in the digital world. Medtechs that understand and proactively manage the growing array of risks are more likely to succeed than those that do not. That's because when they do so, medtechs create trust with their stakeholders.

Simply put, management teams must determine what steps to prioritize to make sure key business processes are compliant with new regulations. In doing so, they build transparency and trust, safeguarding the bottom line today and creating opportunities to outperform in the future.

Conclusion

As we spell out in detail in the related "Industry performance" articles, the aggregate medtech industry is thriving in 2017, even as competition intensifies and customers grow more demanding. In the future, medical technology companies appear well-placed to play a prominent role in this increasingly digital, customer-centric health care ecosystem. Of course, they will need to access new skills and talent in areas such as human-centered design, behavioral science and data analytics to stay relevant.

But if they make the right technological investments and strike the right partnerships, medtechs won't need to worry about relevancy. They will find new ways to capture value and build sustainable businesses, even as the health care ecosystem continues to evolve.

Guest perspective

Creating a framework for future medtech innovation

Nadim Yared

Chairman
AdvaMed

President and
Chief Executive Officer
CVRx

EY: How are shifting definitions of value changing medtech's approach to developing evidence?

Yared: Health care systems in the US and worldwide are undergoing tremendous change, driven primarily by the twin imperatives to keep costs down while providing more and better quality care for patients. Everyone is looking to maximize value.

The challenge for the medical technology industry is that there are numerous health care stakeholders — patients, providers, payers, innovators, etc. — demanding value, but there is no consensus definition of what value is.

Determining how value is assessed and what evidence is needed to support a value claim will be a critical issue in the near term. If we don't get this right, medical innovation — and the patient and societal benefits it generates — could be jeopardized.

AdvaMed has attempted to address this challenge by developing our Value Frameworks. These frameworks, one for medical devices and one for diagnostics, are designed to provide stakeholders across the health care spectrum with an approach to objectively determine the value of a medical technology or diagnostic test and the evidence needed to support its use.

The frameworks provide a comprehensive approach for assessing value based on four key "value drivers": clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and patient/population impact.

These frameworks encourage each stakeholder to view the value of medical technologies and diagnostic tests from a broad perspective. They are also intended to be a guide to the kinds of evidence that medtech developers should consider generating to demonstrate the benefit of a technology to other stakeholders. Medtech companies are willing to

provide evidence to meet the needs of new payment models, but the type of evidence needs to be appropriate for the technology and the risks involved.

The important thing is that the frameworks are not designed as a "one-size-fits-all" formula. They are intended to be flexible, promoting the understanding that technologies will offer value in different ways under the frameworks' value drivers.

EY: How will these value frameworks reduce uncertainty and promote medtech innovation?

Yared: The constant, iterative approach to innovation and its reliance on evolving physician skills and experience raise some challenging issues when trying to assess value. Both factors require adjustments to evidence development approaches and, often, smaller studies.

Value analyses, especially as providers and payers move into more risk-based payment models, must allow for appropriate types of evidence development and be flexible enough to adjust for different time frames and iterative changes in technologies.

The vast range of what we refer to as medical technology is also a factor. Frameworks need to be flexible enough to account for that range. For example, diagnostic technologies, which may or may not directly influence a patient outcome, are distinct from other technologies. This is why AdvaMed developed a separate diagnostic value framework that takes into account specific considerations based on the test being evaluated.

As the CEO of a smaller medtech company, I know the challenges of trying to address multiple stakeholder needs with limited resources. I believe AdvaMed's frameworks can provide a pathway for smaller companies to follow. They are blueprints that will help guide companies' data collection and funding strategies. The frameworks can be used from the very beginning of the development process to guide the value proposition, drive evidence needs and ultimately provide a path for delivering value across multiple stakeholders.

EY: How is this changing definition of value affecting medtech business models?

Yared: As we look to address the value needs of various stakeholders, medical technology companies are being challenged to do more and more. Previously, it was sufficient to produce an innovative technology and get it to a physician or hospital. Now medtech companies are looking to be partners with providers and payers to help them manage patients across the continuum of care.

Many companies in our space are stepping up to this challenge, providing services and expertise that complement and enhance their technology offerings. This speaks to the dynamic, innovative nature of our industry and how we are uniquely positioned to partner with stakeholders for greater efficiencies and improved outcomes.

For example, medtech companies are experts in how their technologies may affect clinical outcomes. They have the ability to collect, aggregate and analyze data that can be used to improve health care, reduce costs and improve the patient experience.

In addition to dedicated medical, clinical and quality specialists, companies have health care economists, reimbursement specialists, data analysts and others who can also help physicians and health systems deliver better patient care.

For such partnerships to work, however, all stakeholders must be willing to look beyond their traditional roles and collaborate in new ways. Government watchdogs will also need to rethink traditional anti-kickback rules that limit how medtech companies can partner with health care providers.

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EY: What is AdvaMed's response to new, non-traditional companies developing medical technologies?

Yared: Any company developing technologies that can help solve today's health care challenges is welcome under our "big tent."

Our creation last year of the AdvaMed Digital sector demonstrates our "big tent" approach. Look at all the incredible ways digital companies are transforming health care, from mobile devices that provide consumers with personalized health care information to big data-enabled solutions for entire patient populations.

These technologies will only achieve their potential for patients and health care systems if public policies are in place that promote innovation along with patient safety. At the same time, these digital companies, many of which have never before marketed health care products, will only succeed if they understand the various regulatory and reimbursement requirements — many of which are still being developed.

In this fast-changing environment, AdvaMed Digital is an essential resource for digital health companies and traditional medtechs. It is also a key stakeholder in shaping the policy environment for this emerging area of health care.

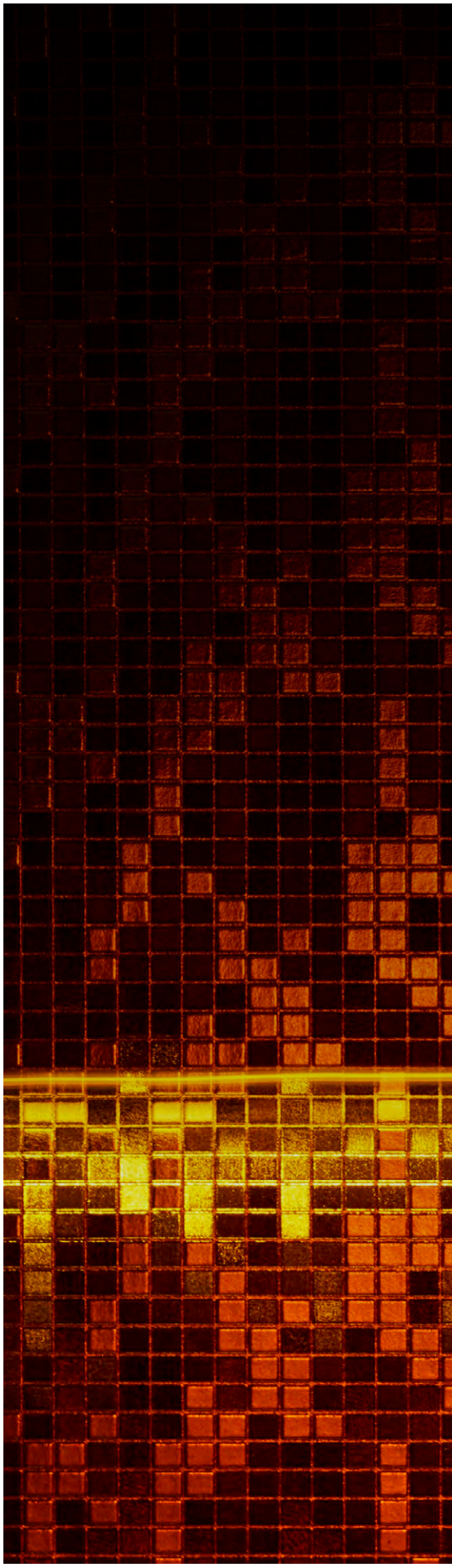
Of course, it is not only new or non-traditional companies that are part of the digital health revolution. Companies such as Medtronic, Boston Scientific and Johnson & Johnson are all very active in this space, and they benefit from being part of AdvaMed Digital as well.

There are so many challenging issues in this space, including software regulation, cybersecurity, interoperability standards and adequate reimbursement. No doubt, other critical issues will also emerge. By bringing together the new entrants and the more traditional players, both groups benefit from hearing different perspectives and can help craft policy positions that foster innovation, not inhibit it.

This is a great example of what AdvaMed can do. I am very proud of the success the association has had as a convener for the entire medical technology community — a place where every segment of the industry feels it has a home and a voice.

And I am excited about expanding that concept to other players in the medtech community so that we can effectively engage investors, contract manufacturers and contract research organizations — really anyone who is part of the innovation ecosystem.

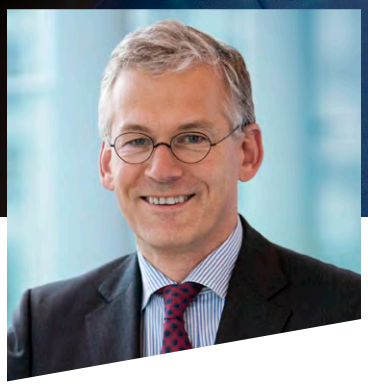
By engaging with all these different stakeholders, I believe we have the opportunity to foster greater understanding of how each piece of the innovation ecosystem works and how it could work even better.




Digital technologies will only achieve their potential for patients and health care systems if public policies are in place that promote innovation along with patient safety.

Guest perspective

How the genius of technology is transforming health care



Frans
van Houten

CEO
Royal Philips

The grand challenges of the health care industry are well-understood: aging populations are expanding, customer expectations are fast-increasing and pressures to manage costs continue unabated. Virtually every citizen, every health care system and every nation is affected.

I firmly believe that technology's potential to transform health care is at least as great as its ability to disrupt the banking, retail and entertainment, transportation and hospitality industries. Yet the usual economic norms governing businesses don't apply to health care in the same way.

As one US hospital CEO points out:

- Health care is the only industry where the person ordering the service likely doesn't *get* the service.
- The person receiving the service likely doesn't *pay* for the service.
- The provider of the service likely doesn't determine what it gets *paid* for the service.
- And the payer for the service likely determines the price but does not *receive* the service.

That's not to say that innovation isn't driving huge, positive change in our industry — it is. Digitization and connectivity are underpinning two major trends: the personalization of care and the industrialization of care. And those trends are changing the way health care literally works for patients, physicians and health systems.

The personalization of care

With the rise of connected devices and big data, consumer and professional health care are converging to advance more effective and individualized

treatment pathways. We call this the personalization of care.

For consumers, increased connectivity and data sharing are driving improvements in self-management and adherence to treatments. In clinical settings, a rich patient context and health informatics data sets are advancing diagnoses that are right the first time, enabling highly efficient, tailored treatment pathways. This trend in care personalization is also changing the relationship between care teams and patients and improving the overall patient experience.

One fine example is the way Arizona-based Banner Health is pioneering telehealth services with its Intensive Ambulatory Care program. Using telemedicine, Banner brings individual self-management and treatment strategies to patients with complex medical situations due to multiple chronic conditions — a demographic that accounts for around half of all health care spending.

Since launching the program in 2014, Banner has reduced hospitalization rates and the number of days spent in the hospital by around half. It has also reduced its 30-day readmission rate by 75%, thus cutting the overall costs of care by more than one-third — all while improving overall patient outcomes. It's an impressive approach that is transforming both personal and professional health care.

The industrialization of care

The second trend is the industrialization of care. Now that digitization has enabled the standardization and optimization of health systems' building blocks, it's possible to drive more complete integration of health systems and reduce procedure variance — delivering improved outcomes at lower cost.

At its most prosaic, digitization means the introduction of standard industry practices such as Lean, Six Sigma and Variance Analysis to reduce waste and improve efficiency.

More tellingly, digitization facilitates the adoption of state-of-the-art clinical decision support algorithms and enables health systems to design scalable, repeatable processes and workflows that optimize care delivery. The end result is first-time-right diagnoses that improve patient outcomes and reduce health care costs.

Sweden's Karolinska University Hospital is using such principles to rethink the stroke care pathway and promote seamless collaboration between emergency responders and the hospital. Patient assessments are conducted in the ambulance rather than the hospital and take advantage of continuously available data, including precision diagnostics and predictive analytics. Upon arriving at the hospital, the patient moves straight to the hybrid operating room for treatment, reducing "call to needle" time, the period between an ER call and the onset of treatment. That's critical because numerous studies show patients have significantly better outcomes when treated within the first hours of a stroke's onset.

The post-operative, rehabilitation phase is just as important for the patient's return to maximal health. After leaving the hospital, treatment effectiveness can be measured using continuous monitoring. Built-in feedback loops allow the fine-tuning of treatments to coach patients back to healthy lifestyles.

A potent platform for innovation

This combination of personalization and industrialization is a potent platform to support further innovation.

For example, consider how we are connecting artificial intelligence and data analytics via cloud-based solutions to accelerate precision medicine and support medical staff.

More and more, we want to unlock insights from rich data sets to gain a deeper understanding of both individual patients and populations. This requires that we make use of *all* data sources — pathology, radiology, genomics and longitudinal, lifestyle-related information. The goal is to customize population-based health recommendations using individual-specific data, resulting in first-time-right diagnoses *and* personalized treatment plans that put patients at the center of care.

Last year, Philips celebrated 125 years as an innovation company, and we have learned to engage more closely than ever with our customers to tackle the challenges that new technologies can bring. For us, that means *co-creating* solutions with organizations such as Banner Health and Karolinska.

Of course, there remains much to do if we are to capitalize on technology's potential. Our industry's incentive systems reward "old" ways of working. We need to learn to put a premium on prevention and patient-centered chronic disease management, for example by rewarding outcomes and behavior change, rather than throughput.

These are big issues — and they won't be solved overnight. However, we can make an important start to tackling health care's biggest challenges by rapidly embracing technologies that simultaneously enable the personalization and industrialization of care.

Guest perspective

Investing in China for the long term

Photo courtesy of Edwards Lifesciences.

Michael
Mussallem

Chairman and CEO
Edwards Lifesciences

In the late 2000s, as emerging economies such as China, Brazil and India grew wealthier, analysts and medtech management teams saw expansion into these geographies as critical to future growth. More recently, as the challenges of doing business in these markets have become better understood, the perceived return on investment may seem less certain — especially compared to the known opportunity in currently larger, more established regions such as the US, Europe or Japan.

At Edwards Lifesciences, we are committed to offering our technologies and therapies to patients around the globe. However, a company of our size needs to prioritize our activities. Within the emerging markets, we are focused on China, which is projected to be the second-largest market for medical devices by 2020.

A deliberate approach

We believe being successful in China requires a deliberate approach that combines up-front investment with a long-term commitment. Simply put, there are no shortcuts. It's not enough to establish a physical presence, perhaps through a joint venture or manufacturing plant. To be successful, companies need to build high-quality teams that have a deep understanding of the patients and providers they serve. Thus, success isn't only about the launch and uptake of specific brands. It's also about establishing an authentic and organic corporate culture that is committed to quality and meeting the needs of Chinese patients.

More broadly, depending on the types of medical technologies a company produces, acquisitions or joint

ventures can provide an important foothold in China. At Edwards, we believe our product portfolio, which is focused on heart valves and critical care monitoring, lends itself to an organic, bottom-up approach. Thus, our approach, with a long-term view in mind, has been to create an Edwards culture in China by hiring local talent to introduce technologies that are already market leaders in other geographies.

Edwards has a long history of developing medical technologies that are highly specialized and not easily commoditized. We have focused less on establishing low-cost manufacturing centers, and instead placed an emphasis on educating Chinese physicians about the quality of our devices and the outcomes they can provide patients.

To nurture our China-based talent pool and accelerate growth, we have also moved experienced personnel to China from other parts of the world, both to help integrate Edwards' patients-first culture and deep technology knowledge, as well as to provide guidance on best practices from other regions. Longer term, however, our strategy in China won't rely heavily on a large expatriate presence. We need teams who have an intimate understanding of our customers and their needs, and we are investing in our team's education and training so that they may best serve their stakeholders in the future. This approach also allows us to tailor our commercial practices so that our sales training and device distribution systems meet local needs. As a result, we are better able to take full advantage of different opportunities unique to China, such as the differences between large, urban centers and more rural centers, and how they approach specific patient needs and treatments.

Value through differentiation

Chinese physicians and consumers are knowledgeable about new medical technologies being utilized elsewhere around the world, and also place an emphasis on quality and value. As in other markets where there are scarce health dollars to be spent, China is very focused on cost. For companies developing medical technologies that are less differentiated, one strategy for China might be to develop high-quality but streamlined versions that still fulfill the medical need, but at lower costs.

We understand the Chinese government's initiative, "Made in China, 2025," seems to be pointed at the cost of medtech as a priority. We also observe that the government sometimes deploys blunt instruments like price controls and regulatory constraints. We are hopeful that the government will recognize that a vibrant, diverse medtech market will encourage competition from both local and global companies. This, in turn, will improve value and the quality of health care for Chinese patients in a faster and better manner, as it has elsewhere around the world. We are working to build bridges with the government to inform them of the value of highly innovative devices.

Developing streamlined or commodity devices hasn't been a focus for Edwards because our products are primarily used in specialized situations where patients are grievously ill. We also recognize that Chinese patients want access to advanced medical technologies. Our focus is on developing high-quality, sophisticated and differentiated products backed by compelling evidence and outstanding clinical outcomes as well as providing comprehensive physician training.

That product differentiation means we also haven't prioritized building a large manufacturing presence in China. Because our devices are easy to transport and high-value, it's not as critical to create supply chain efficiencies and economies of scale as it might be for other kinds of medical technologies.

For now, because of cost, most of the Chinese citizens who have access to our devices pay for them out of pocket. As China and other emerging markets grow wealthier, however, access to technologies such as ours will continue to grow. While we need to customize our commercial model in geographies such as China, the same evidence-driven approach we have taken to promote adoption in the US and Europe applies. It's about building leading-class technologies that are supported by data.

Our journey in China is early, and we are still learning. But, as a result of our long-term outlook, we have already seen significant sales growth. We are confident that focusing on the right opportunities in China will provide an immense benefit to the Chinese patients who need and deserve innovative, high-quality therapies.

> We believe being successful in China requires a deliberate approach that combines up-front investment with a long-term commitment. Simply put, there are no shortcuts.

Guest perspective

Medtech innovation for an aging world

Steven
Collens

CEO
MATTER

Steven Collens is CEO of MATTER, a two-year-old incubator based in Chicago that works with start-ups, universities, hospitals and life sciences companies to develop technology-driven solutions to improve health and health care.

EY: One of MATTER's major initiatives is developing solutions to promote healthy aging. What opportunity do you see for medtechs in this space?

Collens: Medical advances mean that health systems are now very good at addressing acute illnesses. As a result, we have democratized old age; people expect to live into their 80s, if not beyond. But this increase in longevity means many elderly are living with multiple chronic conditions. At MATTER, we believe there are numerous opportunities for technologies to help people live healthier even as they live longer. In addition, technologies can also help people live more years in lower acuity environments, preferably at home or in an independent senior living facility.

EY: In your opinion, what are the most compelling near-term opportunities for healthier aging?

Collens: Technology has improved both remote patient monitoring and the ability to engage patients outside the doctor's office — what I call remote engagement. As a result, it's possible to collect detailed data that are informed directly by people's behaviors and have a direct link to health status and outcomes. There are a number of companies now in the business of collecting data in non-traditional environments, using algorithms to deliver insights that result in prevention-focused, proactive health care decisions.

EY: Who is the customer for these data-driven technologies? Is it the consumer, the caregiver or the physician?

Collens: That is a critical question. For digital solutions to have impact, providers and payers have to be directly engaged. Direct-to-consumer solutions that don't integrate easily with professional medical tools — or don't provide information that supports care delivery — aren't as helpful as services that do. It's not that these data need to be integrated directly in a medical record. But the data does have to have utility for the physician: for instance, by providing information about which patients to prioritize for office visits or another proactive intervention that can limit, or prevent, declining health.

EY: Can you give an example of a solution that uses data in the way you just described?

Collens: I am interested in advances in remote monitoring that allow physicians to deliver the right care to the right person at the right time. There's been a lot of attention on consumer-focused wearables such as Fitbits. I am more interested in tools that allow us to collect physiologically meaningful data in non-intrusive ways. For example, mobile phones can be used to monitor and generate meaningful health information. On average, a person looks at her phone 150 times a day and increasingly uses the phone for many different activities. As a result, it's possible to develop algorithms that capture behavioral data that are linked to a person's cognitive state. One of the companies we work with uses phone-based, remote monitoring to identify recovering drug addicts at risk of relapsing. Imagine a similar algorithm being used to flag potential cognitive changes, indicating the worsening of neurodegenerative disorders such as Alzheimer's disease.

EY: What are some of the challenges to developing solutions that promote healthy aging?

Collens: One key problem is that most of the currently available solutions are "point solutions" designed to solve a very particular need in the marketplace. The issue is providers and payers don't have the capacity — or the desire — to test and then implement 40 different point solutions, especially when they are focused on different patient populations. At the moment, there is no integrating platform for the different solutions that already exist. That would be a key accelerator for the space.

Some digital health executives initially hoped electronic medical records might play this function, but that hasn't turned out to be the case. Which companies will provide this integration is still an open question. Technology companies, consumer giants and certain medtech incumbents have all signaled they might play a role. As the space evolves over the next several years, it will be interesting to watch where those companies place their bets.

> For digital solutions to have impact, providers and payers have to be directly engaged.

Guest perspective

The operating room of the future

Dr. Jens
von Lackum

Deputy Member of
the Executive Board
Aesculap, a subsidiary of B. Braun

Dr. Boris
Hofmann

Head of Business Development
Aesculap, a subsidiary of B. Braun

The operating room (OR) is well-positioned to be one of the primary platforms for digitally enabled health care. These high-tech spaces have the potential to be more than the information-rich settings they already are. Because they integrate data from multiple sources and incorporate a range of tools, including voice recognition and augmented reality, future operating rooms will operate as distinct medical devices in their own right.

Today, unlocking a car with a specific key can automatically set the mirrors and the seat based on personal settings. At Aesculap, a division of the medical equipment supplier B. Braun, we believe the OR of the future will have that same functionality.

Upon the surgeon's entrance into the room, medical equipment will automatically be arranged based on the type of surgery being performed and the physician's predefined preferences. Decision support software that links patient data (e.g., laboratory values or MRI and CT scans) with outcomes reported in the literature will be available in real time.

Devices, such as drills used in knee or hip surgery, will collect procedure-specific information that can be analyzed and displayed to reduce errors or allow more experienced physicians to provide advice remotely.

Augmenting performance through augmented reality

Augmented reality will be a critical enabler of this OR of the future. New visualization systems will allow the juxtaposition of real-time anatomical information with a variety of other types of data, dramatically changing how surgeries are performed.

For instance, augmented reality will allow surgeons to review scan data in conjunction with a patient's anatomy to help guide exactly where — and how much tissue — to cut. For complicated procedures involving soft tissues such as brain surgery or tumorectomies, augmented reality systems could improve patient outcomes by decreasing the amount of tissue a surgeon needs to manipulate during the procedure. This would result in less trauma to the patient and, therefore, a faster overall recovery time.

Augmented reality could also decrease total time spent in the OR, one of the costliest areas of a hospital. Excluding physician costs, researchers at Stanford Medical School estimate a minute of OR time for a basic surgical procedure costs between US$15 and US$20, with at least half that sum tied to fixed overhead costs. Not only could augmented reality eliminate delays linked to surgeons leaving the OR to check test results, but the tool could further standardize procedures that heavily depend on physician judgment and experience.

However, the benefits of augmented reality, both to patients and to a hospital's bottom line, have yet to be proven. Developing that proof is an important area going forward for B. Braun and other developers alike.

Moving to the future

The OR of the future is quickly becoming the OR of the present. Within two years, augmented reality will become mainstream in most hospital ORs. In addition, we will have the ability to interlink all the devices in a surgical suite via common, open-source software. At the moment, if devices are connected, they are part of closed systems that require surgeons to choose equipment made by specific suppliers.

To provide the greatest functionality for surgeons, however, an OR management system needs to be flexible enough and comprehensive enough to interface with existing and future medical devices — no matter the manufacturer. As a first step, we and others are researching how to connect different instruments commonly used in the operating theater so they can safely communicate. We are also embedding sensors into our surgical instruments to collect additional performance information.

We know it won't be enough to add a digital solution to a single OR-based device or piece of equipment. To create a comprehensive platform, we are actively partnering with start-ups and IT mainstays that have experience in fields as diverse as artificial intelligence, robotics, visualization and data analytics. It's about combining capabilities from two very different fields — medicine and information technology — to use data in a fundamentally different way than has been done in the past.

The OR of the future is quickly becoming the OR of the present. Within two years, augmented reality will become mainstream in most hospital ORs.

Guest perspective

How MDR and IVDR are reshaping Europe's medtech industry

Serge
Bernasconi

Chief Executive Officer
MedTech Europe

In May 2017, after years of development, the European Union released final versions of both the Medical Device Regulation (MDR), and its twin, the In Vitro Diagnostic Regulation (IVDR). These regulations, which go into effect in 2020 and 2022, respectively, are spurring a medtech revolution. They will significantly reshape how medtech companies develop and market their products in Europe.

We have strongly advised senior executives at medical technology companies to seriously consider the potential impact of these rules on their current and future operations.

Compliance with the new regulations will require companies to significantly change their existing business practices. Medtechs must not only invest in quality management systems and evidence collection for products in development, but also provide additional clinical data to support already marketed devices.

Companies can't afford to delay their compliance activities any longer. If they haven't done so already, it is critical that medtechs perform gap assessments to understand what steps are required to remediate their devices and diagnostics. MedTech Europe, for one, is already conducting an industry-wide impact assessment of the new regulations, which will be out in early 2018.

Understanding the impact of the new regulations

For companies registering devices in Europe, the MDR and IVDR are set to raise the bar on product safety and function— even as they also raise questions. In the case of MDR, device companies must now measure clinical performance and continue to collect

clinical data following market launch; IVDR also requires diagnostic developers to collect evidence demonstrating a clinical benefit and changes classifications that affect product certification renewal. Also in the case of IVDR, around 80% of IVD products will require CE approval for the first time. Previously, only around 20% were required to obtain them.

Because of the costs associated with compliance, the new legislation could have a significant impact on the product portfolios of medtechs small and large. Historically, medtechs have been able to use general data from other companies as part of their registration dossiers. Because of the changing evidentiary standards for MDR and IVDR, however, that will no longer be the case. Depending on the costs to collect the required clinical evidence, for instance, companies may decide it makes more sense to divest an asset than invest in the mandated product changes.

MDR and IVDR could also impact market access. For instance, studies estimate that the number of medical technologies sold in Europe in 5 to 10 years could be heavily affected as companies assess whether the investments required to make devices compliant are justified based on current and future product sales.

Finally, Europe's notified bodies, the more than 50 groups across Europe that evaluate compliance and have the regulatory authorizations required to grant product certifications, are under significant pressure. They will need to review tens of thousands of medical technologies as a result of MDR and IVDR. A major concern is a potential shortage of notified bodies able to grant CE marks, potentially limiting product approvals.

A challenge to future innovation?

There's still a lot of work to do to clarify how both MDR and IVDR will be implemented. This includes the creation of additional legislation that translates what is essentially a political document into technical language that spells out the practical considerations tied to MDR and IVDR execution. Industry groups such as MedTech Europe will continue to play a key role here, helping device manufacturers interpret key wording in the legislation as they begin their compliance and remediation efforts.

While the costs of implementing MDR and IVDR are significant no matter the size of the manufacturer, they are particularly challenging for smaller players. Indeed, for many smaller medical technology companies, satisfying these new requirements is akin to climbing Mount Everest; the effort required to comply with the legislation is so large, they don't know how to deal with it.

These smaller medical device players are the lifeblood of innovation. As an industry, we have to be careful to build mechanisms that allow them to get the needed support to document the right clinical evidence for continued product registrations.

And, it won't be just product registrations that are potentially affected. These regulations could negatively affect the financing of innovation, too. Venture capitalists are already asking hard questions about the capacity of medtech innovators to develop and market their products according to the new regulations. VCs are also assessing how MDR and IVDR will affect their ability to generate returns on medtech investments, since the cost of introducing a product in Europe is going to go up.

Silver linings

While MDR and IVDR create challenges for medical technology companies, they also create opportunities. As part of the new regulations, monitoring systems will make it quicker and easier to identify specific issues tied to marketed products. Ultimately, such data strengthens the public's perception of the CE mark, and of the medical device industry overall.

Indeed, strengthening the product registration process is critical if medtechs want to build trust with regulators, physicians and patients. In recent years, that trust has eroded steadily as a result of high-profile device scandals. These new regulations offer a major opportunity to reverse course and reinforce the medtech's reputation for quality and innovation.

There's still a lot of work to do to clarify how both MDR and IVDR will be implemented. This includes the creation of additional legislation that translates what is essentially a political document into technical language that spells out the practical considerations tied to MDR and IVDR execution.

EY viewpoint

Europe's medical device regulation: looking beyond compliance

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In May 2017, the EU Medical Device Regulation (MDR) officially became law, giving medtechs three to five years to comply with new protocols that dramatically change how they launch new medical devices and reauthorize the use of already marketed products.

At a minimum, companies must amend a range of activities across the medtech value chain, including clinical evidence gathering, quality management, and product labeling and design. Products that fail to conform with all aspects of the regulation will lose their CE markings — and thus, the authorizations required to market them.

Because the changes are so extensive, medical device companies need an enterprise-wide road map to MDR implementation that is designed and led by regulatory experts but executed by the business teams. This road map must balance the up-front costs of remediation with current business capabilities, operational processes and commercial and strategic priorities. Since companies have no choice but to comply with MDR, one necessary component of this calculus is a gap assessment that defines MDR remediation costs relative to a specific product's future growth prospects. Key questions companies must ask include:

- What percentage of revenue is at risk?
- What is the total cost of compliance?
- Will new clinical studies be required for market certification?
- How harmonized are the technical files?
- Which products are central to the medtech's strategic agenda?

Depending on the answers to these questions, companies may decide to remediate, retire or replace products as part of a portfolio assessment. Once a decision has been taken to

remediate a product, it is also possible, for certain classifications, to accelerate development time lines to launch products under the Medical Device Directive during the transition period prior to full MDR enactment. That scenario provides additional time for remediation while the product is also generating revenue. Companies may also decide to shutter R&D activities, retire the product from the market, or divest it to an owner better suited to carry out the necessary changes. Keep in mind that medtechs must conduct such analyses across their entire product portfolios, and the complexity and scope of the endeavor becomes clear. This is not an activity to undertake lightly.

Navigating an uncertain road

Unfortunately, there is no one-size-fits-all MDR solution. Implementation strategies will vary depending on a medtech's product portfolio, its technology needs, its current business processes and its long-term strategy. To be most successful, companies should consider the following steps:

Develop an integrated strategy

Regulatory executives and business unit leaders must partner to jointly develop and execute a realistic, efficient MDR strategy. Since the steps to successful implementation are interrelated, companies need to think carefully about the sequence in which they alter key business activities to be compliant with MDR's timeline. If not well-planned, the additional time required for two activities — updating product labeling and conducting more stringent clinical evidence gathering — may become bottlenecks. In addition, prior to doing any actual remediation, medtechs should make sure they have upgraded their quality management systems so they have robust mechanisms for monitoring product updates at site, regional and global levels.

Assess current and future product viability

This assessment should proactively anticipate medtech market and regulatory trends and their potential commercial impact. It is important to do this analysis at the product level to make sure teams have a granular understanding of the cost interdependencies associated with different parts of the value chain. As companies create future competitive scenarios, they should also identify gaps in capabilities and calculate the potential costs of implementing and sustaining MDR at the product level. Such analyses will help business leaders better define the cost structure of MDR implementation and the potential merits of remediation versus portfolio rationalization.

Create a strong governance process

The governance process should include tracking and communications practices that provide real-time data on planned and complete regulatory changes. To reduce complexity and standardize approaches between business units, affected products and processes, an important consideration is the creation of cross-functional teams led by dedicated project managers who organize and then oversee MDR implementation efforts.

Involve senior leadership

The expenditures associated with MDR compliance could easily total hundreds of millions of dollars depending on a medtech's portfolio. Having adequate financial resources to make the needed changes is an imperative. As part of their preparation, businesses need to build multi-year implementation plans that not only account for MDR costs but have the full support of senior leadership.

Window for opportunity

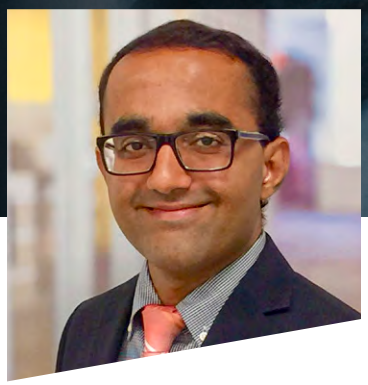
While there are significant up-front costs to MDR implementation, there is also an opportunity to use the regulation to make strategic decisions that improve a medtech's overall strategy and position in the market. For the past several years, medtechs have sought to create category leadership in therapeutic areas that are deemed critical for success. If approached strategically, MDR provides an opportunity to create the needed scale via product divestitures and acquisitions.

It can also be used to increase the efficiencies of routine business processes related to product labeling, reporting and supply chain obligations. The resulting simplicity of streamlined operations should reduce business risks for medtechs and increase compliance in many business functions that are not only related to MDR. Finally, MDR is expected to enhance patient safety and increase transparency related to the creation and marketing of medical devices. Both actions build trust with medtechs' stakeholders — patients, providers and payers — and, as such, will improve the reputation of medtech brands in the marketplace.

Navigating the complexities of MDR will be neither cheap nor easy. However, medtechs that proactively embrace MDR implementation as a springboard for positive organizational change are more likely to be successful than those who view the regulations as a compliance exercise. The question is: how will medtechs seize the upside of the current changing regulatory environment?

EY viewpoint

Securing the future for medical devices



Sri
Vasudevan

Executive Director
Ernst & Young LLP

Increasingly sophisticated ransomware attacks over the past year have infected thousands of computers around the globe and redefined cybersecurity threats. Hospitals are ideal targets for hackers and malware due to the wealth of patient identification information stored in computer systems and potentially inadequate processes for staying ahead of cyber risks. Further compounding vulnerabilities are the increased complexity and connectivity of medical devices, of which hospitals and medical providers are primary users.

The challenge is how to protect against the new risks that come with increased connectivity and complexity. A great example is the drug-infusion pump, which several years ago wasn't a connected device. Now Bluetooth and Wi-Fi connectivity are the norm, which enhances the customer experience and makes the pumps easier for hospitals and clinical technology departments to manage, but also creates new cyber risks. How have medtechs and health systems adapted to keep up with emerging cybersecurity needs?

Borrowing product security leading practices from the technology industry, medtech companies should consider embedding product security capabilities into their different business and product lines. That way, from the earliest phase of development, the right cybersecurity guidance can be incorporated into any connected device project plan. That is easier said than done given the length and complexity of the medtech product life cycle and the need to customize security protections based on the kind of device being developed.

For example, the security of infusion pumps is very different than the security of implantable devices such as pacemakers.

The use of open source software libraries by many medtech companies and hospital systems also adds challenges. A reliable notification process must be in place so that the medtechs and hospitals that use the software are not only aware of vulnerabilities as they are uncovered, but also know how to resolve them. Ransomware attacks in 2017 demonstrate why these notifications are so critical — organizations that hadn't upgraded their computer systems with a software patch distributed in March 2017, including many hospitals in the US and UK, were easy targets.

Proactive management

Device companies have established rigorous safety protocols to safeguard the functionality of medical devices. For instance, engineers rigorously test infusion pumps to make sure they accurately dispense correct drug dosages. Companies now must establish similar protocols to proactively manage potential cybersecurity risks to their devices and related technology systems.

But it isn't just the responsibility of medical device manufacturer. In an environment where new cyber threats can emerge seemingly overnight, hospitals and physician organizations must also be aware of gaps and take steps to quickly implement needed security upgrades.

A new standard, TIR57, was introduced in June 2016 by the Association for the Advancement of Medical Instrumentation (AAMI) to define the requirements for security risk management activities for medical device companies. Underscoring the importance of these guidelines, the FDA formally recognized TIR57 as a foundational standard less than a month after it came out.

With the health care industry still a relatively easy target for cyber criminals, and considering the recent wave of rejected 510(k) FDA submissions due to incomplete or inadequate security risk management sections, it seems only a matter of time before the FDA enforces stringent regulations for the security of medical devices. In August 2017, the FDA demonstrated how closely it continues to monitor potential cyber vulnerabilities, notifying providers and the public about a software update that could improve the safety of an implantable cardiac pacemaker.

Medtech companies shouldn't wait for either safety notifications or formal legislation, however. They need to take preemptive measures now. Setting up a formal security risk management function, including time to train engineers and establish appropriate security engineering processes and protocols, takes about 12 to 18 months to set up. A scarcity of cybersecurity experts proficient in medtech could further slow the process.

What hospitals and medical care organizations want seems simple enough: medical systems that are secure by default; more timely software patches to address the latest security risks; and better communication and guidance about how to deploy the patches. However, there's often a disconnect between medtechs and the health care organizations using their products. Typically, the medtech sales and marketing teams, not the product engineerss or security experts, have the relationships with the health care organizations. Moreover, these relationships are primarily with procurement teams — not the health care organization's cyber security experts. Without a direct communication channel between a hospital's cybersecurity team and a medtech's product engineers, responsiveness to security issues can be unintentionally slow or incomplete. This may cause hospital procurement teams to cancel a contract or eliminate a manufacturer from a contract bidding process because of concerns linked to a device maker's handling of security issues.

Product security can be the first line of defense from diverse and rapidly evolving medical device cyber threats. If cybersecurity is viewed as a strategic issue, the known safety of connected devices becomes a competitive advantage. With patient safety at stake, it is also the right thing to do.

Borrowing product security leading practices from the technology industry, medtech companies should consider embedding product security capabilities into their different business and product lines.

Financial performance

Medtech sets a new pace

Financial metrics
Industry financial metrics rebounded in 2016 as companies, especially pure play medtechs, began to reap results from M&A efforts, creating therapeutic focus.

Top performance
Therapeutic device companies, particularly orthopedics companies that used M&A to drive revenue and net income gains, were top performers.

Capital agenda
R&D spending reached an all-time high in 2016, but an increase in cash returned to shareholders suggests near-term capital allocation priorities remain unchanged.

The US and European medtech industries returned to growth in 2016, as resurgent revenue and net income at pure play medtech companies and conglomerates alike helped the sector recover from a disappointing 2015. Overall, medtech revenue grew 5% to more than US$364 billion in 2016, compared with a 3% decline the prior year.

Acquisitions, which boosted industry metrics, were a key reason for the performance rebound, as were the impacts of prior years' acquisitions. In addition, the industry largely steered clear of the foreign currency exchange volatility that hampered top-line growth in 2015.

With a 3% increase to nearly US$153 billion, revenue at the industry's conglomerates bounced back from a difficult 2015, when divestitures and operational declines combined to cause revenue to fall 6%. Pure play medtechs enjoyed 6% revenue growth in 2016, compared with only 2% in 2015, as acquisitions markedly improved top lines at several of medtech's commercial leaders.

This solid financial performance, in conjunction with investor-friendly capital allocation strategies, helped the US and European medtech sectors keep pace with broader market indices in 2016.

The medtech industry's cumulative market cap rose only 4% in 2016 after a 13% increase in 2015. From 1 January 2017 to 31 August 2017, it has increased another 26% thanks to a series of solid earnings reports. Also helping was strong M&A activity that included two megadeals: the eye care specialist Essilor's US$25.2 billion acquisition of Luxottica and Becton Dickinson's (BD) announced US$24 billion acquisition of minimally invasive device specialist C.R. Bard.

The overall 5% revenue jump is the industry's best year-on-year growth since the financial crisis. Roughly three-quarters (74%) of all medtech companies boosted their top lines in 2016, with 11 medtechs exceeding the US$10 billion revenue threshold. Medtronic, the medtech industry's largest pure play, once again led the way with US$29.7 billion in revenue; the conglomerates Johnson & Johnson

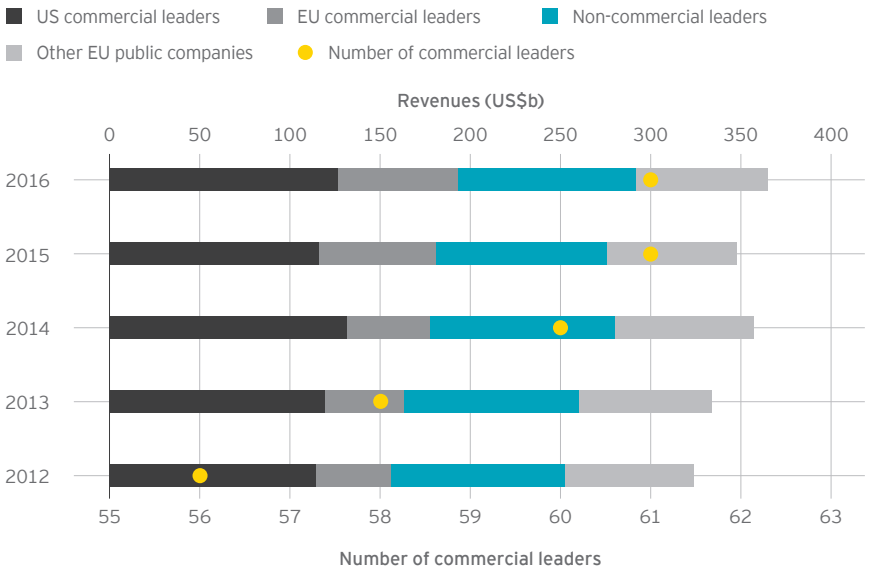
Medical technology at a glance (US$b, data for pure plays except where indicated)

Public company data	2016	2015	Change	% change
Revenues	$364.4	$347.2	$17.2	**5%**
Conglomerates	$152.7	$147.6	$5.1	**3%**
Pure play companies	$211.7	$199.7	$12.0	**6%**
Commercial leaders	$193.3	$180.7	$12.6	**7%**
Non-commercial leaders	$18.4	$19.0	-$0.6	**-3%**
R&D expense	$16.0	$15.3	$0.8	**5%**
SG&A expense	$70.2	$66.8	$3.4	**5%**
Net income	$16.0	$13.7	$2.3	**17%**
Market capitalization	$749.6	$726.7	$22.9	**3%**
Number of employees	807,381	785,833	22,298	**3%**
Number of public companies	431	443	-12	**-3%**

Numbers may appear to be inconsistent due to rounding. Data shown for US and European companies. Market capitalization data is shown for 31 December 2016 and 31 December 2015.

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

US and European public company revenues, including conglomerates



Commercial leaders are companies with revenues in excess of US$500 million. Other companies include figures for conglomerates.

Source: EY and Capital IQ.

and GE Healthcare rounded out the top three, respectively earning US$25.1 billion and US$18.3 billion in medtech revenue.

Among pure play medtechs in the US and Europe, 61 commercial leaders (those medtechs with greater than US$500 million in annual revenue) posted aggregate revenue of US$193.3 billion. Not only was this a 7% year-on-year increase, it was also 91% of all revenue generated by non-conglomerate medtechs. In contrast, non-commercial leaders' aggregate revenue fell 3% in 2016, as US$5.7 billion in revenue was lost due to acquisitions and the transition of Össur, DexCom and Wright Medical to the commercial leader category. With few IPOs during the 2016 calendar year, only US$261 million in revenue was gained from newcomers to the public markets.

Pure play leaders ride M&A gains

In 2016, 8 of the medtech industry's 61 commercial leaders announced acquisitions that boosted revenue by more than US$500 million apiece, as 85% of the cohort increased revenue overall. Orthopedic specialist Zimmer Biomet grew its top line by US$1.7 billion (28%) to US$7.7 billion, as Biomet's financials were included in the group's 2016 figures following the June 2015 completion of the merger that created the company. Without the merger impact, Zimmer sales increased by a more pedestrian 2.2%.

That acquisition-driven gain played out several times across the industry in 2016. Equipment maker Thermo Fisher Scientific, dental company Dentsply Sirona, the hospital equipment company Hill-Rom and manufacturing specialist Integer Holdings (the newly renamed Greatbatch following that company's acquisition of Lake Region Medical) all achieved revenue growth in 2016 via acquisitions.

Stryker's US$1.4 billion (14%) revenue gain was also largely attributable to the diversified company's 2016 acquisitions of the private equity-backed Sage Products (US$2.9 billion) and Physio-Control International (US$1.3 billion). Underlying growth at Stryker did not disappoint either, as sales grew 6.4%, excluding the impacts of those and other deals.

As the Stryker results suggest, not all industry revenue growth was inorganic. Medtronic and Boston Scientific improved their top lines without the aid of acquisitions. Boston Scientific enjoyed solid double-digit growth across multiple businesses in 2016; in its largest business, cardiovascular, worldwide sales grew by 12%. The company's net income also rose significantly, from a net loss of US$239 million in 2015 to a net gain of US$347 million in 2016,

Total R&D spending by pure play medtech companies rose 5% in 2016 to US$16 billion, although it held steady as a percentage of total revenue. However, there were also some big spenders. Illumina increased its R&D spending 39% to US$504 million during 2016, as it continued to refine and improve its genomic sequencing products. Stryker and Zimmer Biomet likewise increased their R&D spending to nearly US$100 million, largely due to acquisitions.

Conglomerate turnaround

Medtech conglomerates, which have over the past few years divested businesses to streamline operations, returned to growth in 2016. Cumulative conglomerate revenue rose 3% to US$152.7 billion, accounting for 42% of the total medtech industry top line.

The biggest gainers among medtech conglomerates were, like their pure play counterparts, lifted by acquisitions. Merck KGaA's MilliporeSigma life sciences business boasted revenue of nearly US$6 billion in 2016, a 60% year-over-year increase driven by its 2015 acquisition of Sigma-Aldrich. Likewise, Danaher's revenue jumped 20% to US$13.1 billion following that company's acquisition of Pall Corporation in August 2015.

Other conglomerates reported solid organic growth. Revenue at the Siemens Healthineers division increased 6% to US$15.2 billion on higher volume across all businesses. And GE Healthcare revenue rose 4% to US$18.3 billion on higher volumes at its Life Sciences and Healthcare Systems businesses, even as it experienced some pricing and currency headwinds.

The year featured relatively few of the portfolio optimization deals that characterized 2015 and other recent years. However, in 2017, recently announced and proposed deals suggest this may be a trend worth watching in the coming months.

Imaging, therapeutic devices post strong gains

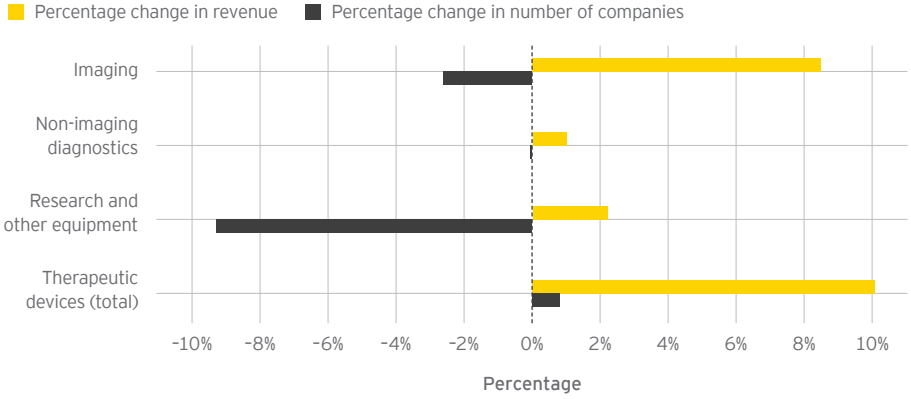
All four major medtech subsectors reported revenue growth from pure play companies in 2016 – as noted, largely driven by M&A.

Therapeutic device companies represent more than two-thirds of the global medical technology pure play market with US$145.7 billion in revenue, and enjoyed 13% revenue gains on the year. Zimmer Biomet's US$1.7 billion (28%) increase led all companies; it was followed by Stryker, up US$1.4 billion (14%), and Dentsply Sirona, up US$1.1 billion (40%).

Imaging enjoyed the second largest year-on-year increase. However, because this subsector contributed less than 2% to the total pure play medtech industry revenue, its performance had only a slight impact on the overall numbers. France's Guerbet added US$276 million (51%) to its top line, helping to lead the imaging subsector nearly 9% higher in 2016. Guerbet sells contrast agents and owed much of its 2016 revenue growth to its acquisition of Mallinckrodt's contrast media and delivery systems business, which closed in November 2015. Conglomerates GE Healthcare, Siemens Healthineers and Philips dominate the imaging market; total revenue from US and European pure play imaging companies reached US$3.6 billion in 2016.

Revenue at non-imaging diagnostics companies was less impressive, although it grew off a larger base. At just over 12% of the pure play market, non-imaging diagnostics revenue topped US$26 billion, up 1% in 2016. This growth came despite the loss of the commercial leader Cepheid, which was acquired by Danaher and had posted US$538 million in 2015 revenue. Among the top performers, the continuous glucose monitoring company DexCom boosted sales by 43% to US$573 million, en route to joining the ranks of medtech's commercial leaders. Exact Sciences' revenue jumped 152% to US$99 million on the strength of increased market access for its non-invasive, stool-based colorectal cancer screening test.

US and European revenue growth by medtech subsector



Data shown for pure play companies only.

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

Generating 17% of all medtech revenue, the research and equipment subsector is the medtech industry's second largest. Top-line growth for this medtech category was a modest 2%, helped by Thermo Fisher's performance. Revenues at that industry stalwart increased 8% in 2016, largely due to its acquisition of the electron microscopy company FEI.

M&A juices growth at orthopedics companies

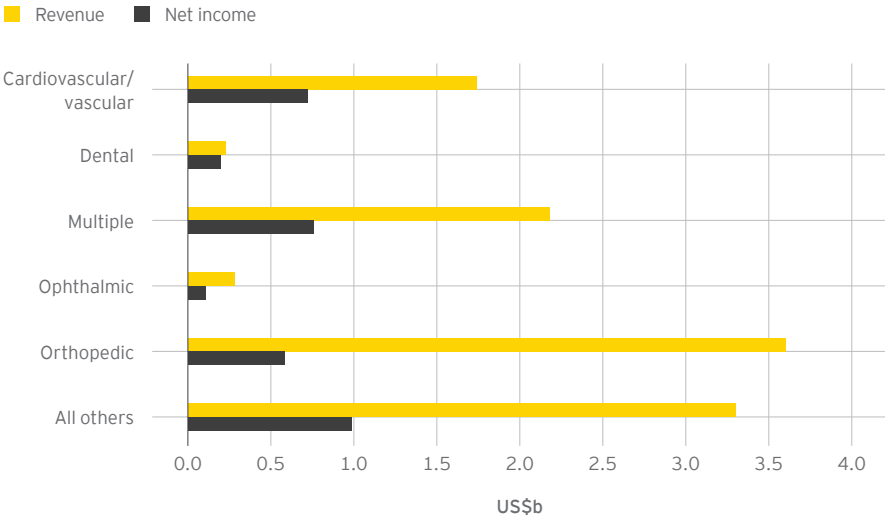
An analysis of the pure play therapeutics device subsector by therapeutic category shows that all 17 disease segments reported stable or positive revenue growth in 2016. (In the gastrointestinal area, the lone public company in our cohort, EndoChoice, was acquired by Boston Scientific, erasing US$72 million in revenue from GI.) Most disease areas saw gains in net income as well, with only four areas (oncology, autoimmune, aesthetics and ear/nose/throat) posting lower bottom lines than in 2015.

Orthopedics companies saw the largest aggregate revenue increase in 2016, as total revenue jumped 16% to US$27.5 billion. Again, that surge can be chalked up to acquisitions, as well as demographic shifts resulting in increased demand in the globally aging population. Overall net income was up in orthopedics as well, with an aggregate US$583 million gain (34%). Stryker, Zimmer Biomet and the UK's Smith & Nephew led the way.

Revenue gains in the cardiovascular space were generally organic, with Boston Scientific gaining US$909 million (12%) to US$8.4 billion and Edwards Lifesciences up US$470 million (19%) to US$3 billion. Edwards' top line benefited from the launch of its Sapien 3 transcatheter heart valve. Boston Scientific's US$586 million jump in net income lifted the cardiovascular area to an aggregate net gain on the year, but absent Boston's contribution, the therapy area's net income would have fallen more than US$41 million compared to 2015.

Companies with revenue spread across multiple therapeutic areas gained nearly US$2.2 billion in aggregate revenue, but that total represents annual growth of only 3%. Medtronic's US$29.7 billion in total revenue dominates the group, and its 3% (US$877 million) increase kept a lid on its overall growth. St. Jude Medical, which was acquired by Abbott in January 2017, jumped US$463 million (8%) to US$6 billion, while increased use of Intuitive Surgical's daVinci Surgical System helped its revenue surge 14% (US$337 million) to US$2.7 billion in 2016.

Changes in revenue and net income by disease category, 2015–16
(US and European pure play therapeutic device companies)



Data shown for pure play companies only.

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

Commercial leader ranks holding steady

Despite the tendency for medtech's rising stars to be acquired by established players, the ranks of the industry's pure play commercial leaders have remained stable for several years. In 2016, there were 61 commercial leaders (defined as companies generating at least US$500 million in annual revenue).

Three US companies disappeared from the list after being acquired. Cepheid was bought by Danaher in September 2016 for US$4 billion; FEI was acquired by Thermo Fisher in May 2016 for US$4.2 billion; and Sirona Dental was acquired by Dentsply Sirona in

September 2015 for US$5.5 billion. Four emerging commercial leaders have been added to the list: DexCom, Össur, Wright Medical and the newly public ConvaTec.

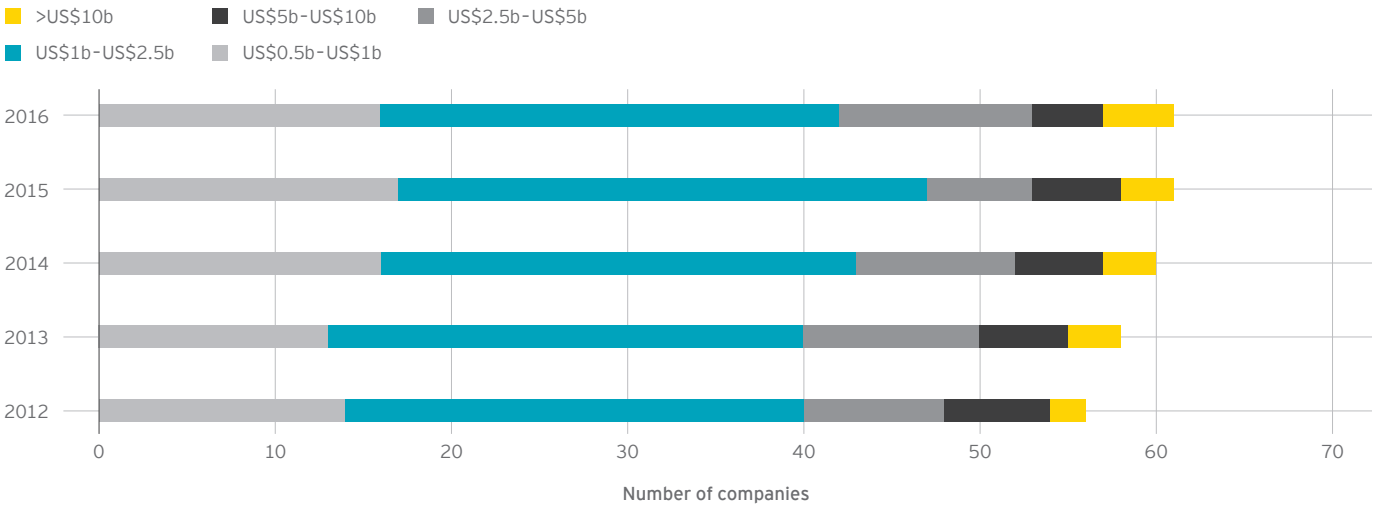
Diabetes management company DexCom was elevated to the ranks after posting US$573 million in 2016 revenue, a 43% jump over the prior year. The specialty orthopedics company Wright Medical boosted revenue 66% to US$690 million. And Össur, the Icelandic prosthetics maker that has hovered around the US$500 million revenue mark for years and bounced on and off the commercial leader list, rejoined the group with US$521 million in 2016 revenue.

ConvaTec, a wound care, incontinence and ostomy specialist sold to private equity backers for US$4.1 billion in 2008 by US drugmaker Bristol-Myers Squibb, joined the list after completing the largest health-related IPO in Europe in decades. ConvaTec went public on the London Stock Exchange in October 2016, grossing roughly US$2 billion and earning an initial valuation of approximately US$5 billion. The newly public company posted 2016 revenue of nearly US$1.7 billion.

In 2016, for the first time in four years, an additional pure play medtech exceeded the US$10 billion revenue threshold. Stryker joined Medtronic, Thermo Fisher and BD in the exclusive club, as its revenue climbed 14% to US$11.3 billion. Stryker's revenue milestone helps cement its position as a large, stable medtech — and likely acquirer of emerging orthopedics-focused companies in the future.

Despite the tendency for medtech's rising stars to be acquired by established players, the ranks of the industry's pure play commercial leaders have remained stable for several years.

US and European commercial leaders



Commercial leaders are pure play companies with revenues in excess of US$500 million.

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

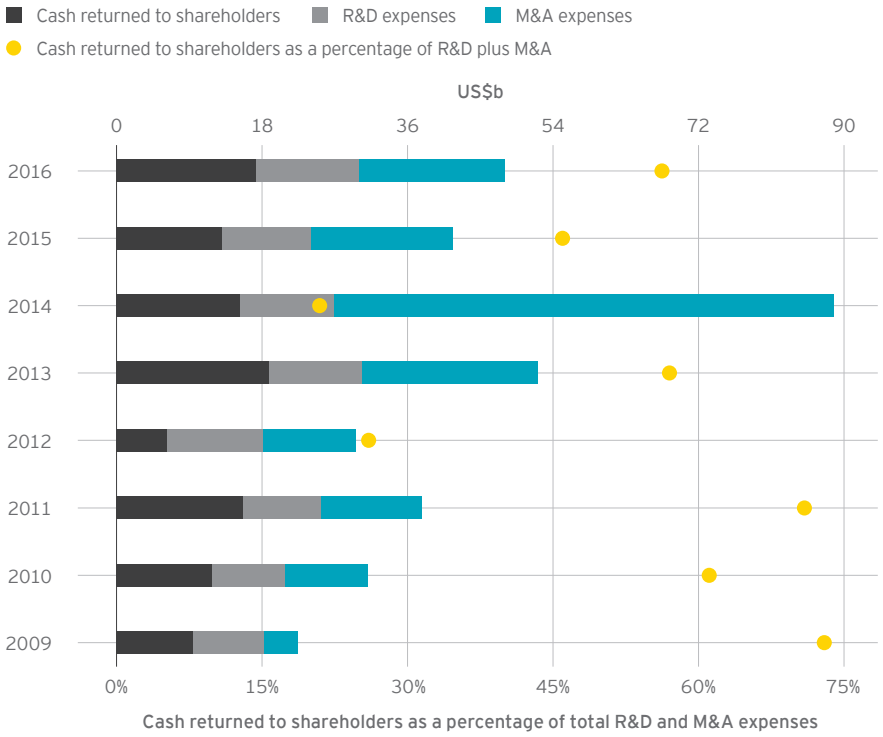
Capital allocation favoring near-term priorities

R&D spending by commercial leaders reached an all-time high of US$12.8 billion in 2016. Medtronic spent nearly US$2.2 billion on R&D, the only medtech to spend more than US$1 billion, but that total was only a little more than 7% of the company's revenue. Boston Scientific (US$920 million, or 11% of revenue) and BD (US$828 million, or 6.6% of revenue) rounded out the top three R&D spenders by dollar value.

Among commercial leaders, DexCom and Illumina stand out in terms of R&D spend as a percentage of revenue. The sequencing giant Illumina poured US$504 million into R&D (more than 21% of total revenue), and newly minted commercial leader DexCom, the glucose monitoring company, spent more than 27% of its revenue on R&D, or about US$156 million. Combined with US$18.1 billion spent on acquisitions during 2016, the drivers of industry growth reached US$30.9 billion, an 8% increase over 2015.

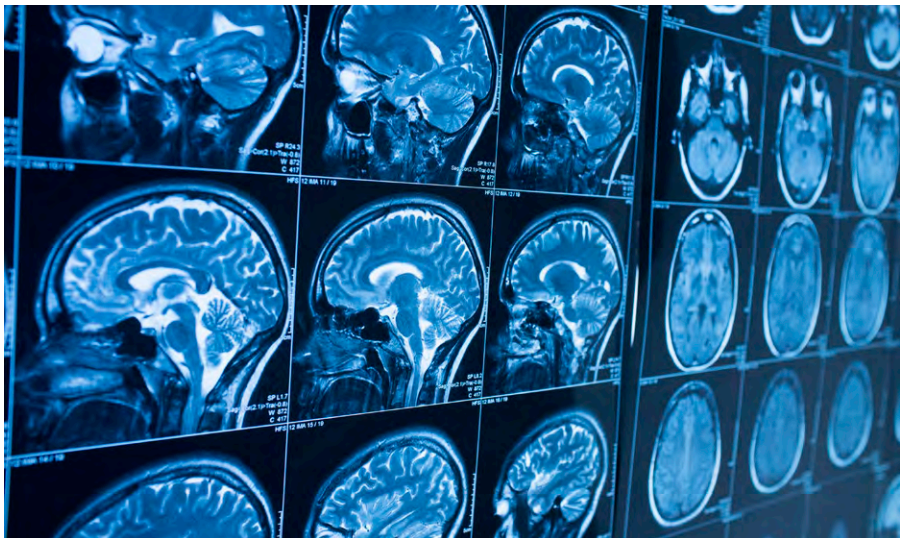
But during 2016, medtech commercial leaders also returned US$17.2 billion to shareholders via share buybacks and dividends, the most since 2013. For the second straight year, the industry's capital allocation priorities edged further away from long-term growth investment, despite the modest increase in R&D spend over the prior year. In all, medtech companies repurchased US$11.2 billion worth of their own shares, with 19 companies executing share buybacks worth at least US$100 million.

US and European medtech commercial leaders spending trend, 2009–16



Expenditures shown only for pure play medtechs.

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



Medtech outpacing broad indices

During 2016, the medtech industry largely kept pace with broader market indices, though its total market capitalization ended the year up only 3%. Since the beginning of 2017, however, the market capitalization for medtechs has surged as the industry's largest companies post strong financials and the M&A environment remains strong.

Unlike the biotech industry, medtech market capitalization didn't appear to be dampened by US election-year rhetoric about health care costs, in particular drug pricing. Medtech companies also did not receive the same boost following November's election, when investors felt the incoming Trump Administration would pursue pro-business policies, particularly corporate tax reforms that might bolster M&A activity. But medtech has nevertheless surged in 2017, with a 26% gain so far on the year.

Since the beginning of 2017, however, the market capitalization for medtechs has surged as the industry's largest companies post strong financials and the M&A environment remains strong.

US and European medtech market capitalization relative to leading indices

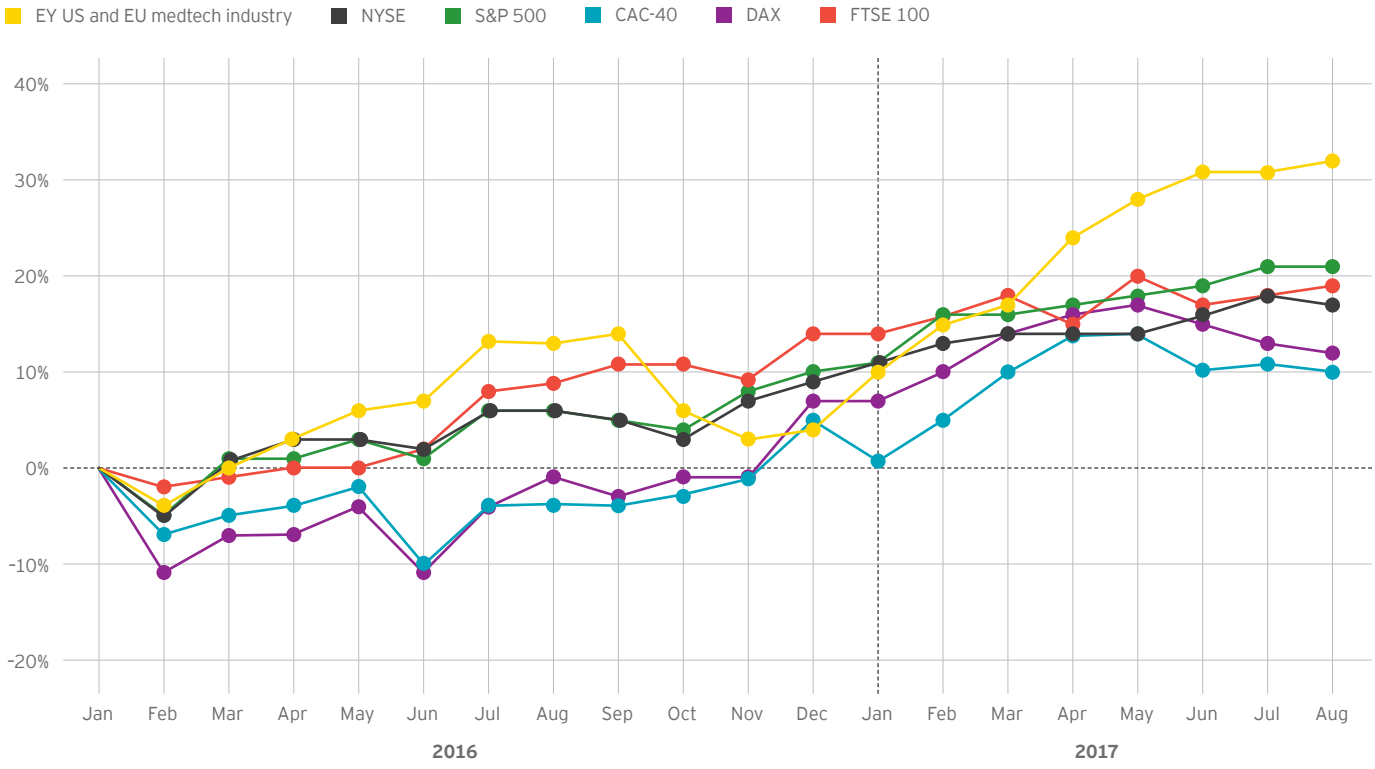


Chart includes companies that were active on 31 August 2017.

Source: EY and Capital IQ.

Financial performance: United States

US commercial leaders thriving

In the US, medtech pure play commercial leaders posted a solid performance in 2016, as revenue increased 9% for the group, driving overall revenue growth for US medtechs up 7%. Net income and market capitalization for the commercial leader cohort also jumped 9%. That same group poured 10% more into R&D in 2016 than the prior year.

Certainly, the addition of glucose monitoring company DexCom and specialty orthopedics company Wright Medical bolstered the commercial leaders' financial metrics and dampened the performance of non-commercial leaders. Together those two newcomers accounted for nearly US$1.3 billion in 2016 revenue. These two companies also bolstered 2016 commercial leader R&D spending by nearly 3%.

Overall, roughly three-quarters of US medtechs generated more revenue in 2016 than in 2015. Among the standouts, spine specialist Nevro boosted revenue 228% to US$229 million on the strength of sales for its Senza spinal cord stimulation system, a neuromodulation platform for treating chronic pain that launched in mid-2015. Another standout was the

Revenue gains
Financial metrics for US medtech commercial leaders improved significantly, as revenue and net income rose 9%, and R&D spend jumped 10%.

New commercial leaders
The improved financial metrics were largely due to the addition of new companies to the ranks of commercial leaders.

IPO weakness
Non-commercial leaders' metrics suffered as M&A removed more than US$1 billion in revenue, and a weak IPO class failed to create investor momentum.

US medtech at a glance, 2015–16
(US$b, data for pure plays except where indicated)

Commercial leaders (pure plays)	2016	2015	Change	% change
Revenues	$126.6	$116.3	$10.3	9%
R&D expense	$8.7	$7.9	$0.8	10%
SG&A expense	$39.1	$35.3	$3.8	11%
Net income	$12.6	$11.5	$1.1	9%
Market capitalization	$452.4	$413.2	$39.2	9%
Number of employees	447,000	421,400	25,600	6%
Number of public companies	42	43	-1	-2%
Non-commercial leaders (pure plays)				
Revenues	$13.3	$13.4	-$0.1	-1%
R&D expense	$2.5	$2.7	-$0.2	-9%
SG&A expense	$7.4	$7.6	-$0.1	-2%
Net income	-$3.1	-$3.4	$0.3	-8%
Market capitalization	$59.8	$65.7	-$5.9	-9%
Number of employees	50,900	53,600	-2,700	-5%
Number of public companies	200	210	-10	-5%
Conglomerates				
Revenues	$85.2	$81.6	$3.7	5%

Numbers may appear to be inconsistent due to rounding. Market capitalization data is shown for 31 December 2016 and 31 December 2015.

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

cardiovascular-focused Abiomed, which is poised to join the ranks of commercial leaders following the success of its Impella family of heart pumps.

Abiomed was also among the leaders in increasing R&D spend – the company poured US$66 million into R&D, a 36% increase. Foundation Medicine, the oncology genomic profiling company in which Roche owns a majority share, increased its R&D investment 54% to US$67 million, leading the pack. Overall, only 57% of US medtechs increased R&D spending during 2016.

Net income metrics were similarly divided, with only 48% of US medtechs improving their bottom lines in 2016. Fewer, only 39%, increased market capitalizations during the year. Abiomed, which ended 2016 with a market value of US$4.7 billion (up 24%), and infusion device specialist ICU Medical (up 34% to US$2.4 billion on the year) outperformed their peers.

Cash-burning medtechs increasingly cash-poor

Of the US medtechs that were not profitable in 2016, 77% ended the year with less than two years of cash reserves, a significant uptick from 2015, and an extraordinary 13% more than at the end of 2014. This suggests that there are fewer "haves" among the group of medtechs that are in the capital-intensive portions of their corporate life cycles, when reaching profitability requires sufficient access to R&D financing.

As noted in the Financing discussion on page 52, medtech financing totals were strong across the board in the 12 months that ended 30 June 2017. However, it appears that these funds are being concentrated among fewer companies.

US public medtech cash index

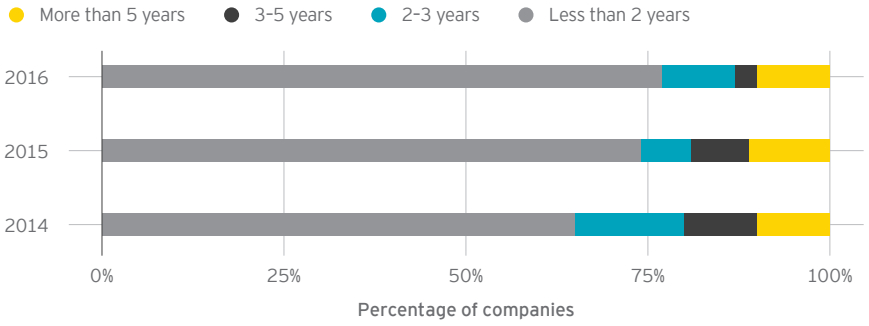


Chart excludes companies that are cash flow positive. Numbers may appear inconsistent due to rounding.

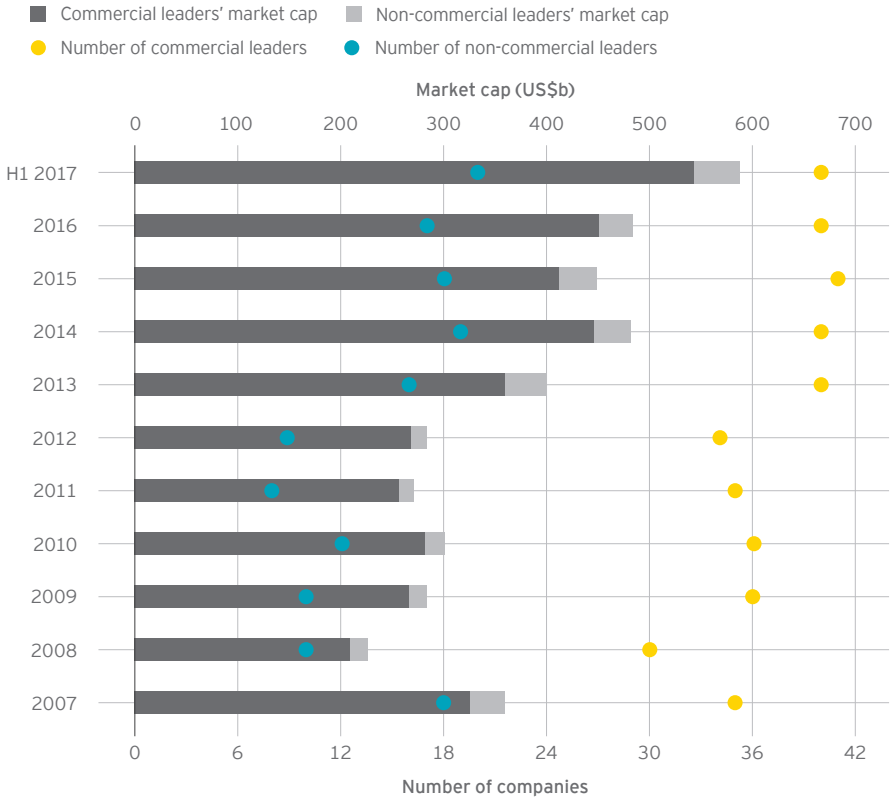
Source: EY, Capital IQ and company financial statement data.

Medtech valuations climbing

The number of US medtechs with at least US$1 billion in market value decreased slightly in 2016 but has since rebounded. As of mid-year 2017, there are 60 medtechs worth more than US$1 billion, up from 57 at the end of 2016 and 59 at the end of 2015. Despite the earlier decline in their ranks, the cumulative market capitalization for these 60 companies rose 8% from 2015 to 2016.

More impressively, since the outset of 2017, market values have jumped nearly 22% for this cohort, reaching US$589 billion as of 30 June 2017. This valuation boost reflects investors' expectation of further M&A, as well as a spate of solid early-year earnings reports across the industry.

US public medtech companies with market cap greater than US$1b: pure plays



Commercial leaders are companies with revenues in excess of US$500 million. Market cap as of 30 June 2017.

Source: EY and Capital IQ.

But strong five-year valuation growth

Medtech leaders have enjoyed stunning valuation growth over the past five years. Nine of the largest gainers in dollar terms have at least doubled their market value from 1 January 2012 to 30 June 2017. The top 10 US medtechs by market value have added an extraordinary US$223 billion in shareholder value since 2012, a compound annual growth rate (CAGR) of 22%.

As noted previously, much of this valuation expansion has been fueled by M&A. Thermo Fisher alone has completed four deals worth at least US$1 billion, topped by its 2013 acquisition of Life Technologies for US$13.6 billion. BD has done two megadeals, acquiring CareFusion for US$12.2 billion in 2014 and announcing its purchase of C.R. Bard for US$24 billion in 2017.

Illumina's 38% CAGR is the most impressive of the bunch; the genome sequencing company's rapid growth has been driven by its ability to provide increasingly affordable technologies to accelerate precision medicine. Boston Scientific's 36% CAGR has been largely driven by organic growth in businesses including neuromodulation and interventional cardiology, with only an occasional bolt-on acquisition (such as the US$415 million deal to acquire Bayer's interventional cardiology unit in 2014).

The top 10 US medtechs by market value have added an extraordinary US$223 billion in shareholder value since 2012, a compound annual growth rate of 29%.

Top 10 changes in the US market capitalizations, H2 2012–H1 2017 (US$b)

Company	Market cap 30 June 2017	Market cap 1 July 2012	Market cap change	CAGR
Thermo Fisher Scientific	68.3	19.1	**49.2**	29%
Stryker	51.9	21.0	**30.9**	20%
Boston Scientific	38.0	8.1	**29.9**	36%
Becton Dickinson	44.4	15.2	**29.2**	24%
Illumina	25.3	5.0	**20.3**	38%
Zimmer Biomet	25.9	11.3	**14.6**	18%
C.R. Bard	23.0	9.1	**13.9**	20%
Edwards Lifesciences	24.8	11.8	**13.0**	16%
Intuitive Surgical	34.5	22.0	**12.5**	9%
Dentsply Sirona	14.9	5.4	**9.5**	23%

CAGR = compound annual growth rate

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

Financial performance: Europe

Mixed year for European medtech

Aggregate revenue for European medtech companies grew only 3% overall in 2016, with pure play medtechs (up 4%) once again outpacing conglomerates (up 2%), and commercial leaders growing more quickly than their smaller counterparts.

The addition of ConvaTec to Europe's commercial leaders following its record-setting IPO helped to boost the cohort's aggregate revenue. Further bolstering the commercial leaders' metrics was the addition of Icelandic prosthetics maker Össur to the group's ranks. Össur's revenue rose to nearly US$521 million in 2016, far more than the combined US$2.1 million in revenue that the eight other newly public European medtechs contributed to the non-commercial leaders' total.

During 2016, 60% of all European medtechs increased revenue. Novocure, the UK-based glioblastoma device marketer, grew its top line 151% to US$83 million as sales for its Optune System ramped up. The Swiss laboratory automation company Tecan appears poised to join the commercial leaders cohort in 2017, as its 2016 revenue rose 9% to US$498 million.

Revenue growth
Aggregate revenue for European medtech companies grew more slowly than that of their US counterparts.

Cash runway
Nearly 70% of Europe's loss-making medtechs have less than two years' worth of cash.

New balance
The addition of Medtronic to the continent's tallies helped to create some balance with US metrics.

European medtech at a glance, 2015–16
(US$b, data for pure plays except where indicated)

Commercial leaders (pure plays)	2016	2015	Change	% change
Revenues	$66.8	$64.4	$2.4	4%
R&D expense	$4.0	$4.0	$0.0	0%
SG&A expense	$21.5	$21.4	$0.1	-1%
Net income	$7.6	$6.3	$1.3	20%
Market capitalization	$210.2	$223.6	-$13.4	-6%
Number of employees	285,600	284,500	1,100	0%
Number of public companies	19	18	1	6%
Non-commercial leaders (pure plays)				
Revenues	$5.1	$5.5	-$0.4	-6%
R&D expense	$0.8	$0.7	$0.1	22%
SG&A expense	$2.1	$2.2	-$0.1	-6%
Net income	-$0.9	-$0.7	-$0.2	24%
Market capitalization	$27.3	$24.1	$3.2	13.3%
Number of employees	23,700	23,100	600	3%
Number of public companies	170	171	-1	-1%
Conglomerates				
Revenues	$67.5	$66.0	$1.5	2%

Numbers may appear to be inconsistent due to rounding. Market capitalization data is shown for 31 December 2016 and 31 December 2015.

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

Tecan's US$54 million net income was also a bright spot – only 48% of European medtechs increased net income over 2015.

Likewise, fewer than half were able to grow their market capitalization during 2016. Among the European medtechs gaining favor with investors, Swiss insulin pump marketer Ypsomed grew its market cap 26% to US$2.3 billion by the end of 2016. Ambu, a Danish maker of anesthesia, patient monitoring and emergency care devices, saw its value rise 30% to US$1.9 billion by the end of 2016.

Fewer cash-burning European medtechs have long cash runways

Loss-making European medtechs weren't exactly flush with cash in 2016, but the percentage of companies with less than two years' worth of cash on hand was only 66%. (In the US, that figure was 77%.)

As with their US counterparts, European medtechs enjoyed a successful financing year during the 12 months that ended 30 June 2017. In fact, total funding of European medtech soared to an all-time high of US$9.7 billion, and IPO, follow-on and debt financing hit decade-long highs.

But, as in the US, that capital is hardly evenly distributed. ConvaTec's IPO and a subsequent US$1.3 billion follow-on account for nearly one-third of Europe's total; a US$2 billion debt offering from Medtronic accounted for nearly half the total financing in that category.

In short, the well-capitalized continue to find financing, while fewer of Europe's loss-making medtechs, often a significant driver of future growth, have more than two years' worth of capital.

European public medtech cash index

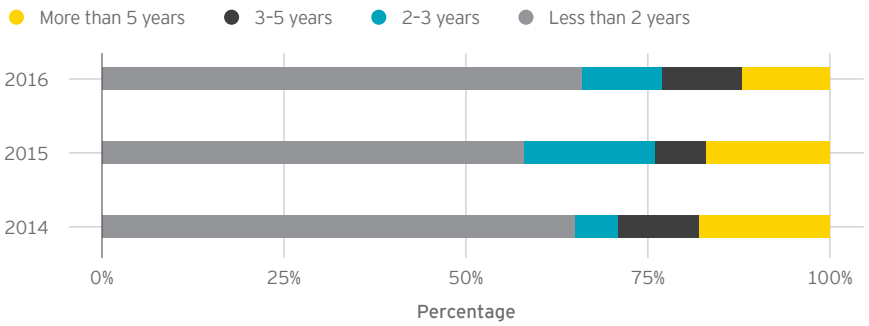
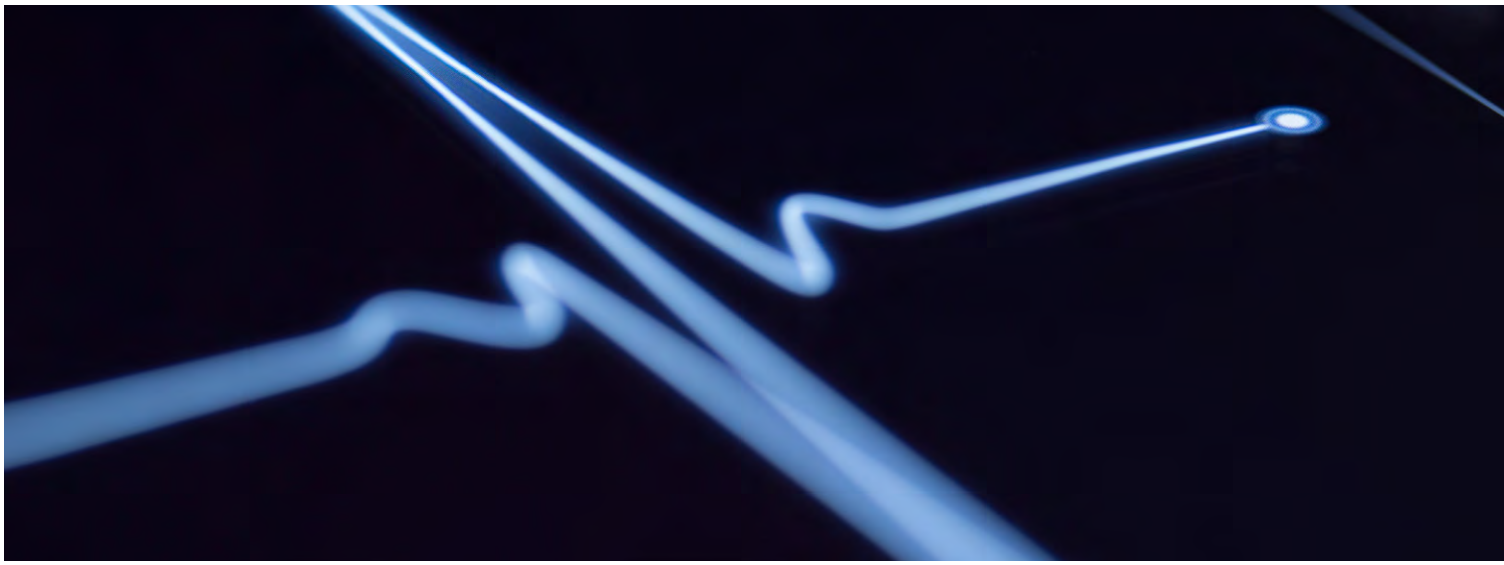


Chart excludes companies that are cash flow positive. Numbers may appear inconsistent due to rounding.

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

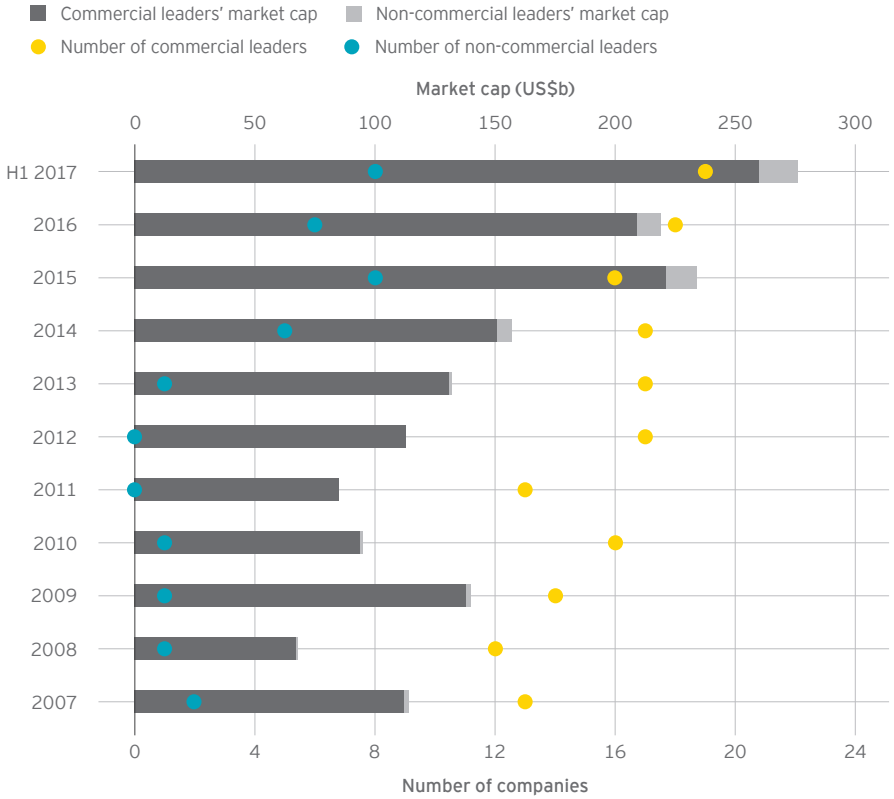


Market value holding steady

Among European medtech companies with market values greater than US$1 billion, the aggregate market value declined slightly in 2016, dropping about 5% to US$222 billion, still well above the decade-long average of roughly US$136 billion. Mirroring the US results, that total market capitalization has jumped more than 25% to US$276 billion as of mid-year 2017. This marked increase is due in part to three companies recently joining the valuation cohort. As of 30 June 2017 there were 27 European medtechs with at least US$1 billion market capitalization, up from 24 in 2015 and 2016.

Most impressively, the brain cancer device company NovoCure more than doubled in value during the first half of 2017, rejoining the US$1 billion cohort thanks to stronger adoption of its Optune device for glioblastoma. As with US medtechs, investors see brighter growth prospects for European medtech in 2017 – as well as additional M&A on the horizon.

European public medtech companies with market cap greater than US$1b: pure plays



Commercial leaders are companies with revenues in excess of US$500 million.
End-of-year market cap for 2007-16; June 30th end for 2017.

Source: EY and Capital IQ.

As with US medtechs, investors see brighter growth prospects for European medtech in 2017 – as well as additional M&A on the horizon.

During 2016, 60% of all European medtechs increased their revenue. Fewer than half, however, grew their market capitalization in the same time period.

Solid five-year returns for market leaders

Like their US counterparts, Europe's leading medtechs have enjoyed significant growth in market value since 2012 – and Medtronic's addition to the continent's leaderboard following its acquisition of Covidien and subsequent relocation of its corporate headquarters to Ireland brings Europe a medtech crown jewel. Indeed, Medtronic added nearly US$81 billion in market capitalization over the past five years – much more than the rest of the top 10 European medtechs combined.

Most of the companies on Europe's medtech leaderboard have grown organically over the past five years, unlike their US counterparts. Danish diagnostic company Ambu's value has risen dramatically over the five-year period to more than US$3 billion by mid-2017 and a CAGR of 61%. Sartorius, a German laboratory equipment maker, has gained US$5.4 billion in market cap during the five-year period, resulting in a CAGR of 44%.

Most of the companies on Europe's medtech leaderboard have grown organically over the past five years, unlike their US counterparts.

Top 10 changes in the EU market capitalizations, H2 2012–H1 2017 (US$b)

Company	Market cap 30 June 2017	Market cap 1 July 2012	Market cap change	CAGR
Medtronic	120.6	39.7	**80.9**	25%
Coloplast	17.8	7.6	**10.2**	19%
Essilor International	27.2	19.4	**7.8**	7%
Straumann Holding	8.7	2.3	**6.5**	31%
Smith & Nephew	15.0	9.0	**6.1**	11%
Sartorius	6.5	1.1	**5.4**	44%
Biomerieux	8.5	3.2	**5.3**	21%
Sonova Holding	10.6	6.4	**4.2**	11%
QIAGEN	7.6	3.9	**3.7**	14%
Ambu	3.1	0.3	**2.8**	61%

CAGR = compound annual growth rate

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

Questions for medtech companies to consider

In an era of M&A-driven growth, should you focus – or diversify?

How can you combine your inorganic and organic capital strategies to ignite revenue growth?

Is cybersecurity a top priority to safeguard your bottom line?

What's the right investment prescription for sustainable growth?

Financing

Medtech financing clears new heights

A record year
Medtech financing enjoyed a banner year in the 12 months that ended 30 June 2017, with capital raised across all categories besting the 2015-16 totals—in some cases by multiples.

Robust financing
Venture financing, especially capital for early stage deals, remained buoyant, rising for the fourth consecutive year and beating the record total set in 2016-17.

Unequal benefits
Though the year's record financing totals are cause for celebration, they didn't benefit all medtechs equally, with a small handful of companies responsible for the bulk of public capital raised.

Medtechs set several records in 2016–17, but a new high in total financing wasn't one of them. Still, medtech financing in the US and Europe increased 101% compared to the prior year, to US$43.9 billion. This is the second-highest total in the past decade and significantly higher than the prior nine-year average of US$25.6 billion. With the exception of debt financing, capital raised via venture, IPO and follow-on financings reached all-time highs.

In venture capital (VC) financing, the year's US$7.7 billion total was a 23% year-on-year increase, featuring a healthy mix of traditional VCs and strategic investors. What's more, the year featured the three largest medtech VC deals completed since Pulse began tracking the industry more than a decade ago: a US$973 million Series B from Grail and a US$360 million later-stage round from Guardant Health, two diagnostics companies developing so-called liquid biopsy technologies, and a US$800 million round from Verily, the life sciences and health care-focused subsidiary of Alphabet (formerly known as Google).

These rounds illustrate another key trend: the financing success of medtechs that are developing tools for the biopharma industry, which is eager for novel technologies that either improve drug development or deliver differentiated therapies.

The record £1.5 billion (US$2 billion) IPO from ConvaTec, a Bristol-Myers Squibb spin-off focused on wound care, incontinence and ostomy products, accounted for the largest portion of all IPO proceeds in 2016–17. As a result of this financing, total IPO funding soared 331% compared to 2015–16, to a record US$2.6 billion.

ConvaTec also raised US$1.3 billion in a follow-on round, joining Becton Dickinson (BD), which raised US$4.5 billion in the largest follow-on ever tracked by Pulse to dominate that category as well. Cumulative follow-on funding was up 227% to US$8.8 billion, another record haul.

Debt financing was likewise boosted by BD, which raised US$10.7 billion to help pay for its planned acquisition of C.R. Bard. Five other medtechs raised debt financings of at least US$1 billion, helping the category double its prior-year total to nearly US$25 billion.

Notably, investment in Asia-Pacific-based medtechs fell for the second consecutive year, down 16% to US$1.5 billion. But the region boasted a handful of strong venture rounds and IPOs that rivaled those in the West, and Asia-Pacific investors were active backers of US and EU medtechs as well.

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

Period	Venture	IPO	Follow-on and other	Debt	Total
July 2016 to June 2017	$7.7	$2.6	$8.8	$24.9	**$43.9**
July 2015 to June 2016	$6.3	$0.6	$2.7	$12.4	**$21.9**
July 2014 to June 2015	$5.2	$2.3	$2.4	$42.0	**$51.9**
July 2013 to June 2014	$4.9	$1.5	$2.0	$22.3	**$30.7**
July 2012 to June 2013	$4.4	$0.2	$4.2	$25.0	**$33.8**
July 2011 to June 2012	$4.7	$0.4	$1.1	$20.1	**$26.3**
July 2010 to June 2011	$4.2	$0.8	$2.4	$11.8	**$19.1**
July 2009 to June 2010	$5.0	$0.4	$2.4	$13.3	**$21.1**
July 2008 to June 2009	$4.7	$0.02	$1.8	$6.4	**$12.9**
July 2007 to June 2008	$5.3	$1.3	$2.1	$4.5	**$13.2**

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

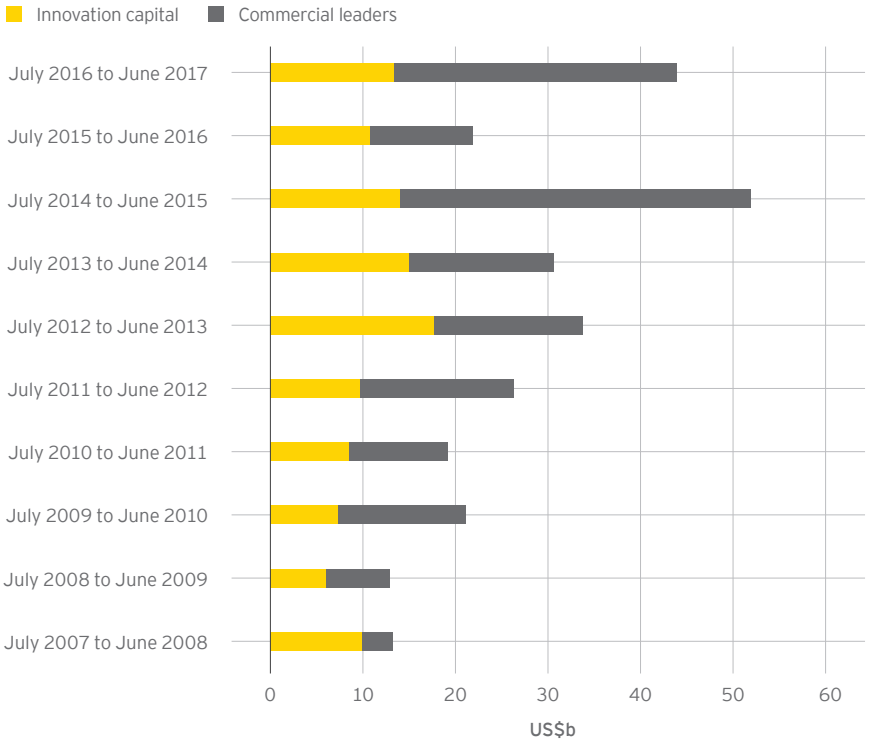
Source: EY, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

Minor uptick in innovation capital

To understand the financial health of smaller, primarily earlier stage companies, EY tracks innovation capital, defined as the capital raised by so-called non-commercial leaders, which have less than US$500 million in revenue. In 2016–17, while the total amount of innovation capital increased, it remained below the prior four-year average. This was in large part due to ConvaTec vaulting immediately to commercial-leader status, taking its significant IPO and follow-on capital along with it. In all, non-commercial leaders raised US$13.4 billion on the year, up 24% over 2015–16.

The increase in capital raised by commercial leaders, which was led by stalwarts (BD, Thermo Fisher Scientific and Medtronic) and newcomers (ConvaTec) alike, meant that innovation capital's share of total financing fell from 50% to 30% on the year. The total capital raised by commercial leaders in 2016–17 trails only 2014–15, which featured massive amounts of debt raised to fund acquisitions, in particular Medtronic's acquisition of Covidien.

Innovation capital raised in the US and Europe by year



Innovation capital is the amount of capital raised by companies with revenues of less than US$500 million.

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

For the first time in a decade, early stage companies captured 52% of all venture dollars, surpassing the total for later-stage rounds.

Early stage VC rounds surge

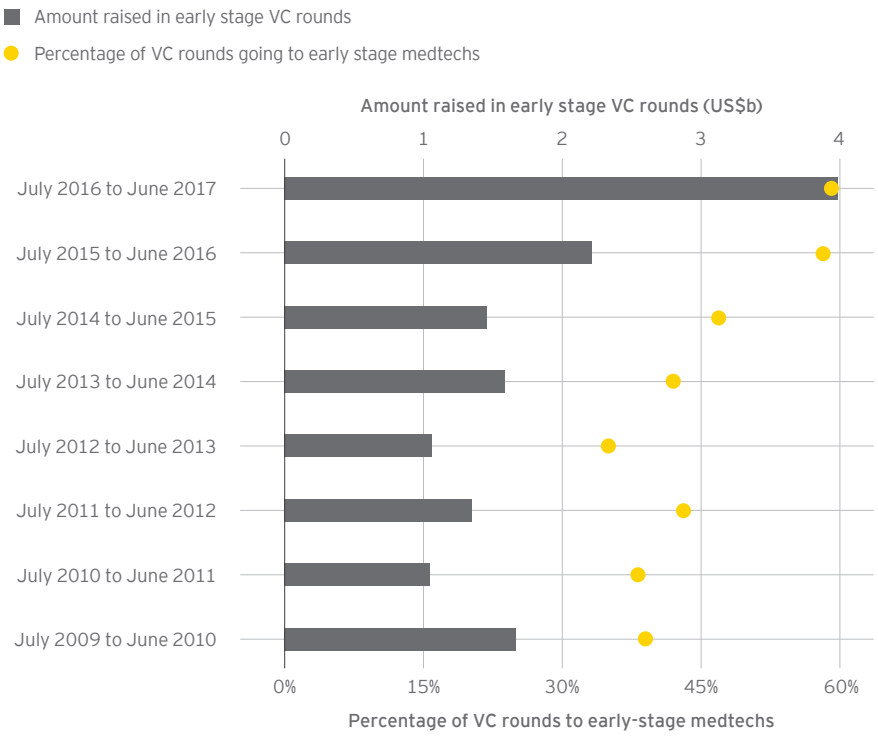
A not-inconsequential share of the innovation capital raised in 2016–17 went to early stage medtech venture capital financing rounds, defined as seed, first- and second-round investments. In all, nearly US$4 billion was raised in 407 early stage venture deals, beating the prior 12 months' then-record US$2.2 billion total. This included 126 venture rounds worth at least US$5 million. Though the number of early stage deals just failed to reach the high enjoyed during 2015–16 (416 deals), a small handful of enormous rounds dragged the average raised to US$9.8 million, an all-time high that is nearly double last year's US$5.3 million.

The percentage of total venture capital devoted to early stage rounds similarly set a new standard. For the first time in a decade, early stage companies captured 52% of all venture dollars, surpassing the total for later-stage rounds.

The liquid biopsy company Grail's US$973 million Series B was the largest venture round of the year, followed by Verily Life Sciences' US$800 million financing. In addition to the investment from Singapore state capital firm Temasek, Verily inked deals with pharma giants GlaxoSmithKline and Sanofi to establish a pair of joint ventures.

With Sanofi, Verily created Onduo in September 2016 to create a comprehensive diabetes management platform that combines devices, software, medicine and services for Type 2 diabetes patients. With GSK, Verily in August 2016 created Galvani Bioelectronics, a joint venture focused on bioelectronic medicines that are a distinct, but complementary, therapeutic modality to both pharmaceuticals and medical devices.

US and European early stage VC investment



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

Source: EY, Dow Jones VentureSource and Capital IQ.

Led by Grail, non-imaging diagnostics companies boasted the majority (more than 41%) of early stage venture funding, up from 35% the prior year. Therapeutic device companies attracted 29% of all early stage funding, down from 39% during 2015–16. Within that group, orthopedics and cardiovascular devices, which are perennial therapeutic area leaders, received the most attention from investors in early stage deals.

Non-imaging diagnostics companies raised a plurality of all venture financing during 2016–17, with 36% of combined early and later-stage financing.

Guardant Health's US$360 million late-stage round to support its liquid biopsy technology joined the historically large round from Grail to help non-imaging diagnostics approach the funding levels earned by therapeutic devices (44% of the total). Within the therapeutic device category, cardiovascular companies captured nearly 25% of the total financing, edging out all other therapeutic categories. Boosted by Verily, the "other" category accounted for 23% of total early stage VC investment, up from 14% the prior year.

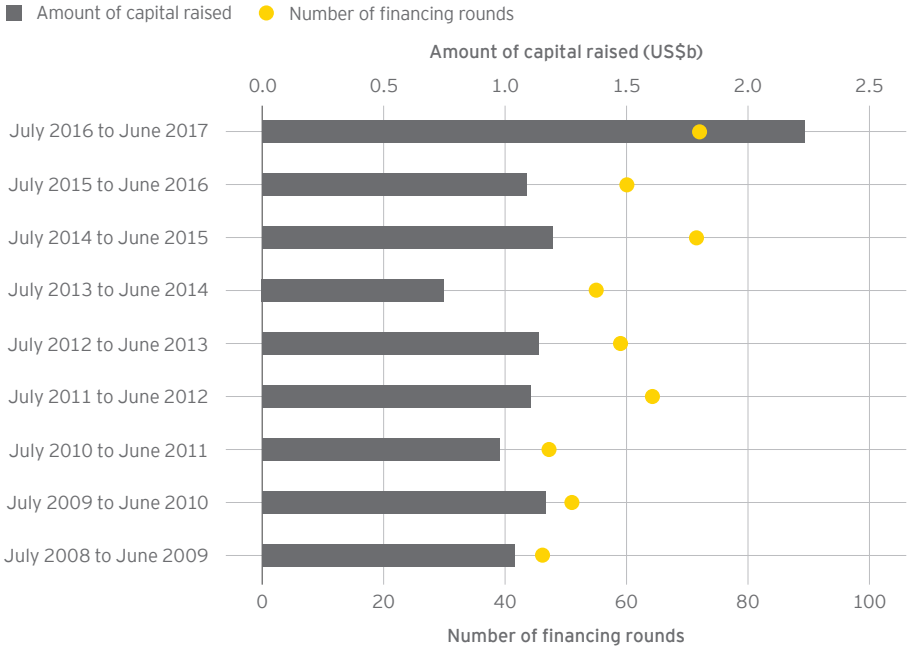
Getting strategic

As has been true in prior years, in 2016–17 strategic investors from medtech, high tech and pharma bolstered the early stage medtech ecosystem and some of its high-risk/high-reward endeavors. During 2016–17, corporate venture capitalists participated in at least 72 financing rounds for medtech companies, up from 60 the prior year. Total funding in those rounds soared 105% to US$2.2 billion, and that figure excludes the investments Sanofi and GSK made in Onduo and Galvani.

A large chunk of that record amount can be chalked up to Grail's US$973 million Series B, which included backing from a number of strategic investors in the health care, biopharma, medtech and retail sectors. But even without that record venture round, the 2016–17 total involving corporate venture would still have easily been an all-time record, well above the prior decade average of US$1.1 billion.

In addition to the Grail round, another 18 venture financings featured multiple strategic backers. Johnson & Johnson was the most active corporate VC during 2016–17, backing at least five medtechs developing technologies in therapies as diverse as orthopedics, urology and wound care. Among the diversified conglomerate's investments were the financings of molecular diagnostic company Atlas Genetics, ophthalmic device maker ReVision Optics and incontinence device company Torax Medical.

Corporate venture capital investment in US medtech companies, July 2008–June 2017



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

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IPOs: less than meets the eye

ConvaTec's IPO comprised 79% of all capital raised in medtech IPOs during the 2016–17 period. As such, it puts a misleading shine on the year's metrics for the category. In all, US and European medtechs raised US$2.6 billion in IPO capital across 21 deals. That total is 11% greater than the previous high reached in 2014–15 and the highest since EY has been publishing *Pulse*.

But removing that private equity-backed outlier reveals that US and European medtechs raised only US$547 million in IPO capital during 2016–17, an 8% drop over the prior year's anemic total and below the prior decade average of US$830 million. In short, medtech IPO financing in 2016–17 was much more like the pre-boom years of 2009–12 than the heyday of 2013–15.

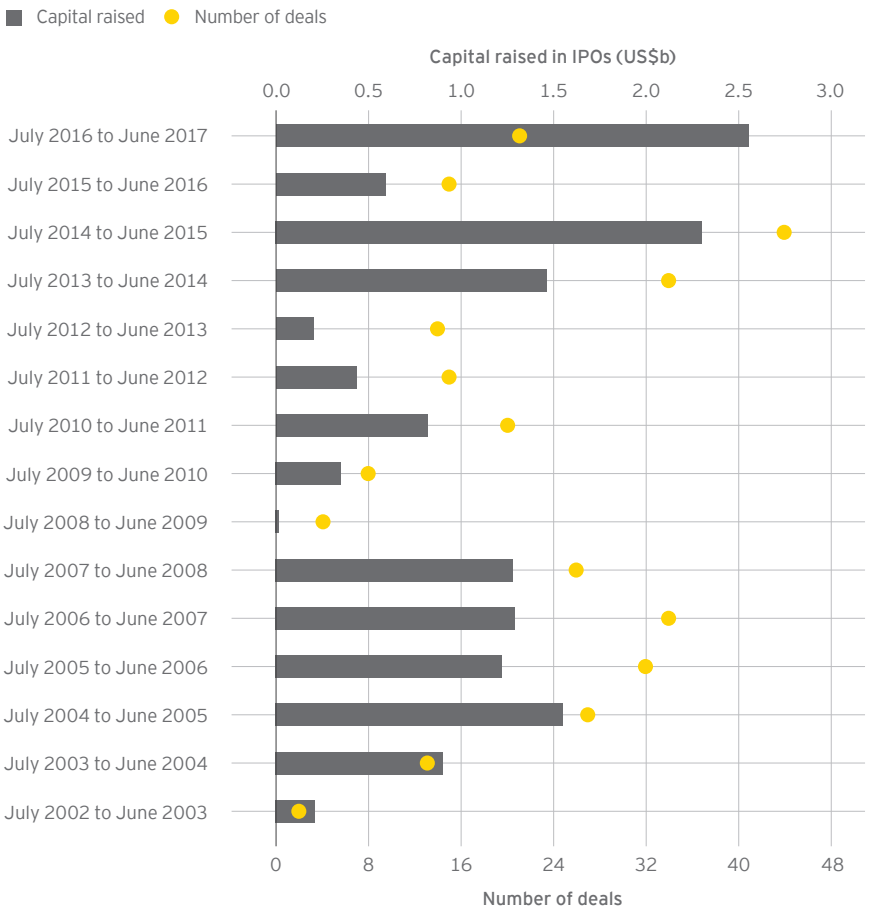
Twenty-one US and European medtech companies went public in 2016–17: 13 therapeutic device companies, 5 non-imaging diagnostics companies, 2 imaging companies, and 1 research and other equipment company.

Twelve of the offerings took place in Europe. In fact, there were more IPOs in Sweden during 2016–17 (10) than in the US (9), though many of the Swedish deals were tiny compared to the average. The remaining two European IPOs were for UK medtechs ConvaTec and Creo Medical Group, the latter of which raised US$27 million to fund development of its minimally invasive surgical tools.

The majority of medtech IPOs priced within their expected ranges, with just iRhythm Technologies pricing above the range. iRhythm, the San Francisco-based wearable heart monitor company, raised US$123.1 million in its October 2016 debut, pricing more than 7.2 million shares at US$17 apiece, US$2 more than the upper bound of its anticipated range. Between 2007 and 2014, the company raised nearly US$100 million in venture capital to fund development of its Zio wearable sensor, which monitors arrhythmias in cardiac patients.

Rounding out the top three deals by dollar value, San Diego-based Obalon Therapeutics raised US$75 million in its October 2016 IPO to boost the commercialization of its 3-Balloon System, a weight-loss device.

US and European medical technology IPOs, July 2002–June 2017



Source: EY, Capital IQ, BioCentury and VentureSource.

Top medtech IPOs, July 2016–June 2017

Company	Ticker	Product type (disease)	Gross raised (US$m)	Change in closing price on 30 June 2017 vs. IPO price
ConvaTec Group UK	CTEC	Therapeutic devices (infection)	**2,010**	36%
iRhythm Technologies US – Northern California	IRTC	Non-imaging diagnostics	**123**	150%
Obalon Therapeutics US – Southern California	OBLN	Therapeutic devices (gastrointestinal)	**75**	-34%
Bonesupport Sweden	BONEX	Therapeutic devices (orthopedic)	**58**	-1%
Valeritas US – New Jersey	VLRX	Therapeutic devices (hematology/renal)	**53**	-32%
Fulgent Genetics US – Southern California	FLGT	Non-imaging diagnostics	**43**	-29%
Tactile Systems Technology US – Minnesota	TCMD	Therapeutic devices (dermatology)	**41**	186%
InDex Pharmaceuticals Holdings Sweden	INDEX	Non-imaging diagnostics	**29**	-43%
Creo Medical Group UK	CREO	Therapeutic devices (multiple diseases)	**27**	9%
Visioneering Technologies US – Georgia	VTI	Therapeutic devices (ophthalmic)	**25**	4%
Acarix Sweden	ACARIX	Non-imaging diagnostics	**16**	14%
Sedana Medical Sweden	SEDANA	Therapeutic devices (multiple diseases)	**12**	9%
Endra Life Sciences US – Michigan	NDRAU	Imaging	**10**	-22%
Imagion Biosystems US – New Mexico	IBX	Imaging	**9**	1%
BioServo Technologies Sweden	BIOS	Therapeutic devices (orthopedic)	**8**	-26%
Myomo US – Massachusetts	MYO	Therapeutic devices (neurology)	**5**	45%
Paxman AB Sweden	PAX	Therapeutic devices (aesthetics)	**4**	12%
hemCheck Sweden Sweden	HEMC	Non-imaging diagnostics	**4**	-20%
Integrum Sweden	INTEG B	Therapeutic devices (orthopedic)	**3**	9%
Scandinavian ChemoTech Sweden	CMOTEC B	Therapeutic devices (oncology)	**2**	1%
AcouSort Sweden	ACOU	Research and other equipment	**1**	46%

Source: EY, Capital IQ, BioCentury and VentureSource.

Financing: United States

US medtechs bounce back

US medtechs improved on all financing metrics in 2016–17, raising a total of US$34.2 billion, up 88% from the prior year's total but still below the record 2014–15 period. The US contributed only 78% of the combined US and European total financing of US$43.9 billion, down from 83% and 94% in 2015–16 and 2014–15, respectively.

Venture financing for US medtechs rose 31%, led by liquid biopsy companies Grail (US$973 million) and Guardant Health (US$360 million), as well as Alphabet subsidiary Verily (US$800 million). These three venture rounds were the largest since Pulse began tracking the medtech industry more than a decade ago.

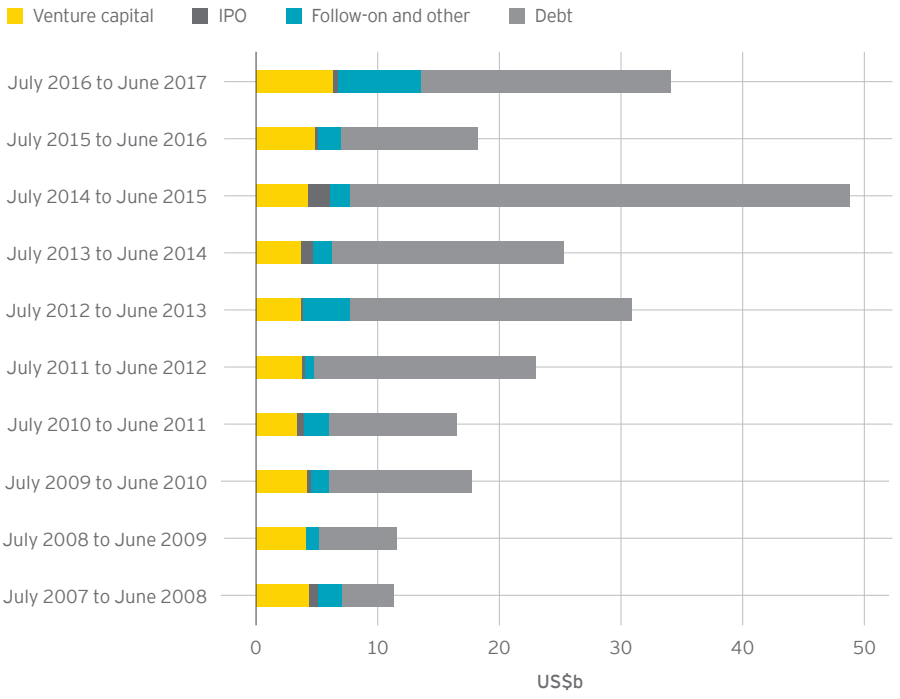
Public capital financing jumped considerably during 2016–17, with aggregate IPO financing for US medtechs up 63% to US$384 million across nine public market debuts (still only a fraction of the record set in 2014-15 during the medtech boom). Follow-on financing skyrocketed 272% to US$6.8 billion, led by the US$4.5 billion follow-on financing by BD to help fund its pending US$24 billion acquisition of C.R. Bard.

Solid results
US medtechs enjoyed a solid financing year, led by follow-on and debt financing from industry leader Becton Dickinson.

Big venture rounds
Venture financing for US medtechs reached an all-time high, as Grail, Verily and Guardant Health raised significant rounds.

Concentrated capital
Financing was highly concentrated among a few companies; 40% of all venture funding, for example, was raised by only 10 medtechs.

US financings by year



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

That BD follow-on was the largest since we began publishing Pulse and helped total US medtech follow-on financing set a new record.

Debt financing increased 83% to US$20.7 billion during 2016–17. BD again led the pack with US$10.7 billion in debt, largely to help pay for C.R. Bard. The financing marked the medtech industry's second-largest debt offering in the past decade. Thermo Fisher (US$3.5 billion), Acelity (US$2.2 billion) and Zimmer Biomet (US$1.1 billion) also made meaningful contributions to the year's total debt financing.

Venture trends upward

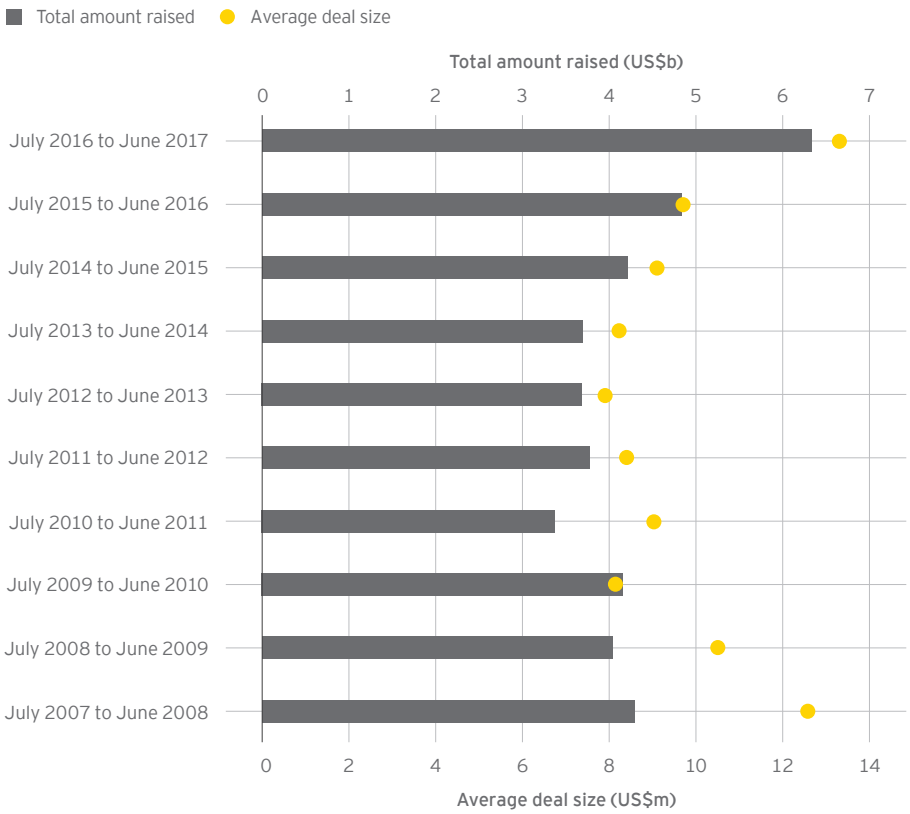
US venture capital investment easily surpassed the prior 10-year average of US$4 billion thanks to the impact of early stage financing rounds from Grail and Verily. The average US venture round reached US$13.3 million during 2016–17, up 37% from the prior year and surpassing the prior decade high of US$10.5 million. Although the total number of US venture deals declined from 499 to 477, that figure remained well above the prior decade average of 437. Still, capital remained highly concentrated, with more than 40% of all venture funding for US medtechs raised by only 10 companies.

The extraordinary venture rounds from Grail, Verily and Guardant comprised one-third of all US venture financing during 2016–17. The liquid biopsy field also has an emerging deep bench, as illustrated by the US$65 million Series A round from Freenome.

Two diabetes-focused companies, Intuity Medical and Livongo, helped non-imaging diagnostics companies take 5 of the top 10 slots on the venture leaderboard. Intuity raised US$55 million to support the launch of its Pogo blood glucose monitoring system, which received FDA clearance in April 2016. Livongo raised US$52.5 million to expand its diabetes management program into other chronic conditions and to fund international expansion plans.

Among therapeutic device companies, Outset Medical's US$76.5 million Series C will help the Northern California company expand the use of its Tablo Hemodialysis System from acute and chronic care settings into home use. In all, Outset Medical has now raised more than US$185 million in venture funding. Meanwhile, Earlens' US$73 million Series C will help the company to scale manufacturing of its Earlens Light-Driven Hearing Aid.

US venture capital by year



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

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Top US venture rounds, July 2016–June 2017

Company	Product type (disease)	Gross raised (US$m)	Quarter	Round type
Grail Bio Northern California	Non-imaging diagnostics	**973**	Q1 2017	Early stage
Verily Life Sciences Northern California	Other	**800**	Q1 2017	Early stage
Guardant Health Northern California	Non-imaging diagnostics	**360**	Q2 2017	Late stage
Outset Medical Northern California	Therapeutic devices (hematology/renal)	**77**	Q2 2017	Late stage
EarLens Northern California	Therapeutic devices (ear, nose and throat)	**73**	Q2 2017	Late stage
AcuFocus Southern California	Therapeutic devices (ophthalmic)	**66**	Q3 2016	Late stage
Freenome Northern California	Non-imaging diagnostics	**65**	Q1 2017	Early stage
Intuity Medical Northern California	Non-imaging diagnostics	**55**	Q4 2016	Late stage
Livongo Health Northern California	Non-imaging diagnostics	**53**	Q1 2017	Late stage
Ivenix Massachusetts	Therapeutic devices (multiple diseases)	**50**	Q1 2017	Late stage
Moximed Northern California	Therapeutic devices (orthopedic)	**50**	Q1 2017	Late stage
NeuroPace Northern California	Therapeutic devices (neurology)	**50**	Q1 2017	Late stage
Pulmonx Northern California	Therapeutic devices (respiratory)	**50**	Q2 2017	Late stage
Auris Surgical Robotics Northern California	Therapeutic devices (ophthalmic)	**49**	Q3 2016	Late stage
VytronUS Northern California	Therapeutic devices (cardiovascular/vascular)	**49**	Q3 2016	Late stage

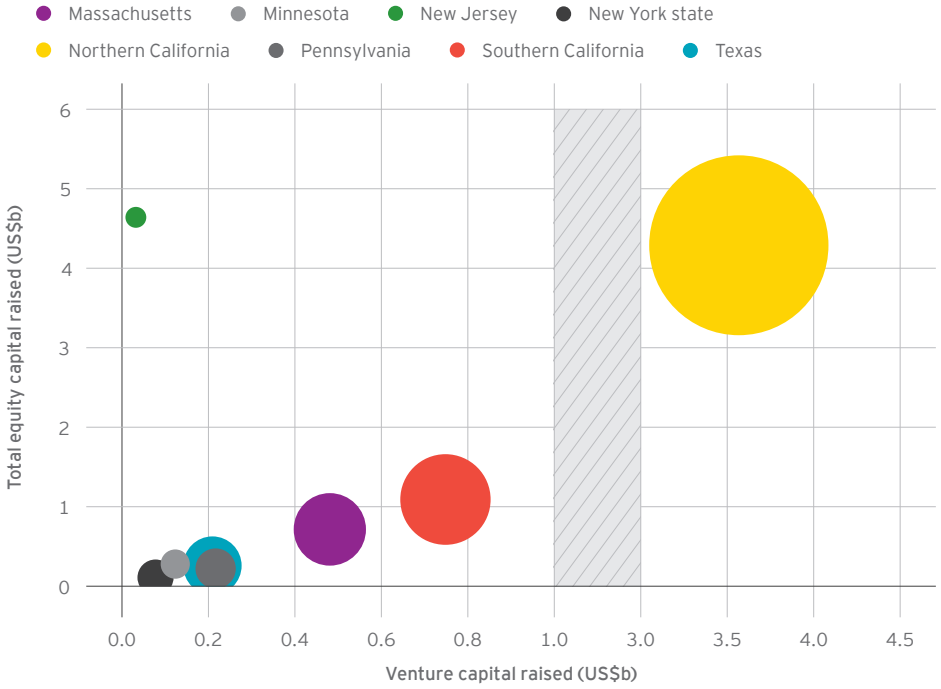
Source: EY, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

Each of these significant funding rounds underscores the increasing interest in shifting care from expensive, in-patient settings to lower-cost home settings. They also reinforce medtech investors' interest in companies attempting to address problems of aging. (See the guest perspective, "Medtech innovation in an aging world," by Steven Collens.) Earlens may also benefit from legislative efforts to allow consumers to purchase hearing aids directly from manufacturers without visiting a physician.

The US venture leaderboard very clearly demonstrates that VCs are finding most of their key opportunities in California. The Northern California cluster received 9 of the top 10 VC rounds by dollar value and 13 of the top 15. Outside Northern California, Southern California's Acufocus raised US$66 million in a late-stage venture round to accelerate commercialization for its lead ophthalmology devices, the Kamra corneal inlay and the IC-8 intraocular lens.

BD's US$4.5 billion follow-on sent New Jersey to the top of the regional table, challenging California for dominance in total capital raised. Northern California-based medtechs retained the lead in total number of financings (128), leaving Southern California (66 financings) and Massachusetts (52 financings) far behind.

Capital raised by leading US regions excluding debt, July 2016–June 2017



Bubble size shows relative number of financings per region.

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

Financing: Europe

Newcomer boosts European medtechs

Total funding for European medtech companies leapt 164% to a record US$9.7 billion during 2016–17, nearly double the prior high for the continent set in 2013–14. This new high was driven by strong financing from the continent's recent and biggest members, ConvaTec and Medtronic. Together, those two companies accounted for US$5.3 billion of the record total.

ConvaTec's IPO and subsequent US$1.3 billion follow-on were responsible for the largest portion of total funding in those two categories. Medtronic's US$2 billion debt round, meanwhile, comprised nearly half of all debt financing for European medtechs during 2016–17.

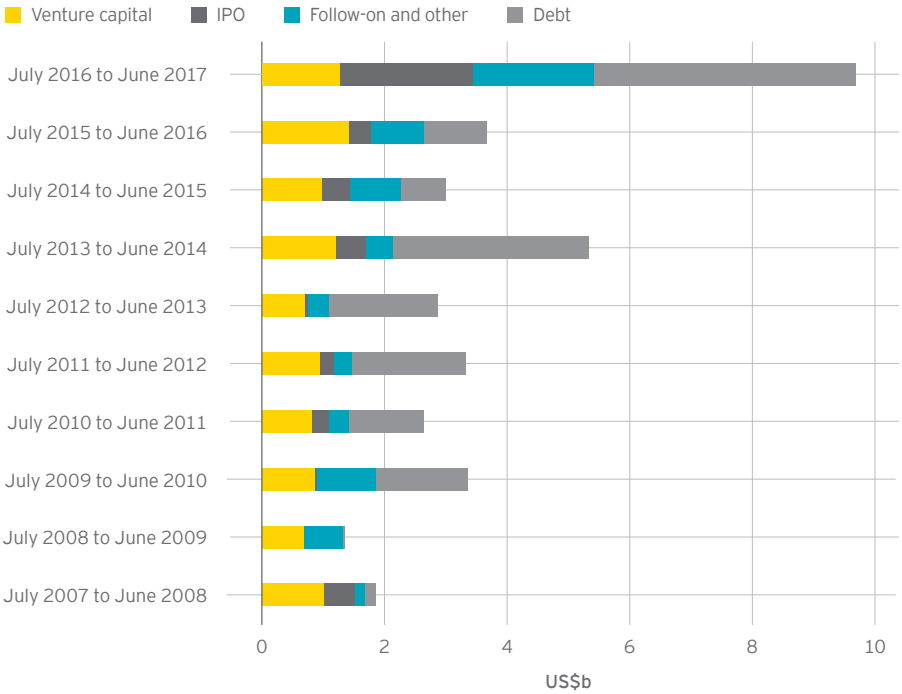
Overall public capital financing reached new heights on the backs of those companies. IPO funding was up 507% to US$2.2 billion, but without ConvaTec's massive debut, it would have fallen 54% year-on-year. Follow-ons were likewise up 130%, but without ConvaTec's follow-on round, they would have dropped 24%. Total debt financing was augmented by US$771 million from Swiss hearing specialist Sonova and US$553 million from Swedish wound care and surgical products company Mölnlycke Holding.

Totals eclipse
Medtronic and newly public ConvaTec gave the European medtech sector a jolt in 2016–17, as total funding reached an all-time high.

Venture pulls back
Financing totals increased significantly year-over-year in all areas but venture capital, which fell slightly from the prior year's decade-long highs.

Europe lags
Despite Europe's record year, its overall financing still lags behind the US, with only 22% of the combined continents' total funding.

European financings by year



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

European VC total ebbs

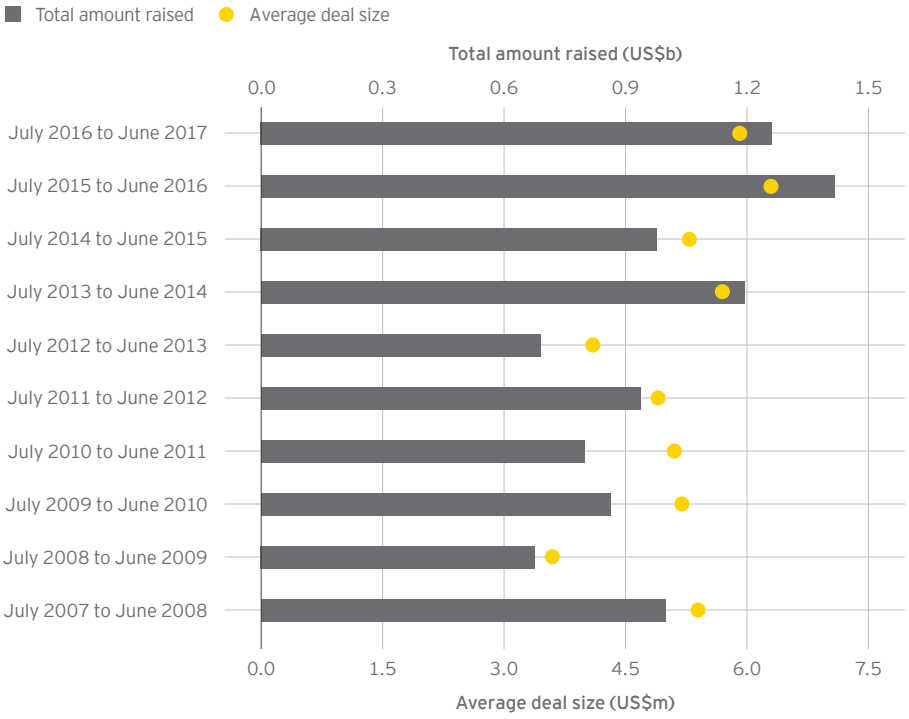
Total venture capital funding for European medtechs dropped 11% in 2016–17, to US$1.3 billion. Despite this lull, that US$1.3 billion remains the second-highest VC total in the past decade. The number of venture rounds and average deal size also dropped 5% to 213 and 6% to US$6 million, respectively.

For the fourth year running, UK sequencing specialist Oxford Nanopore Technologies raised the largest European medtech venture round. In December 2016, Oxford Nanopore raised US$126 million, which will be invested in R&D and the commercialization of its MinION portable DNA sequencer and other devices. The company has now raised nearly US$445 million in venture financing since inception.

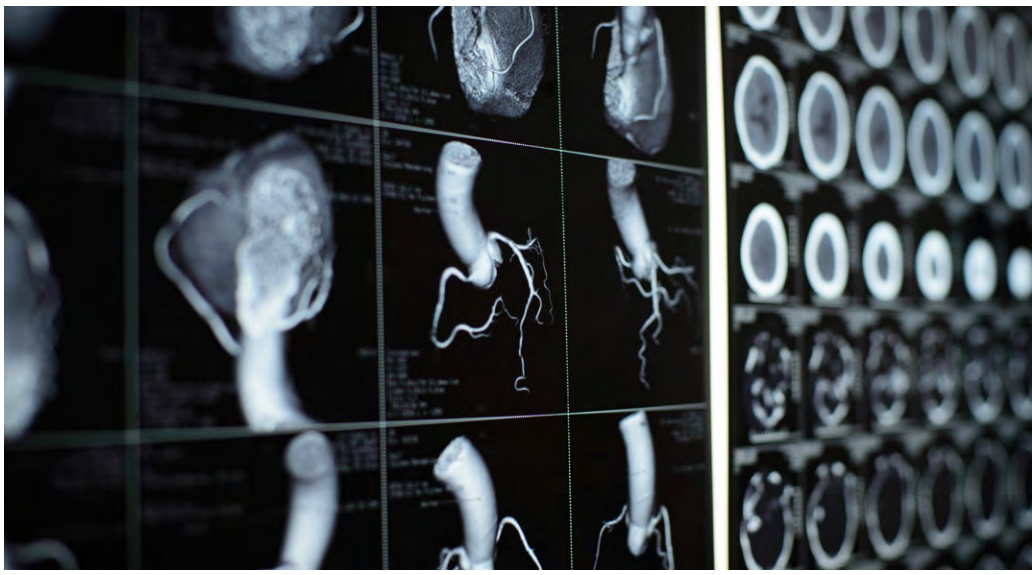
Oxford Nanopore's continued dominance at the top of the European medtech venture leaderboard has not been a harbinger of increased investment in the research tools space. Instead, in 2016–17, therapeutic device companies garnered the largest venture rounds, with imaging and non-imaging diagnostics companies sprinkled in.

Among the leading non-imaging diagnostics rounds was Israel's Cnoga Medical's US$50 million financing by BOE Technology Group, China's largest manufacturer of liquid crystal displays. Cnoga makes devices that monitor vital signs using optics that measure changes in the color of a person's fingertip skin. BOE has taken a 23% stake in Cnoga, and the two companies will jointly market Cnoga's devices in China. The deal was one of three of the top eight European medtech venture rounds to feature Chinese investors, alongside Impulse Dynamics (US$45 million) and Atlas Genetics (US$35 million).

European venture capital by year



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



Top European venture rounds, July 2016–June 2017

Company	Product type (disease)	Gross raised (US$m)	Quarter	Round type
Oxford Nanopore Technologies UK	Research and other equipment	**135**	Q4 2016	Late stage
Cnoga Medical Israel	Non-imaging diagnostics	**50**	Q1 2017	Late stage
Breath Therapeutics Germany	Therapeutic devices (respiratory)	**48**	Q1 2017	Early stage
Impulse Dynamics Germany	Therapeutic devices (cardiovascular/vascular)	**45**	Q2 2017	Late stage
OrCam Technologies Israel	Therapeutic devices (ophthalmic)	**41**	Q1 2017	Late stage
Medlumics Spain	Imaging	**38**	Q1 2017	Early stage
Bonesupport Sweden	Therapeutic devices (orthopedic)	**37**	Q4 2016	Late stage
Atlas Genetics UK	Non-imaging diagnostics	**35**	Q1 2017	Late stage
Laser Quantum UK	Therapeutic devices (multiple diseases)	**35**	Q1 2017	Early stage
SpineArt Switzerland	Therapeutic devices (orthopedic)	**33**	Q3 2016	Early stage
MOTUS GI Israel	Imaging	**30**	Q1 2017	Early stage
Aspect Imaging Israel	Imaging	**30**	Q2 2017	Early stage
Cambridge Medical Robotics UK	Therapeutic devices (multiple diseases)	**20**	Q3 2016	Early stage
Aspect Imaging Israel	Imaging	**20**	Q3 2016	Early stage
ART Medical Israel	Non-imaging diagnostics	**20**	Q2 2017	Early stage
Ornim Medical Israel	Non-imaging diagnostics	**20**	Q3 2016	Late stage
Nyxoah Belgium	Therapeutic devices (respiratory)	**20**	Q3 2016	Early stage

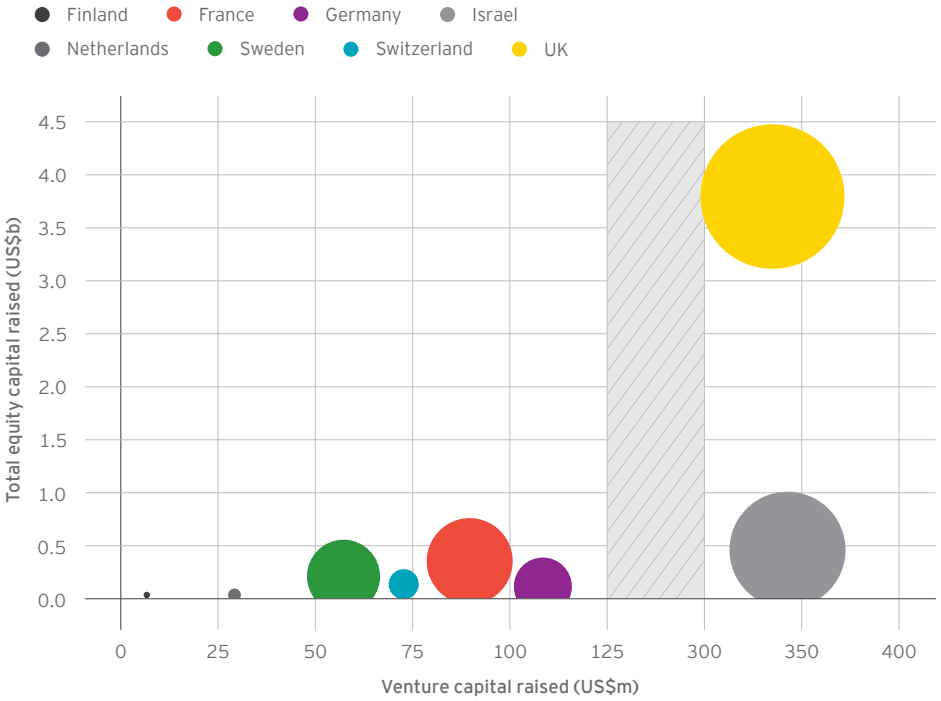
Source: EY, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

Of the top five European venture deals by dollar value, three were investments in therapeutic device companies. Breath Therapeutics, a German medtech developing an inhalable drug/device combination product for rare lung conditions, raised US$48 million in conjunction with spinning off PARI Pharma, a German drug formulation and delivery company. Impulse Dynamics, also in Germany, raised US$45 million to expand the commercial footprint of its Optimizer implantable chronic heart failure device. And, OrCam Technologies, an Israeli maker of wearable ophthalmic devices for the visually impaired, raised US$41 million as it expands commercialization of its MyEye device.

Fears that the UK's departure from the European Union might impact investment in the UK's thriving medtech sector appear to be unfounded. Brexit has yet to dent the UK's dominance of Europe's medtech markets, as UK companies raised nearly US$4 billion in equity capital during 2016–17. Though much of that capital was raised by a single company — ConvaTec — the UK also enjoyed the most financing rounds of any European market, with 67.

Led by Mölnlycke Holding's US$553 million debt financing and an unusually strong showing in the IPO table, Sweden-based medtechs raised US$1 billion in 2016–17, just ahead of Swiss medtechs (US$911 million). Excluding debt deals, Israeli medtechs raised US$463 million to remain a distant second behind the UK. Israel surpassed the UK in venture financing, however, raising US$342 million in venture capital to the UK's US$335 million in 2016–17. German medtechs raised the third-highest amount of venture capital with US$108 million.

Capital raised by leading European countries excluding debt, July 2016–June 2017



Bubble size shows relative number of financings per region.

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

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Financing: Asia-Pacific

Debt drags on financing metrics

Despite a second consecutive drop in overall financing, the emerging medtech ecosystem in Asia enjoyed a solid year, as venture and IPO financing bounced back from a disappointing 2015–16. Total financing in 2016–17 fell 16% to US$1.5 billion, due largely to a steep decline in debt financing.

Although debt fell 90% to only US$84 million, venture capital, IPOs and follow-ons each enjoyed gains. Follow-on financing comprised the largest chunk of total financing, up 25% to US$693 million on the year.

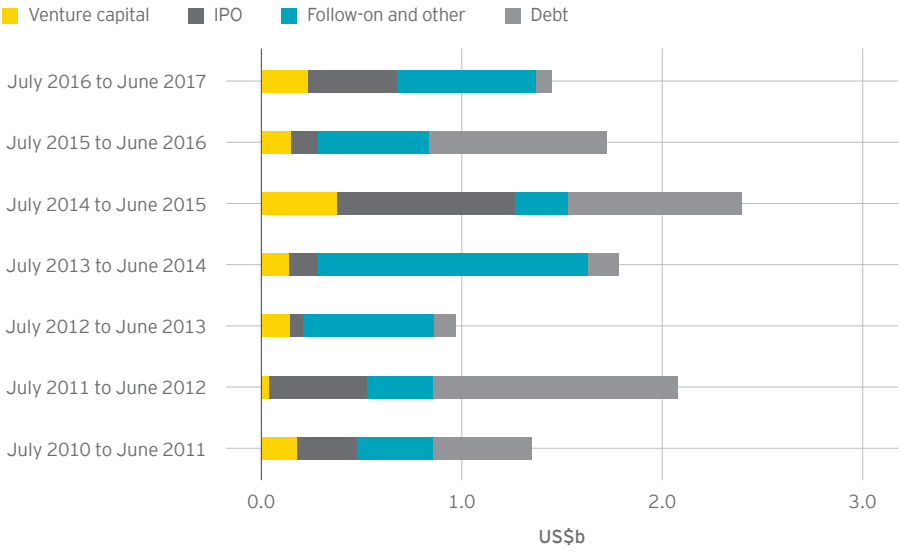
Asia-Pacific medtech venture capital rose 58% to US$228 million during 2016–17, the second-highest amount in the past seven years. China led the way, with 5 of the top 10 venture rounds by dollar value. In all there were 25 venture deals in the region, split nearly evenly between non-imaging diagnostics companies (13) and therapeutic device companies (12).

Year-on-year increases
Asia-Pacific medtech financings had a solid year in 2016–17, with venture, IPO and follow-on financings all increasing year-on-year.

Chinese medtechs shine
China is increasingly flexing its medtech muscle, with Chinese companies responsible for three-quarters of total Asia-Pacific medtech financing.

From East to West
Investors in Asia have become increasingly active in US and European medtechs, highlighting the flow of capital from East to West.

Asia-Pacific financings by year



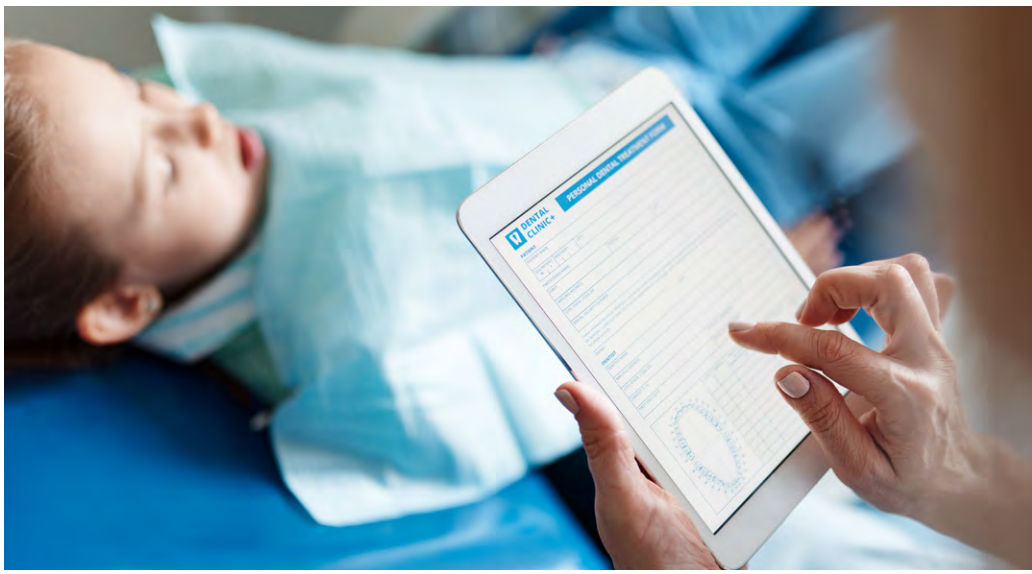
Source: EY, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

Select Asia-Pacific venture rounds, July 2016–June 2017			
Company	**Product type (disease)**	**Gross raised (US$m)**	**Quarter**
WuXi NextCODE China	Non-imaging diagnostics	**75**	Q2 2017
Saluda Medical Australia	Therapeutic devices (neurology)	**39**	Q2 2017
Wanbang Biopharmaceuticals China	Non-imaging diagnostics	**26**	Q4 2016
Bionic Vision Technologies Australia	Therapeutic devices (ophthalmic)	**17**	Q2 2017
Zhejiang POCTech China	Non-imaging diagnostics	**15**	Q2 2017
EndoMaster Singapore	Therapeutic devices (oncology)	**15**	Q1 2017
Nuokang Medical Equipment China	Non-imaging diagnostics	**10**	Q3 2016
Osstem Global South Korea	Therapeutic devices (dental)	**7**	Q1 2017
Weili Medical Technology China	Therapeutic devices (multiple diseases)	**6**	Q3 2016
Immunostics South Korea	Non-imaging diagnostics	**3**	Q4 2016

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

WuXi NextCODE, the Massachusetts-based division of China's WuXi AppTec, raised US$75 million in its May 2017 Series B to advance commercialization of its consumer genomics offerings in China. The round was backed by Temasek, Yunfeng Capital and Amgen Ventures, among others.

Australia-based Saluda Medical raised the year's top therapeutic device round, bringing in US$39 million led by GSK's Action Potential Venture Capital fund. Saluda's May 2017 Series D will support development of its Evoke spinal cord stimulator system, for patients with chronic pain.



IPO financing rose by 223% during 2016–17, to US$447 million across 11 financings. China-based medtechs completed the top seven IPOs by dollar value, bringing in a cumulative US$416 million and led by Autobio's US$92 million IPO on the Shanghai Exchange.

Autobio, a clinical diagnostics manufacturer, went public in August 2016, raising the third-largest medtech IPO in any geography during 2016–17.

Showcasing China's growing global clout, Shanghai Kindly Enterprise Development Group, which sells medical puncture devices and raised US$75 million in its November 2016 IPO, tied for the fourth-largest medtech IPO globally.

Select Asia-Pacific IPOs, July 2016–June 2017

Company	Product type (disease)	Gross raised (US$m)	Quarter
Autobio Diagnostics China	Non-imaging diagnostics	**92**	Q3 2016
Shanghai Kindly Enterprise Development Group China	Therapeutic devices (multiple diseases)	**75**	Q4 2016
Jafron Biomedical China	Therapeutic devices (hematology/renal)	**68**	Q3 2016
Hybribio Biotech China	Non-imaging diagnostics	**62**	Q2 2017
Thalys Medical Technology China	Non-imaging diagnostics	**52**	Q4 2016
Transtek Medical Electronics China	Non-imaging diagnostics	**35**	Q4 2016
SonoScape Medical China	Imaging	**31**	Q2 2017
Logos Biosystems South Korea	Research and other equipment	**16**	Q4 2016
The Sincere Japan	Therapeutic devices (ophthalmic)	**10**	Q4 2016
Neurotech International Australia	Non-imaging diagnostics	**5**	Q4 2016
KMS Medisurgi India	Therapeutic devices (non-disease specific)	**0.4**	Q2 2017

Source: EY, BMO Capital Markets and Capital IQ.

Questions for medtech companies to consider

How will new sources of funding help medtechs sprint to the next value inflection point?

How are medtechs tapping multiple pools of capital to build a winning financing strategy?

As medtechs increasingly compete for public capital, does your organization have an inside track?

Is funding right before your eyes but just difficult to see?

Guest perspective

Building value through creative deal structures

Steven
Dyson

Health Care Partner
Apax Partners

It is an exciting time for private equity investors looking at medtech. The industry continues to grow and evolve thanks to technological advances transforming how health care is delivered and paid for. While we have seen an abundance of M&A activity in recent years, more recently, private equity has often been outbid by corporate buyers demonstrating a willingness to pay premium prices, particularly for those medtech assets enjoying high revenue growth.

At Apax Partners, a leading global private equity advisory firm, we see a number of diverse and interesting investment opportunities, but are mindful of record-high valuations. We believe it's important to seek out niche opportunities off the beaten path to execute investments at reasonable valuations. To do this, we think creatively around deal sourcing and how transactions can be structured to reduce competition. For example, this could include looking at product niches less popular with corporate buyers or assets that are not currently growing very fast, but have the potential to do so in the future. Indeed, the ability to create more complicated deal structures, such as carve-outs from a parent company or joint ventures, can create a unique angle.

Often, divesting non-core assets via so-called carve-outs isn't the highest priority for a seller as it is easier to sell the asset to another corporate buyer. In some cases that is because the assets don't generate enough revenue to justify the effort to create a new stand-alone company. You need a certain amount of scale to build a viable commercial entity, particularly in the current environment where category leadership is important. In other cases,

it is simply easier to sell products or entire product lines to another company if the synergistic fit is good.

Sometimes a joint venture is the best option for all parties. This was the case when funds advised by Apax ("Apax Funds") partnered with Becton Dickinson to create Vyaire Medical. In 2015, when Becton Dickinson completed its acquisition of CareFusion, it inherited a Respiratory Solutions business with a global footprint of approximately 5,000 employees and a product portfolio including diagnostics, ventilation products, patient monitoring services and anesthesia.

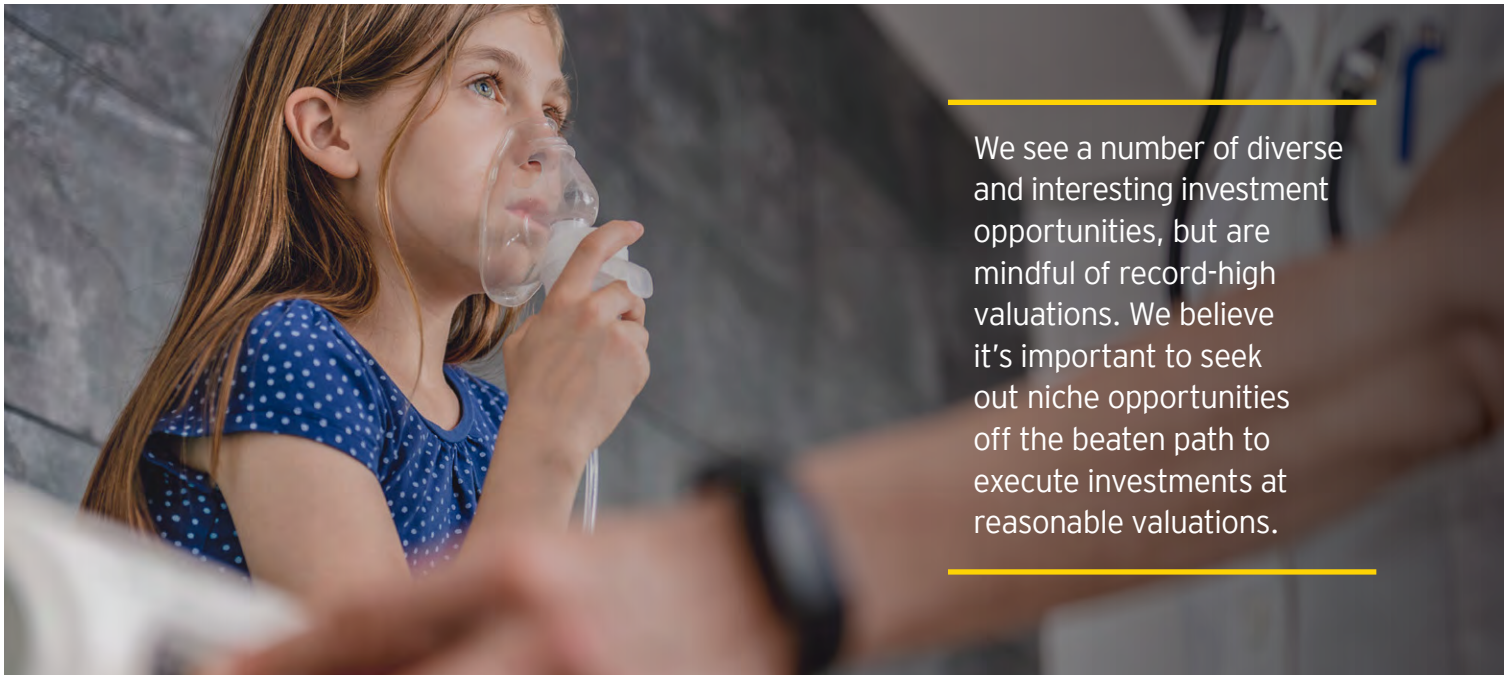
Embracing complexity to create value

Even though the Respiratory Solutions business earned around $800 million in annual revenue with value creation potential, its therapeutic focus wasn't a priority for Becton Dickinson. They believed generating new growth was going to require significant investment which they weren't in a position to make due to their focus on integrating other parts of the CareFusion business. At Apax, we saw an opportunity to reposition the Respiratory Solutions business as a stand-alone company through a joint venture in which Apax Funds acquired 50.1% and Becton Dickinson retained 49.9%. The business was later renamed Vyaire Medical.

In a carve-out, business functions such as HR, finance, legal and quality management departments have to be rebuilt from scratch. This requires a lot of engagement from the owner divesting the assets, as well as the new company itself, and can often lead to mixed success. With a traditional sale, the parent can often lose interest at a critical time.

In the instance of Vyaire, because Becton Dickinson retained an equity stake and a seat on Vyaire Medical's board, it had a greater understanding of the ongoing operational issues and was incentivized to share in the future value creation.

The joint venture ownership model for Vyaire works for all parties. For the company itself, its independence from a parent allows strategic focus and the ability to attract the best managerial talent. For Becton Dickinson, its minority ownership provides participation in future growth. And, for Apax Funds, its investment and health care experience strengthens Vyaire's position as a leading global player, enabling us to back a business with an exciting future.



We see a number of diverse and interesting investment opportunities, but are mindful of record-high valuations. We believe it's important to seek out niche opportunities off the beaten path to execute investments at reasonable valuations.

Mergers & acquisitions

M&A races ahead

Buying opportunity
Slowing organic growth, provider consolidation and payer pressure boosted acquisitions to record heights in the 12 months that ended June 2017.

Geographic balance
M&A activity was more geographically balanced in the US and Europe after a lopsided 2015-16, as medtechs used dealmaking to fuel growth.

Focused growth
Larger medtechs continued to divest non-core businesses, pursuing focus and scale in fewer, chosen therapeutic spaces.

Essilor's US$25.2 billion acquisition of ophthalmology retailer Luxottica and Becton Dickinson's announced US$24 billion acquisition of minimally invasive device specialist C.R. Bard put a pair of exclamation points on an exceptional year for medtech M&A. In all, the total value of medtech M&A in the US and Europe reached US$100.4 billion, an increase of 46% over the prior 12 months and an industry record.

But the continued growth in value of non-megadeal acquisitions, defined as deals valued at less than US$10 billion, illustrates how medtechs employ inorganic growth to bolster revenue shortfalls. Indeed, in the 12 months that ended 30 June 2017, total non-megadeal acquisition value increased for the fourth straight year to US$51.2 billion. Though that figure is only 14% higher than the prior 12-month period, which might suggest growth in this medtech M&A category is leveling off, the 2016–17 sum is more than double the total for July 2012–June 2013.

This increase in M&A value occurred despite a drop in the total number of non-megadeal acquisitions with announced terms. During 2016–17, 198 US and European medtechs were acquired, a 15% decline from 2015–16. The declining volume led to a corresponding jump in average deal value: during 2016–17, the average medtech acquisition value surged 73% to US$507 million, the highest average in at least five years.

In fact, the number of acquisitions valued at greater than US$1 billion has remained in the double digits since 2014–15, jumping from 10 in 2015–16 to 14 in the most recent period. This suggests the industry's larger players prefer robust assets that can be bolted on to existing businesses to create greater depth in chosen therapeutic areas. Meanwhile, rising market valuations over the past few years mean there are more US$1 billion companies to buy, as investors bet that medtechs seeking growth will repeatedly use M&A to satisfy strategic objectives.

M&As in the US and Europe by year

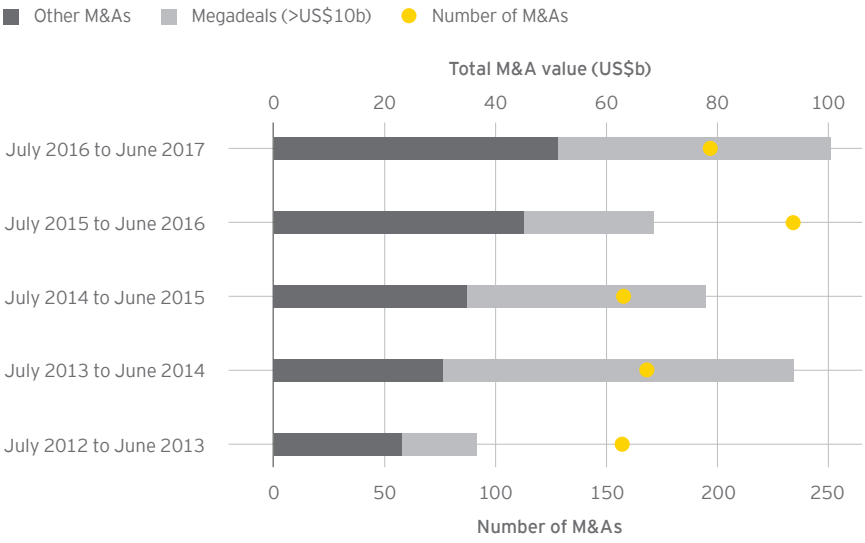


Chart includes M&As with value disclosed (medtech M&A where either acquirer or target is located in the US or Europe).

Source: EY, Capital IQ and Thomson ONE.

Scale and diversification dominate medtech M&A strategies

An analysis of the top deals by dollar value during 2016–17 reveals the underlying drivers of this heightened M&A activity. Pure play medtechs continue to chase economies of scale, as category leadership in a therapeutic area or business and an ability to provide end-to-end solutions remain top priorities. Pure play medtechs are also pursuing diversification strategies, buying businesses that complement their existing offerings or enable them to boost their offerings in more quickly growing geographies such as China. Meanwhile, conglomerates are pruning portfolios in the wake of prior acquisitions.

The year's megadeals illustrate the need for scale in increasingly competitive medtech areas. Essilor's US$25.2 billion Luxottica acquisition combines the largest ophthalmic device manufacturer

Selected M&As, July 2016 to June 2017

Buyer	Seller	Value (US$b)	Buyer's deal driver (disease or business category)
Essilor International France	**Luxottica** Italy	**$25.2**	Build scale (ophthalmic)
Becton Dickinson US-New Jersey	**C.R. Bard** US-New Jersey	**$24.0**	Build scale (multiple)
Thermo Fisher Scientific US-Massachusetts	**Patheon** US-North Carolina	**$7.2**	Diversification (services)
Cardinal Health US-Ohio	**Medtronic (medical supplies)** Ireland	**$6.1**	Diversification (medical supplies)
Johnson & Johnson US-New Jersey	**Abbott (Abbott Medical Optics)** US-Illinois	**$4.3**	Build scale (ophthalmic)
Danaher US-District of Columbia	**Cepheid** US-California	**$4.0**	Build scale (diagnostics)
Svenska Cellulosa Aktiebolaget Sweden	**BSN medical** Germany	**$3.0**	Diversification/spin-out
Allergan Ireland	**Acelity (LifeCell)** US-Texas	**$2.9**	Diversification (regenerative medicine)
Allergan Ireland	**ZELTIQ Aesthetics** US-California	**$2.5**	Build scale (aesthetics)
Philips Netherlands	**Spectranetics** US-Colorado	**$2.1**	Build scale (cardiovascular/vascular)
Hologic US-Massachusetts	**Cynosure** US-Massachusetts	**$1.7**	Diversification (aesthetics)
PerkinElmer US-Massachusetts	**EUROIMMUN** Germany	**$1.3**	Build scale (diagnostics)
Terumo Japan	**St. Jude Medical (select cardiovascular products)** US-Minnesota	**$1.1**	Build scale (cardiovascular/vascular)
Integra LifeSciences US-New Jersey	**Johnson & Johnson (Codman Neurosurgery)** US-New Jersey	**$1.0**	Build scale (neurology)
Teleflex US-Pennsylvania	**Vascular Solutions** US-Minnesota	**$1.0**	Build scale (cardiovascular/vascular)
ICU Medical US-California	**Pfizer (Infusion Systems)** US-New York	**$0.9**	Build scale (medical supplies)
Stryker US-Michigan	**Novadaq Technologies** Canada	**$0.7**	Diversification (imaging)

Values rounded to the hundredths.

Source: EY, Capital IQ and Thomson ONE.

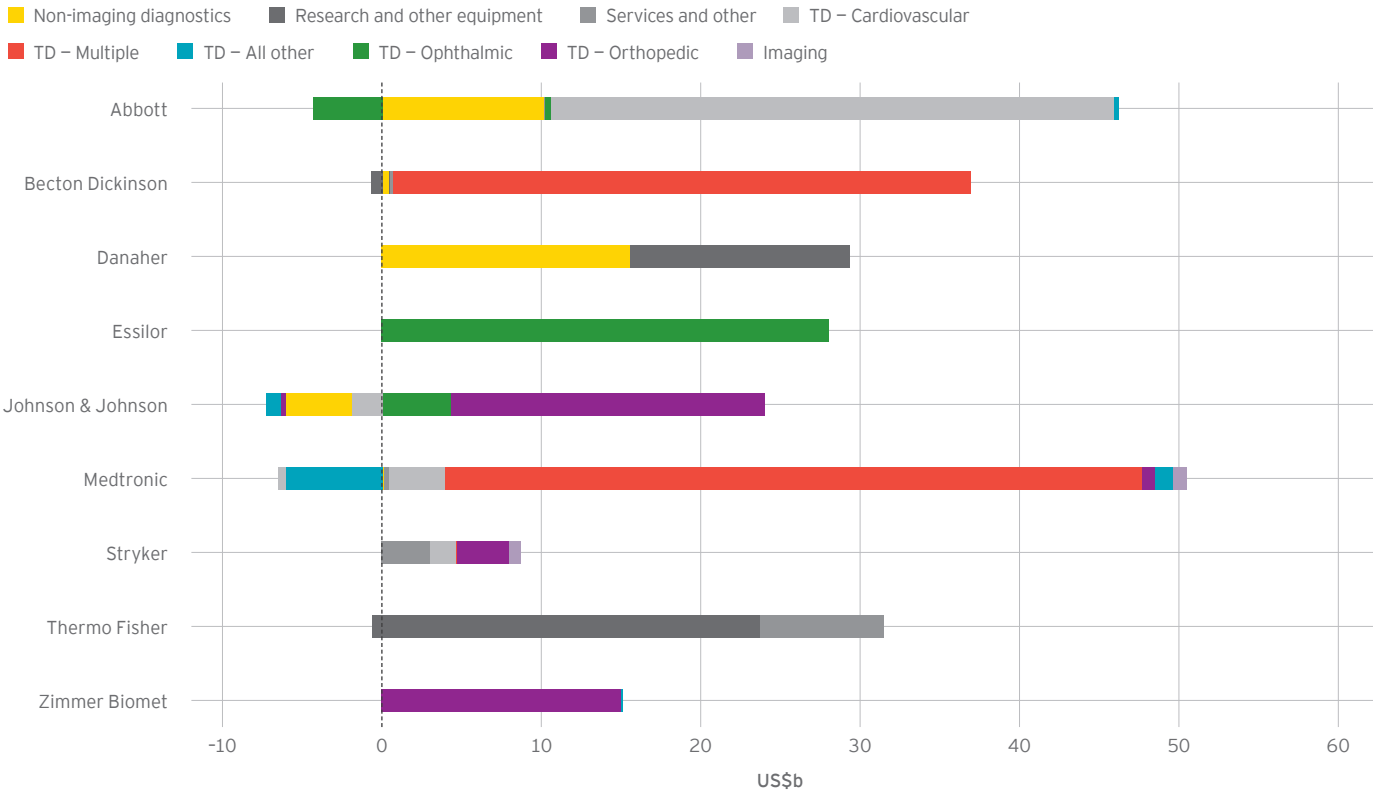
with the biggest retailer in the eyewear space, creating a visual health and eyewear group with combined revenue of more than €15 billion. The deal is the fourth-largest medtech acquisition ever and Essilor's biggest deal by far. (Prior to the Luxottica acquisition, Essilor's largest deal was its 2013 US$1.9 billion acquisition of Transition Optics.) Scale matters in a space where both Essilor and Luxottica have experienced slowing sales growth as a result of competition from less expensive, online rivals.

Becton Dickinson's (BD) announced acquisition of C.R. Bard for US$24 billion is BD's second megadeal in recent years, following the US$12.2 billion acquisition of CareFusion in 2014. When the deal is finalized, Bard will give BD scale in hospital supplies, combining Bard's minimally invasive devices and ports in the peripheral vascular, urology, hernia and high-growth oncology and surgery areas with BD's offerings in intravenous drug delivery systems. Consolidating these businesses should enable BD to grow revenue in an area where hospital systems, which have increased their own heft via mergers, are focused on reducing care costs.

By adding Bard's products to its portfolio, BD hopes efficiencies of scale and greater volume can boost its fortunes in an era where margins are increasingly tight. The companies' combined revenue exceeds US$16 billion. Similarly, PerkinElmer's US$1.3 billion acquisition of Euroimmun adds scale to the company's in vitro diagnostics business while also boosting PerkinElmer's footprint outside the US, particularly in China — a stated priority for the company.

Thermo Fisher Scientific's May 2017 US$7.2 billion acquisition of the contract development and manufacturing organization Patheon seems designed to help the world's top scientific instrument manufacturer become a soup-to-nuts partner for its

Portfolio optimization by select medtechs, 2011–H1 2017



Source: EY, Capital IQ and Thomson ONE.

Figure includes previous M&As of companies that were later acquired. The therapeutic device (TD) category was subdivided by therapeutic area. TD- Multiple refers to deals that included assets from multiple therapeutic areas. TD–All other refers to a deal in a therapeutic area other than the cardiovascular, ophthalmic, or orthopedic areas.

biopharmaceutical industry customers. The move will significantly boost Thermo's Laboratory Products and Services business, which generated more than US$7 billion of the group's total US$18.3 billion in 2016 revenue.

Meanwhile, Cardinal Health's US$6.1 billion acquisition of Medtronic's medical supplies business in April 2017 helps Cardinal continue to diversify beyond its core pharmaceutical distribution business. Medtronic's supplies business expands Cardinal's medical products unit into the operating room and long-term care areas. Cardinal strengthened that division in 2015 with its US$2 billion acquisition of Johnson & Johnson's Cordis business, which gave Cardinal a portfolio of cardiovascular surgical devices such as catheters, filters and stents.

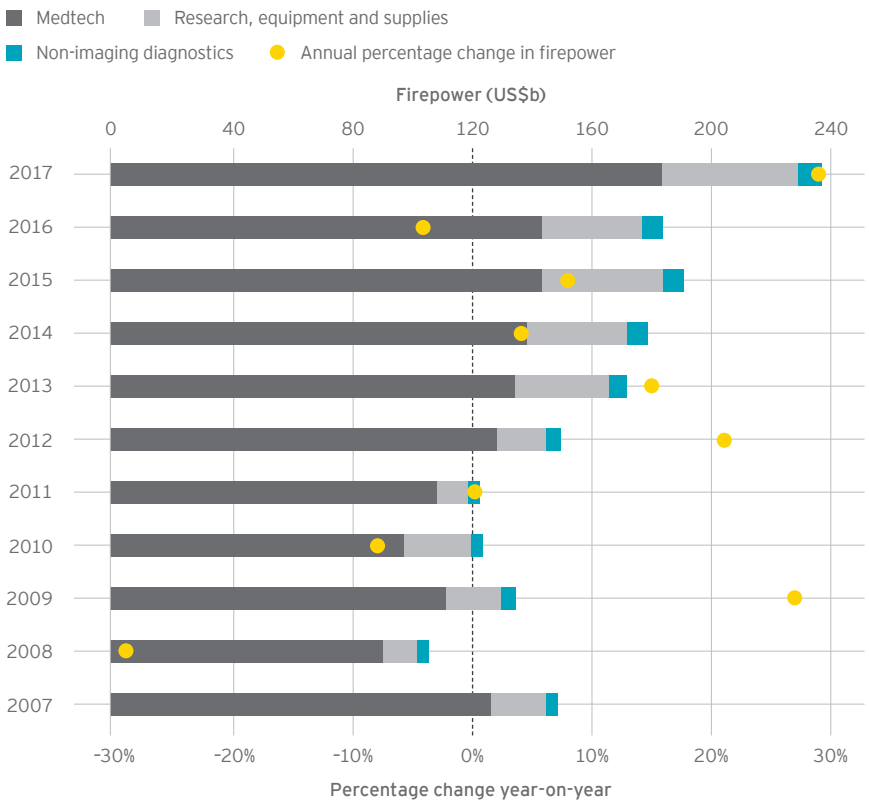
From Medtronic's perspective, the deal allows it to jettison a slower-growing business unit that it gained as part of its US$50 billion Covidien acquisition and focus on higher-growth opportunities in its core cardiac and vascular and minimally invasive therapies businesses.

As portfolio optimization continues, the divestiture of assets should generate additional dealmaking firepower for medtechs.

Pfizer likewise offloaded an infusion systems business, gained via its 2015 acquisition of Hospira, in a deal with ICU Medical for US$900 million in October 2016. Johnson & Johnson also continued to streamline its portfolio with the sale of its Codman Neurosurgery business (part of its DePuy Synthes device group) to Integra LifeSciences for US$1 billion in February 2017.

As portfolio optimization continues, the divestiture of assets should generate additional dealmaking firepower for medtechs. In absolute terms, the medtech industry's purchasing power has risen since 2010. Based on the EY Firepower Index, this transactional capacity increased 29% year-over-year to nearly US$240 billion in 2017. Not surprisingly, an analysis by medtech subsectors shows that therapeutic devices companies, which make up the bulk of the industry, continue to command the most firepower and have seen the biggest annual increase in purchasing power.

Medtech industry's firepower at an all-time high



The EY Firepower Index measures a company's ability to do M&A based on the strength of its balance sheet. Together, a company's market capitalization, cash equivalents and debt capacity provide the "firepower" for deals. Thus, a company's firepower increases when either its market capitalization or its cash and equivalents rise – or its debt falls.

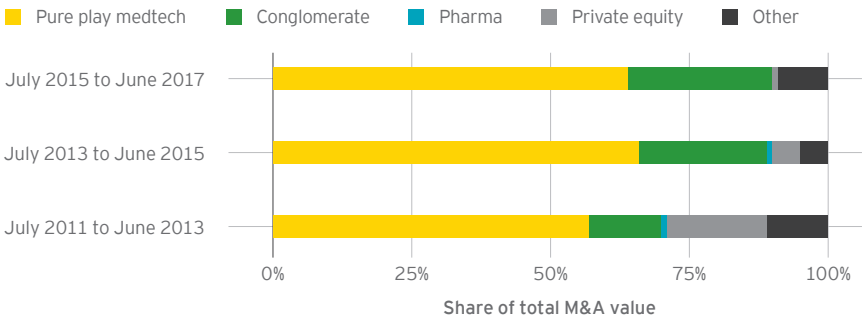
Source: EY, Capital IQ and Thomson ONE.

Private equity cashing out

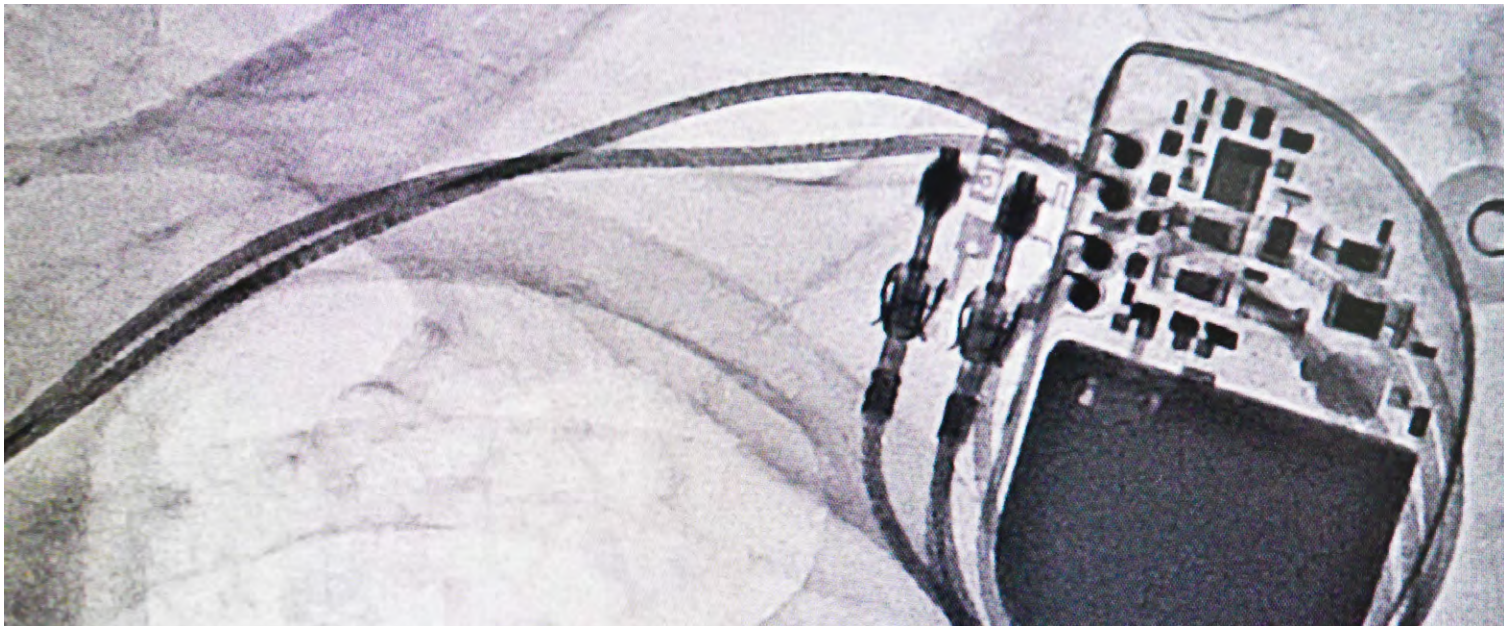
What's different about these portfolio-optimizing deals is the lack of private equity buyers. In 2016–17, private equity firms focused on selling rather than buying as valuations for medtech assets continued to make it difficult for private equity buyers to achieve the same deal synergies as strategic buyers. A number of deals illustrate the trend: EQT Partners AB sold the wound-care- and orthopedics-focused BSN medical to Sweden's Svenska Cellulosa for US$3 billion in December 2016; Apax Partners-owned Acelity divested the regenerative medicine company LifeCell to Allergan the same month for US$2.9 billion.

Indeed, over the past four years, private equity groups have made up an increasingly vanishing sliver of medtech buyers. Their share of deals has fallen from 18% in July 2011–June 2013 to only 1% in the most recent two-year period. In that same time period, traditional pure play medtechs have been responsible for roughly two-thirds of all medtech acquisitions. For now, deal flow suggests private equity firms see greater growth opportunities in the digital health, health care services, and contract research and manufacturing spaces than traditional medtech, although opportunities to roll up underperforming medical device assets do still exist. (See the guest perspective by Steven Dyson, "Building value through creative deal structures.")

US and European M&A by type of buyer



Source: EY, Capital IQ and Thomson ONE.



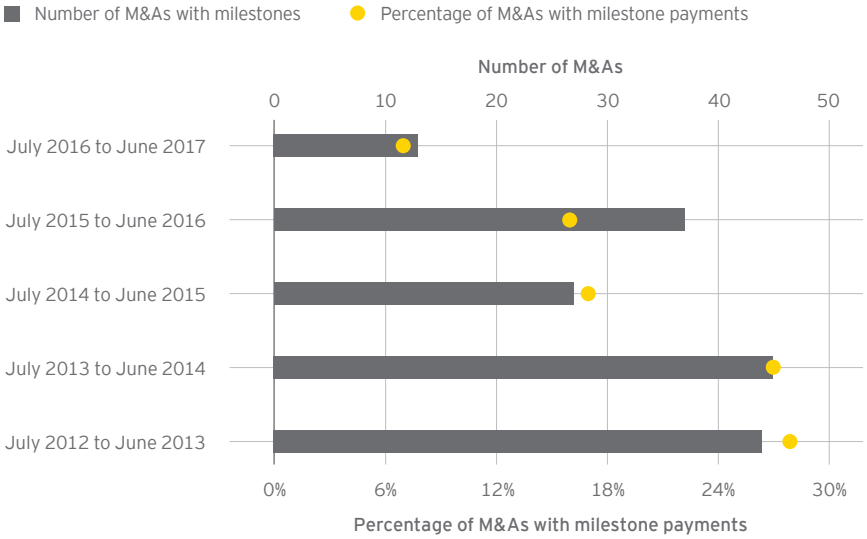
Structured deals increasingly rare

With larger medtechs on the hunt for future revenue growth and competition for validated assets fierce, sellers are less likely to agree to structured acquisitions than in the past. The tail-off in structured acquisitions continues a trend from recent years. During the 2016–17 period, only 13 acquisitions (down from 37, or 7% of all deals) featured milestone payments. Only US$3.4 billion worth of M&A included potential milestone payments, down from US$4.7 billion during the prior period and US$6.9 billion during 2014–15.

But deals that included milestone payments tended to tie up a larger chunk of potential value in those earn-outs than in prior years. Unsurprisingly, given their risk-sharing nature, these deals tended to be larger, in terms of total potential and average value, than deals that lacked milestone payments and involve privately held companies.

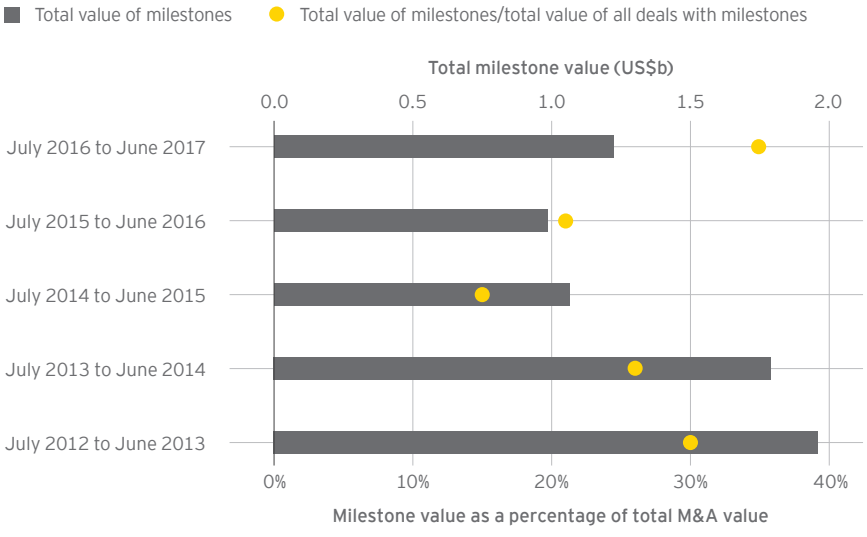
During 2016–17, those 13 acquisitions with milestone payments featured an aggregate US$1.2 billion worth of milestones, a 24% increase over the prior period. That US$1.2 billion represented roughly 35% of those deals' potential total value (or an average of US$94 million in milestones). The average total potential deal value for milestone laden acquisitions was US$267 million in 2016–17, compared with an average of about US$227 million for (non-megadeal) acquisitions that did not feature milestones.

Milestone payments in US and European medtech M&A by year



Source: EY, Capital IQ and Thomson ONE.

Milestone share in US and European medtech M&A by year



Source: EY, Capital IQ and Thomson ONE.


With larger medtechs on the hunt for future revenue growth and competition for validated assets fierce, sellers are less likely to agree to structured acquisitions than in the past.

The largest deal featuring milestone payments was Edwards Lifesciences' acquisition of Israeli medtech Valtech for US$690 million (including US$350 million in milestone payments, based on regulatory success and achieving sales targets). Edwards gains Valtech's transcatheter valve repair technology and an option to acquire an additional early-stage valve replacement technology.

In the US, a smaller piece of the overall pie

In contrast to 2015–16, when 92% of M&A total deal value was driven by the acquisition of US-based medtechs, there was more geographic parity in 2016–17. Indeed, US-based medtechs accounted for only 59% of total deal value during 2016–17, or US$59.6 billion. Megadeal activity didn't overly influence the 12 months' results: US medtechs contributed 70% to the 2016–17 non-megadeal total value.

While the average deal size for US medtech acquisitions jumped 4% to US$294 million, and the number of non-megadeals fell 12% to 122, each metric was well above the prior four-year average. Including BD/C.R. Bard, there were ten additional US medtech acquisitions valued at greater than US$1 billion.

Ireland's Allergan, a prolific dealmaker across the biopharmaceutical and medtech industries, accounted for two of those deals. Allergan bought the regenerative medicine company LifeCell from Acelity (formerly known as Kinetic Concepts) for US$2.9 billion in December 2016 and Zeltiq Aesthetics for US$2.5 billion in February 2017. (During the 2016–17 period, Allergan bought a third aesthetics-focused device company, the privately held Keller Medical, for undisclosed terms, as well as at least five biopharmaceutical companies.)

In 2016–17, aesthetics continued to be a therapeutic area of great interest to dealmakers, underscoring the demand for revenue that falls outside payer-dominated reimbursement channels. After posting seven straight years of double-digit revenue growth, medical aesthetic player Cynosure, for instance, was acquired by Hologic in a February 2017 transaction valued at US$1.7 billion.

US M&A by year

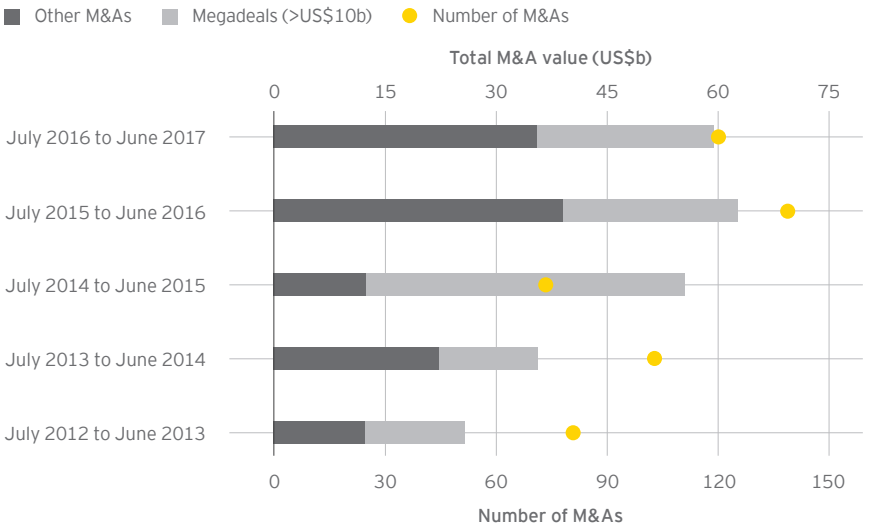


Chart includes all deals with disclosed values where the seller is headquartered in the US.

Source: EY, Capital IQ and Thomson ONE.

In 2016–17, aesthetics continued to be a therapeutic area of great interest to dealmakers, underscoring the demand for revenue that falls outside payer-dominated reimbursement channels.

Europe bounces back

Acquisitions of European medtechs rebounded nicely during 2016–17. In addition to the Essilor/Luxottica megadeal, the region saw nearly US$15 billion worth of additional M&A over the 12 months that ended 30 June 2017. In all, the total value of M&A in Europe surged 613% from US$5.6 billion in 2015–16 to US$40 billion in 2016–17. Though non-megadeal M&A jumped 164% over last year, it remained below the category's high point in 2014–15.

As in the US, deal volume actually dropped year-on-year, with 69 deals during 2016–17, below the prior four-year average of 72. But average deal size rocketed 254% to US$219 million, thanks in part to three non-megadeals valued more than US$1 billion. (In 2015–16, none occurred).

Medtronic's move to Ireland following its acquisition in 2015 of Covidien helped to increase Europe's 2016–17 tally, as the US$6.1 billion sale of its medical supplies business to Cardinal Health ranked behind Essilor/Luxottica as the continent's second-largest deal. Svenska Cellulosa's US$3 billion BSN medical acquisition and PerkinElmer's US$1.3 billion acquisition of Germany's Euroimmun followed. Euroimmun helps PerkinElmer further scale in the in vitro diagnostics area, with new offerings in autoimmune and allergy diagnostics, as well as add products in infectious diseases, where PerkinElmer was already active.

European M&A by year

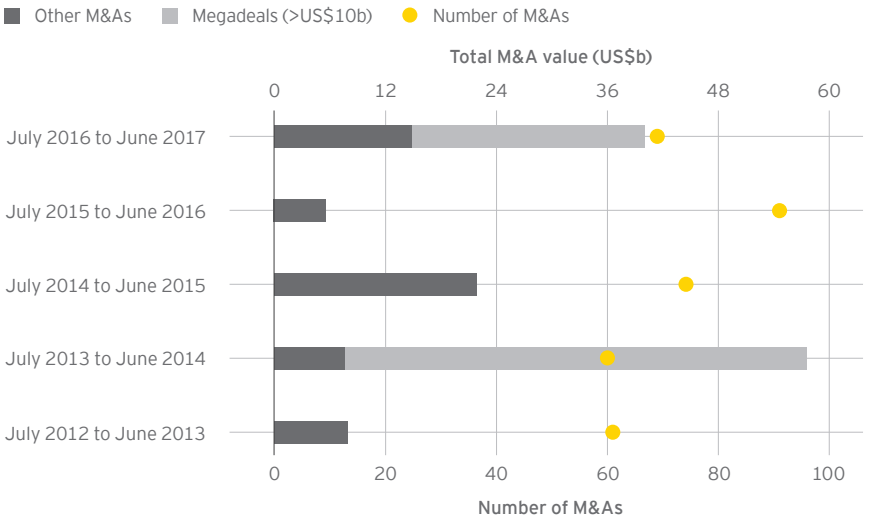


Chart includes all deals with disclosed values where the seller is located in Europe.

Source: EY, Capital IQ and Thomson ONE.

Capital flowing East to West

As measured by total deal value, Asia-Pacific-based buyers of medtech assets were less active in 2016–17 than the prior 12 months, with dollars spent declining 54% year over year. Still, at US$4.1 billion, the sum easily surpassed the previous nine-year average. What's more, the US$2.8 billion spent by Asia-Pacific buyers on Western medtech assets was up 177% over the prior period and the most spent in five years, illustrating the increasing flow of capital from East to West. This phenomenon is not restricted to medtech assets. As discussed in Beyond borders: staying the course, buyers in Asia are increasingly interested in extracting value from life sciences assets around the world.

In 2016–17, there were 96 deals featuring Asia-Pacific buyers with announced terms, of which 33 deals were for US or European assets. In this subset of deals, the top transaction by dollar value was Japanese-based Terumo's US$1.1 billion acquisition of certain vascular closure products from St. Jude Medical, a deal prompted by the latter company's acquisition by Abbott the prior year.

Chinese buyers were particularly active, announcing 47 deals worth a total value of US$1.7 billion in 2016-17. Nearly US$500 million of this M&A total was deployed to buy US or European companies. Among the cohort's largest deals, China-based private equity firm Cathay Fortune International acquired German diagnostics company Epigenomics, the maker of a blood test that detects colorectal cancer, for US$186 million.

Even as capital flowed from East to West to support medtech acquisitions, no corresponding cash flowed in the opposite direction. Indeed, US and European medtech buyers were quiet in 2016–17, announcing only US$36 million in medtech purchases in the Asia-Pacific region. This dearth of deals is at odds with expectations from industry analysts, who forecasted a dealmaking land grab following Medtronic's 2012 acquisition of China Kanghui Holdings for US$816 million.

Swiftly changing reimbursement regulations in the region, geopolitical uncertainty and more attractive opportunities closer to home – or some combination of all three – may have resulted in the current lack of interest from US- and EU-based medtech buyers. Regardless, for now it seems most Western-based medtechs prefer to use alliances and joint ventures, not acquisitions, to build capabilities in a region that will eventually become important for future growth.

Medtech M&As with Asia-Pacific buyers

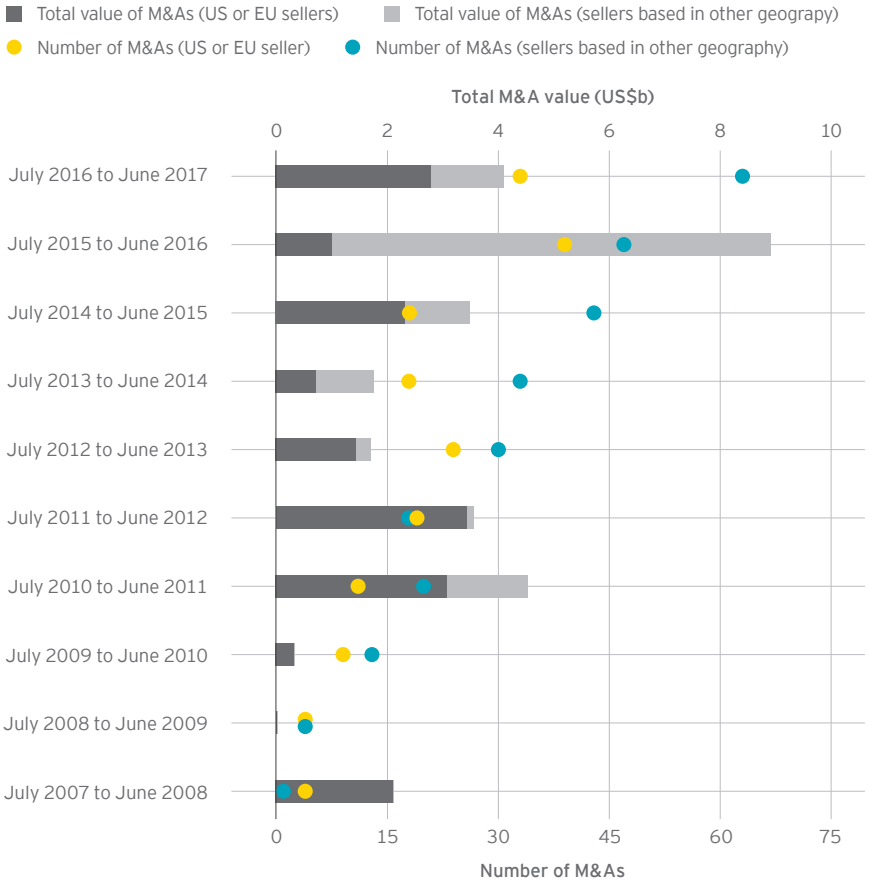


Chart includes all deals (including the deals without value) where buyer is from APAC region, and either the buyer or seller company is medtech.

Source: EY, Capital IQ and Thomson ONE.

Questions for medtech companies to consider

If you're a buyer in a seller's market, how do you get a good deal?

When everyone else is buying, could selling be your smartest move?

When valuations are high, what deal structures create long-term value?

As industries converge, what steps must you take to be the partner of choice?

Guest perspective

Looking beyond China to create a global IVD company

Richard
Ding

CEO
Shanghai Kehua Bio-Engineering (KHB)

Diagnostics is the gatekeeper for health care, enhancing the ability to diagnose disease — and even predict outcomes — with accuracy and efficiency. China is a large and fast-growing in vitro diagnostics (IVD) market — in fact, only second to the US in size. Historically, large multinational corporations have dominated IVD sales in China; today, domestic companies — KHB being one of the largest — are now gaining market share.

Building on our success in China, KHB wants to expand its geographic footprint to capture value for the global IVD market. To jump-start our global ambitions, KHB is currently focused on using alliances and acquisitions as a critical mechanism for adding geographic reach as well as technological capabilities.

In December 2015, we announced our first major acquisition outside of China, purchasing Technogenetics (TGS), an Italian diagnostic maker focused on immunodiagnostics. The assets and know-how from the transaction strengthen our R&D and technical capabilities, particularly in the area of diagnostics for infectious and autoimmune diseases. It also marks our first step to establish a commercial network in the complex but attractive European market.

Our growth strategy is currently focused more on acquisitions than alliances. That's because acquisitions provide a more direct route to building our portfolio of products and capabilities and expanding our network.

It's also about ownership and efficiency — with acquisitions you can control how you build your commercial strategy and own the two-way transfer of knowledge and R&D capabilities.

You also aren't limited by market or product exclusivities, which can be an issue when licensing a product in a given territory or region.

As other China-based companies look to expand globally, they must first take a step back and understand their core competencies. Building on these successes, they must take the time to clearly define objectives and a strategy for international expansion that utilizes the knowledge and experience of local advisors. Creative financing for acquisitions may need to be considered as well. In the past year, there seems to be increasing pressure from the government in foreign currency outflow.

Long-term planning is also essential. For KHB, preparation for the TGS acquisition began years before the actual transaction took place. As we outlined our growth strategy, we developed a wish list of features we were looking for in acquisition targets. Critical factors we weighed as part of our decision-making process included the size of the company, the scale of its operations, its location, and its portfolio of products and capabilities.

We continue to actively look for additional deals outside China, but with an eye to balancing what is best for the market and our business in the short term against where we need to invest for the long-term sustainability of our company.

We're building a culture, we're building a product portfolio, and we're building commercial channels that I believe give us the best foundation for sustainable growth on the global stage.

Shanghai Kehua Bio-Engineering (KHB), which was founded in 1981 and went public in 2004, is one of the first in vitro diagnostics companies in China. It develops, manufactures and markets a range of IVD products and is a global supplier of tests to international health agencies such as the World Health Organization.

As other China-based companies look to expand globally, they must first take a step back and understand their core competencies. Building on these successes, they must take the time to clearly define objectives and a strategy for international expansion that utilizes the knowledge and experience of local advisors.

Appendix

Scope of this report

Defining medical technology

Except as otherwise noted, medical technology (medtech) companies are defined for this report as companies that primarily design and manufacture medical technology equipment and supplies and are headquartered within the United States or Europe. For the purposes of this report, we have placed Israel's data and analysis within the European market. The "global" data represent combined metrics from US and European medtechs. Our definition of medtech is wide-ranging and includes medical device, diagnostic, drug delivery and analytical/life sciences tool companies, but excludes distributors and service providers, such as contract research organizations or contract manufacturing organizations.

By any measure, medical technology is an extraordinarily diverse industry. While developing a consistent and meaningful classification system is important, it is anything but straightforward. Existing taxonomies sometimes segregate companies into scores of thinly populated categories, making it difficult to identify and analyze industry trends. Furthermore, they tend to combine categories based on products (such as imaging or tools) with those based on diseases targeted by those products (such as cardiovascular or oncology), which makes it harder to analyze trends consistently across either dimension. To address some of these challenges, we have categorized medtech companies across both dimensions — products and diseases targeted.

All publicly traded medtech companies were 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

In addition to product groups, this report tracks conglomerate companies that derive a significant part of their revenues from medical technologies. While a conglomerate medtech division's technology could technically fall into one of the product groups listed above (e.g., GE Healthcare into "imaging" and Allergan into "therapeutic devices"), all conglomerate data are kept separate from that of the non-conglomerates. This is due to the fact that while conglomerates report revenues for their medtech divisions, they typically do not report other financial results for their medtech divisions, such as research and development spending or net income.

Foreign exchange rates converted from local currencies to US dollars are calculated on a blended annual rate.

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
- GE Healthcare
- IDEX: Health & Science Technologies
- Johnson & Johnson: Medical Devices & Diagnostics
- Pfizer: Infusion Systems

Europe

- Agfa HealthCare
- Allergan: Medical Devices
- 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
- Philips Healthcare
- Quantel Medical
- Roche Diagnostics
- Sanofi: Genzyme Biosurgery
- Semperit: Sempermed
- Siemens Healthineers
- Smiths Medical

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Project leadership

Ellen Licking, EY Life Sciences Senior Analyst, was the managing editor for *Pulse of the industry*. Taking a hands-on approach, she was responsible for content development, including the creation of the *Year in review* article and the guest articles and EY perspectives.

Chris Morrison, Senior Contributing Writer, helped develop the overall story line and was responsible for writing the three *Industry performance* articles. **Susan Lavin Jones** and **Ginni Wadhwa** also made important contributions to the report, respectively shaping two of the perspectives and providing analysis and commentary for the *Year in review*.

Jason Hillenbach was the report's project manager, with direct responsibility for all data and trend analysis, research and the overall quality of this publication.

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Jason Hillenbach, **Kim Medland** and **Tanya Mehra** conducted fact-checking and quality review of the numbers presented throughout the publication.

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Kevin Daniels was the report's copy editor. **Troy Smith** was the report's proofreader. **Julie McQueen** provided editing assistance on the *Year in review* article.

Their patience, hard work and attention to detail were unparalleled.

Public relations and marketing

Public relations and marketing efforts related to the report and its launch were led by **Madeleine Lewis** and **Laura Powers**.

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

Our Global Life Sciences Sector brings together a worldwide network of 15,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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