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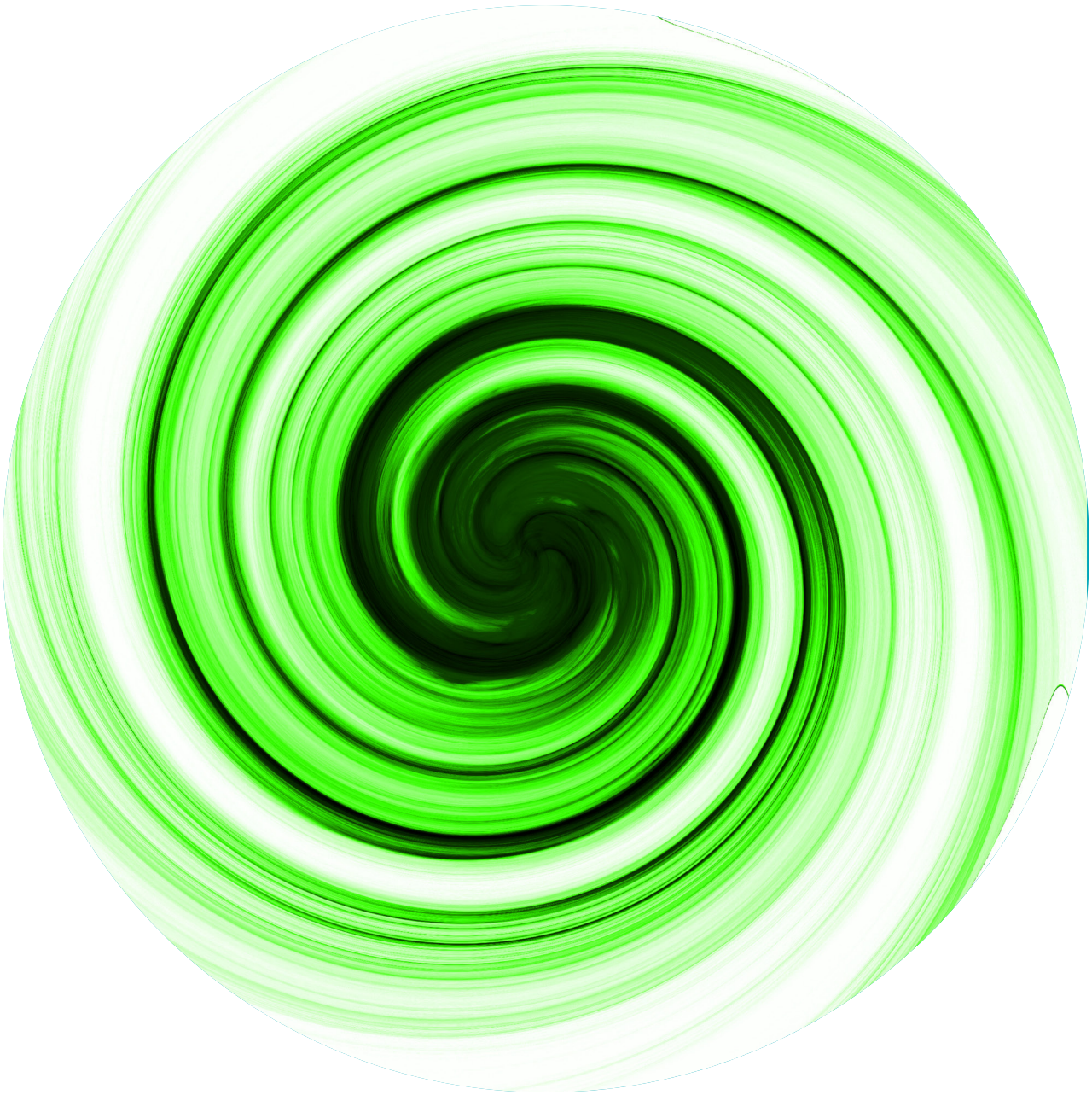
AdvaMed
Advanced Medical Technology Association



Out of the valley of death

How can entrepreneurs, corporations, and investors reinvigorate early-stage medtech innovation?

Dear colleagues:

We have been tracking a worrying trend: Investment and startup activity in medtech has been declining, putting future innovation at risk. This was among the findings of AdvaMed-supported research released last fall.[1] If the medtech industry is to continue to deliver innovative, effective, and lifesaving new treatments and technologies, this trend should be addressed. Importantly, AdvaMed and Deloitte have worked together to uncover strategies and solutions that could help turn the tide.

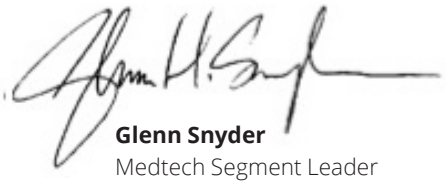
Together we examined data, reviewed literature, and interviewed executives cutting across the medtech innovation ecosystem, including those at well-established global medtech companies, startups and small companies, incubators, and venture funds. We convened a roundtable discussion with these stakeholders in Washington, DC to dive further into the topic and to collectively define recommendations that could promote a robust pipeline of innovation.

We present these recommendations in the following pages. They are organized into two sections: those that help to fix the problem of too little capital finding its way to promising medtech innovation, and those that help to reduce risks of obtaining reimbursement and achieving commercial success.

New ways of collaborating, sharing knowledge, and investing can help medtech overcome its innovation challenges, establish a thriving innovation ecosystem, and help patients live better lives.

We want to thank the many executives, entrepreneurs, and industry leaders who contributed their time, insights, and collaborative spirit to this research. Together we can bridge—in the words of our research participants—the "valley of death" that sometimes lies between life-changing ideas and the bright future for patient care.

Scott Whitaker
President and CEO
AdvaMed



Glenn Snyder
Medtech Segment Leader
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Executive summary

Venture capital (VC) investment in medical technology (medtech) has declined over the past several years, placing the development of lifesaving innovations at risk. Many startup companies are struggling to make it out of the "valley of death," the period between initial investment and creation of a commercially viable product. And while large medtech companies depend on a thriving external innovation ecosystem for acquisition targets and new sources of growth, many shy away from investing in early-stage, unproven technologies.

Financial pressures generated by health care reform, the transition to value-based care, and tougher insurance coverage and regulatory requirements for medtech innovations have deterred some corporate and VC investors. Those who do invest often need to commit more time and money than ever before to mature a startup and, in the end, struggle to realize a meaningful return.

Without sufficient funding, early-stage medtech innovation might not survive and patients might never benefit from potentially lifesaving technologies. Through interviews and a roundtable with more than 20 industry leaders, the Deloitte Center for Health Solutions and AdvaMed sought to define strategies that could reinvigorate early-stage medtech innovation. Our research made clear that two fundamental issues should be addressed: the lack of capital available for early-stage investment, and increased reimbursement and commercialization risks for new products. These two issues are not mutually exclusive. Early-stage medtech companies could benefit from significantly more capital, but investors may be more willing to invest in technologies that can demonstrate differentiated value, quickly gain coverage, be commercially successful, and generate a sufficient return.

To fix the capital problem, study participants suggested that:

- Similar to the biopharma industry, large medtech companies, entrepreneurs, and the venture funds that back them should consider engaging in strategic partnerships, such as co-development, co-marketing, or contingent merger and acquisition (M&A) deals.
- Entrepreneurs should leverage alternative funding sources such as family offices, state programs, and accelerators; and consider investment by non-medtech partners such as providers and technology companies.
- The medtech industry might consider supporting aspects of tax reform that might motivate greater investment in innovation; for example, repealing the medical device excise tax or establishing a federal angel investor tax credit.

To reduce coverage and commercialization risk, medtech entrepreneurs should:

- Develop a more sophisticated understanding of who their customers are, how they define value, and tailor research and development (R&D) plans and value propositions accordingly
- Engage in partnerships with customers who are focused on population health, such as integrated delivery networks and large employers, to co-develop products
- Consider new contracting approaches that allow for market adoption of products and services while real-world evidence (RWE) is still being gathered.

As study participants told us, finding the right opportunity, the right people, and the right partners is essential to finding "the innovation that fits." Indeed, stakeholder collaboration is likely to be the key to ensuring that the medtech industry can continue to deliver lifesaving innovations to patients.

Decline in early-stage medtech investment has begun to threaten innovation

A decline in early-stage investment could put medtech innovation at risk. The proportion of VC investment in medtech companies declined from 13 percent in 1992 to four percent in 2016.[2] Even smaller is the proportion of funding that goes into Series A, the first round of venture capital funds raised by startups. Medtech Series A investments as a percent of total venture investments in the sector declined from 19 percent in 2006 to 10 percent in 2016.[3] This decline is accompanied by rising research costs for innovative products and solutions, resulting in fewer new startups focused on medtech—and fewer lifesaving innovations making it to patients.[4] Meanwhile, without a robust pipeline of acquisition opportunities, large, established medtech companies could face challenges in finding new technologies to fuel future growth.

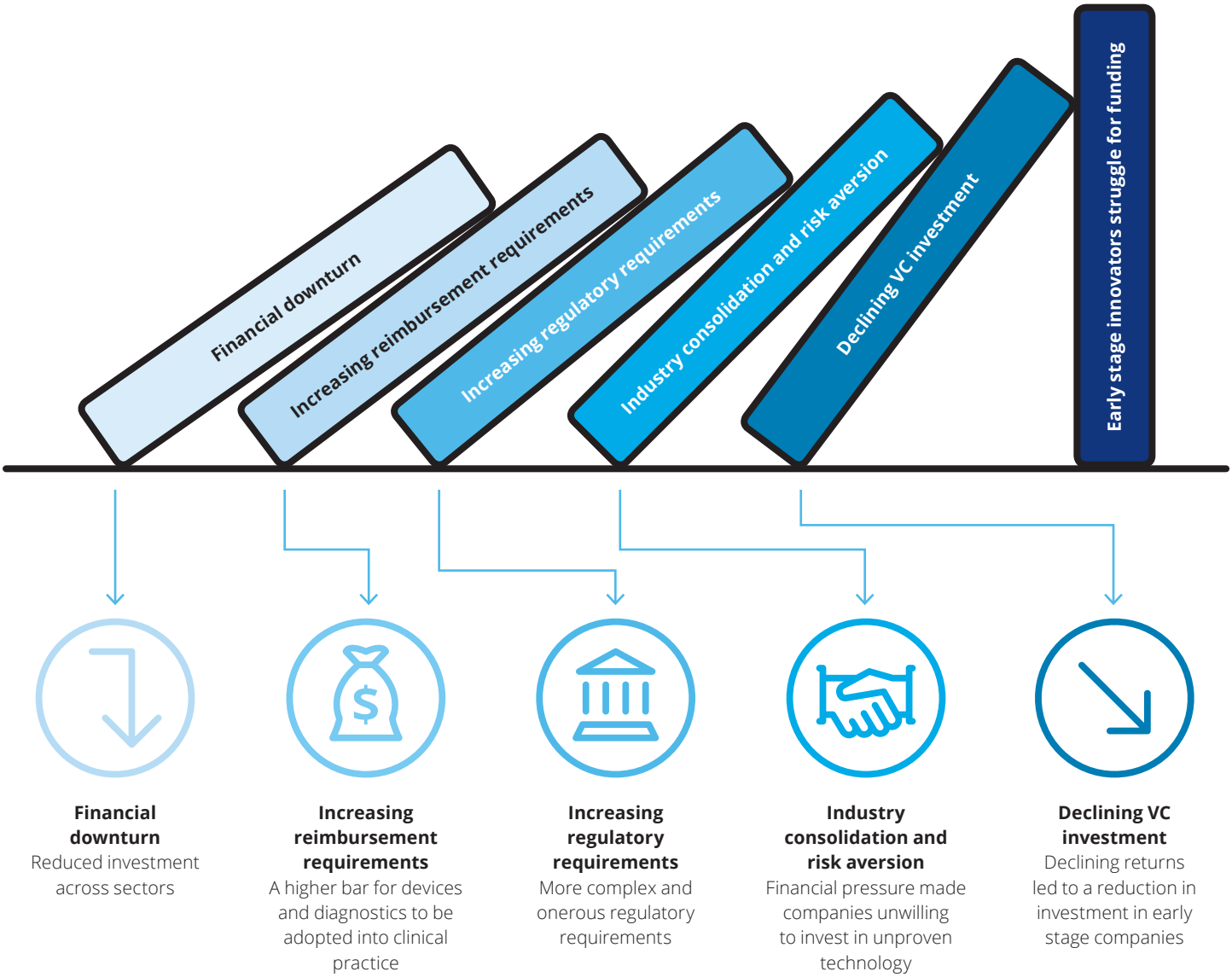
How can large medtech players, startups, investors, incubators, and the government collaborate to advance early-stage innovation? The Deloitte Center for Health Solutions partnered with AdvaMed Accel to answer this question. Together, we interviewed 23 executives from large medtech companies and startups, venture capital funds, and incubators. We then facilitated a roundtable discussion with a similar cross-section of industry experts. During this dialog, we shared findings from our initial interviews, and asked participants to help vet potential solutions. This paper presents these solutions and suggests ways for all stakeholders to work together to reinvigorate the medtech innovation ecosystem.

A decline in early-stage medtech investment in recent years has begun to threaten innovation. How can large medtech players, startups, investors, incubators, and the government better collaborate to significantly advance early-stage innovation?

Market pressures have squeezed early-stage medtech innovation

Executives we interviewed unanimously agreed that future medtech innovation faces some significant challenges. While they did not always concur about the extent of the problem, executives agreed that a decline in early-stage medtech investment is already threatening future innovation. Our research indicates that several factors have produced this worrying decline in investment: the recent financial downturn, increasing regulatory and reimbursement requirements, industry consolidation and shifts in strategic focus, and declining VC funding (see Figure 1).

Figure 1. Medtech innovation at a crossroads



Source: Deloitte Center for Health Solutions analysis

The financial downturn, health care reform, and reimbursement hurdles have created new market pressures. Recent medtech industry funding challenges began with the financial downturn in 2008-2009, according to executives we interviewed. The downturn reduced available VC funding across virtually all industries, including medtech. In 2010, the Affordable Care Act (ACA) was enacted, which placed additional financial pressure on the industry in the form of a 2.3 percent medical device excise tax.

At the same time, the industry was experiencing pressure from a cost-constrained health care system. The ACA served as catalyst for a renewed focus on health care spending and how to manage it. As provider groups and hospitals merged, the decision-making process for purchasing medical devices typically shifted from physicians to hospital purchasing committees.

The ACA, through the creation of the Center for Medicare and Medicaid Innovation (CMMI), also helped accelerated payment reform with new reimbursement models that tie physician payment to the value of services they provide, rather than volume. CMMI has been piloting a number of different value-based payment models, such as accountable care organizations (ACOs) and bundled payments. Notably, many private health plans also have been experimenting with these payment models. This emphasis on value-based care continues to change how physicians and health systems evaluate new medical technology—considering both clinical and economic factors. The shift to a holistic focus on overall value, rather than clinical benefit alone, raises the bar for the adoption of diagnostics and devices created by early-stage companies.

As one VC investor noted, "Payers are pulling back on paying for new things. It is difficult to get new technologies covered. It's taking companies three to five years after Food and Drug Administration (FDA) approval" to collect enough data and go through the processes to obtain coverage following FDA approval.

It is also more difficult and takes longer to receive insurance coding, coverage, and payment for new devices.

Regulatory requirements have increased. Interviewees agree that regulatory hurdles have increased for medtech companies. The FDA has been "getting a lot tougher," one interviewee asserts. But predictability for regulatory approval appears to have improved. FDA's support of the recent passage of the 21st Century Cures Act is indicative of the agency's desire to streamline the medical device regulatory process. Notably, the Cures Act creates a breakthrough pathway for devices that treat life-threatening conditions or impact small populations. The Cures Act also provides more clarity on the regulatory pathway for devices, including updates to devices that will be classified as Class I and Class II.

Global regulatory challenges

Startups historically have sought to market products in Europe before the United States to take advantage of what used to be considered a more efficient regulatory pathway—gaining a CE mark (Conformité Européenne), a conformity marking required for certain products sold in Europe. According to an executive from a small-device manufacturer: "You used to be able to start with the easier pathway in the EU, and then go to the US for the more challenging pathway."

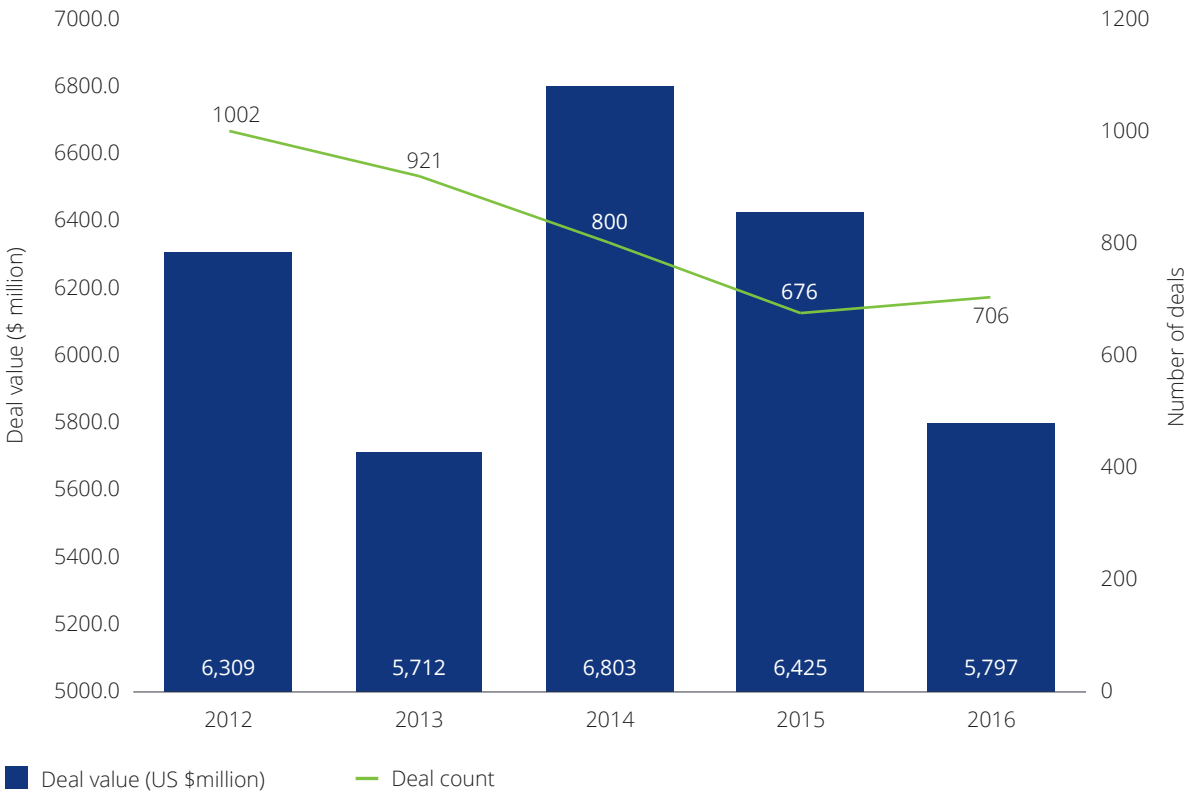
As described in the recent report from the Deloitte UK Centre for Health Solutions, *Preparing for the future: The new European Union medical devices regulations*, these regulations are expected to have a major impact on the medtech industry.[5] The European Union Medical Devices Regulation (EU MDR) and In-Vitro Diagnostics Regulations (EU IVDR) call for large-scale changes to the regulatory approval process, including clinical evidence requirements; third-party pre-market certification; and the processes, partners, and technology needed to meet these standards. The regulations provide harmonized standards and common specifications for all EU member nations, and clearly define roles and responsibilities of all stakeholders. As a result of these changes, some medtech companies may need to review their entire product portfolio and pipeline to determine conformance. Not all products may warrant the investment required to bring them into conformance or to market.[6] Some startup CEOs told us that they are now bypassing European markets altogether, and are instead testing commercial viability in targeted regions in the US.

Many large companies have consolidated and some are avoiding risky investments. Many large, established medtech companies have felt significant financial pressure in recent years. Price competition has escalated,[7] squeezing margins accordingly. Several companies have begun to implement a number of strategies to help them compete more effectively in an increasingly cost-constrained health care market, including consolidation. More than 40 mega-deals (i.e., M&A deals valued at more than $2 billion) helped companies build scale between 2010 and 2016. This consolidation has resulted in fewer large players competing in each major medtech therapeutic market.

Many financially pressured large companies have avoided making risky investments in external innovation. Some interviewees suggest that external investments must now be "accretive on day one," meaning that they either have to be immediately profitable on their own or be "funded" by cuts to other parts of the business, such as R&D. Further, these companies would only consider an external innovation that has been largely or fully "de-risked," which implies that the technology is FDA-approved, has obtained sufficient coverage, and has demonstrated commercial success. Business unit leaders—often tasked with taking ownership of external investments—would have to make tough calls on whether to invest in uncertain innovation or in opportunities that are more closely aligned to short-term business goals.

Venture capital returns have declined. Some VC investors are struggling to realize sufficient returns on medtech investments. The total dollar value and number of deals have been declining in recent years (see Figure 2).

Figure 2. Medtech VC investments have declined by total dollar value and number of deals



Source: Deloitte analysis of Global Data[8] medical device investments in the US

Venture funds that invest in medtech typically realize a return on investment (ROI) once they exit that investment—either when a large company acquires the startup or when the company goes public via an Initial Public Offering (IPO). IPOs are not common in the medical device sector, with only three occurring in 2016.[9] Most funds pursue M&A as a preferred, more viable exit. However, it appears to be taking longer—and is requiring more funding—to get startups to a level of maturity where large medtech companies are willing to consider acquiring them.

Many large companies have decided to acquire startups after or near successful product commercialization. And with only a few major players remaining in each therapeutic market, the number of potential buyers is limited. Silicon Valley Bank (SVB) analyzed large M&A transactions (exits)* for VC-backed companies over the past five years. Of the big M&A exits between 2015 and the first half of 2017, 19 out of 20 510(k) products and 11 out of 17 pre-market authorization products were commercialized at the time of the transaction. Further, the SVB analysis showed that it takes longer to get to an M&A exit. Four out of 13 exits that occurred in 2016 took 10 years or more from the close of Series A funding to M&A exit.[10]

Most venture funds are investing more in existing-portfolio companies to get them closer to acquisition, but this often results in less lucrative returns. Average deal size increased from an average of $6.3 million in 2012 to $8.2 million in 2016, due in part to the larger investment needed to push existing-portfolio companies over regulatory, reimbursement, and commercialization hurdles.[11] The increased capital required to support each company leaves less money to support early investment in future innovation; over time, a constant level of investment by medtech-focused VCs could mean that fewer startups would receive funding. In addition, greater capital investment in each portfolio company is associated with lower returns (see sidebar on the following page), making investment in the sector less attractive overall.

As medtech capital investments increase and returns decline, venture funds are facing increasing pressure from their investors or limited partners (LPs) to put their money elsewhere. As a result, many medtech-focused venture funds are shifting new investment dollars to more lucrative sectors such as biopharma and health IT.

Many large companies have decided to acquire startups after or near successful product commercialization. With only a few major players remaining in each therapeutic market, the number of potential buyers is limited.

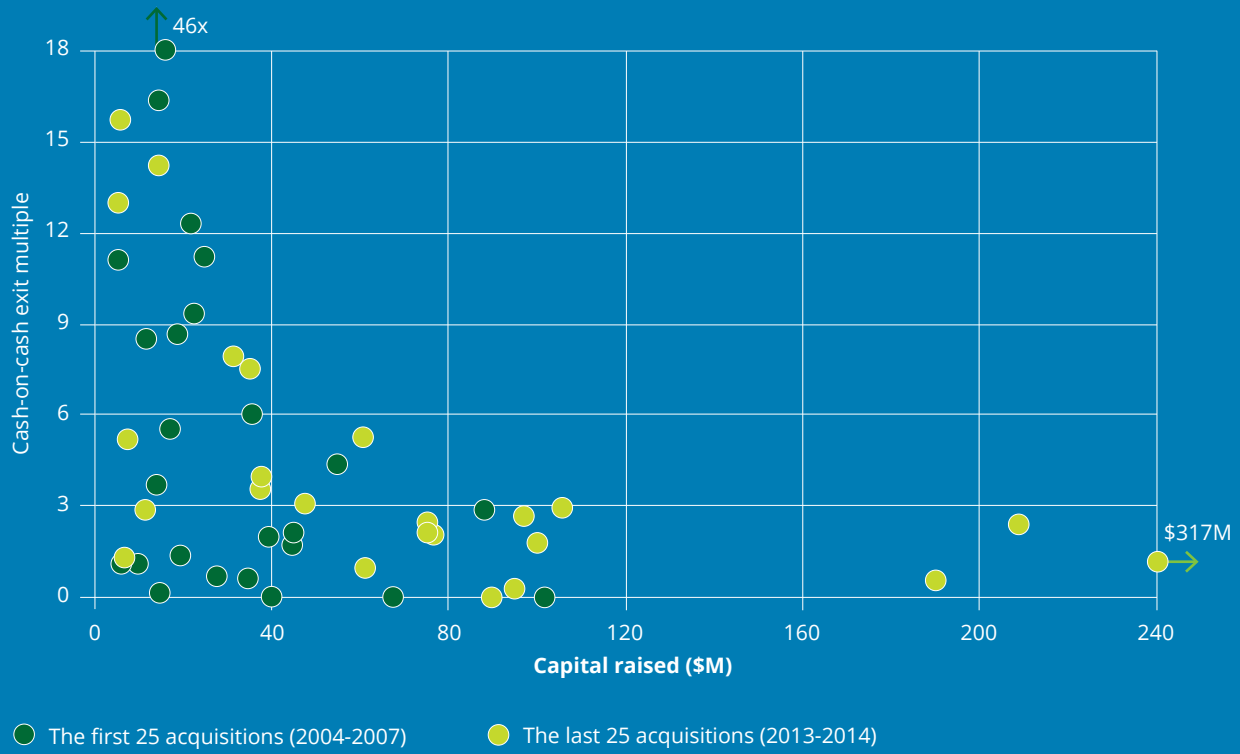
* According to Silicon Valley Bank, a "big exit" for medical device and diagnostics/tools is a private, venture-backed M&A transaction in which the upfront payment is $50 million or more for device and diagnostics/tools.

Venture funds are investing more, but making less in medtech

Aaron Sandoski, co-founder and managing director of Norwich Ventures, evaluated returns as cash multiples against total capital invested for VC-backed M&A exits between October 2004 and October 2014[12] (Figure 3). His analysis determined that medtech startups that raised more than $40 million saw lower returns to venture funds than those where less than $40 million was invested. He also found that there has been a trend in investments that exceed $40 million and, as a result, venture funds are realizing lower returns. The first 25 deals in the analysis, which occurred between 2004 and 2007, raised an average of $32.2 million and had a multiple of 4.1x. The 25 deals that took place more recently—between 2013 and 2014—raised an average of $73.5 million but averaged a multiple of only 2.3x. The increase in funding required to get a company far enough along to exit, along with the lower returns (multiples), illustrates the challenge facing many medtech-focused venture capital investors.

Our roundtable participants suggest that these lower returns could be due to the fact that investment made during late stages often goes toward building commercialization capabilities (such as building a sales force), which are not always considered valuable in an M&A deal. While large companies may be interested in buying revenue from new products that have demonstrated commercial success, they are not necessarily interested in the commercial infrastructure that comes with it.

Figure 3. Medtech investment returns compared to capital raised



Source: Pitchbook, Norwich Ventures analysis

Many entrepreneurs are struggling to obtain early-stage financing. As VC investors stray from making new medtech investments, some entrepreneurs are struggling to attract early-stage funding. Many of the entrepreneurs we interviewed pointed to the first round of venture investment, or Series A, as particularly challenging. To illustrate, Series A investments as a percent of total VC investments in medtech declined from 19 percent in 2006 to 10 percent in 2016 (Figure 4).

Many medtech entrepreneurs also are facing new challenges in developing their business plans, which makes it more difficult to obtain funding. A business development executive from a large medtech company noted that early-stage companies might "put lots of weight on building clinical evidence but relatively less on areas of importance to strategic buyers, such as ability to build manufacturing scale, reimbursement strategy, and a compelling economic value proposition." Most of today's investors want to know much earlier in the development process how the technology will be reimbursed and be commercially differentiated. In response, entrepreneurs are expected to demonstrate a sophisticated knowledge of their customers—patients, providers, and payers—and explain how they will navigate the potentially years-long process of obtaining coding, coverage and, eventually, payment for their product. This often means generating additional evidence early in development that demonstrates improved outcomes at a lower cost.

Figure 4. Series A investments have decreased as a percentage of total VC investments

Source: Deloitte analysis of Global Data medical device investments in the US

While funding has declined, innovation has not

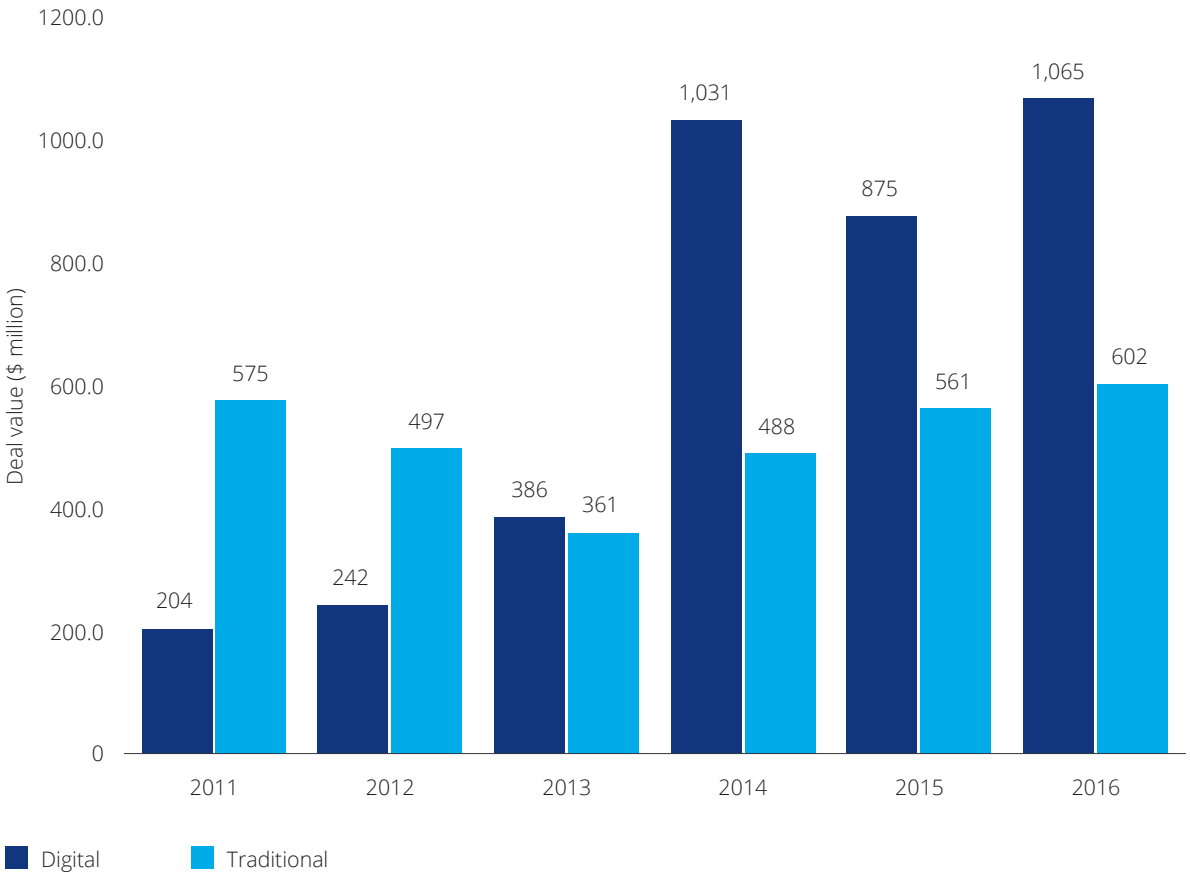
"There's no lack of great ideas....I see 20 different companies a week. It's not an innovation problem."

—Venture capital investor, roundtable participant

Fueled by exponential advances in technology, medtech is ripe for innovation. More and more devices are becoming "smart" and connected. Sensors can monitor the effectiveness of devices, and wireless technology can share data with patients and providers to indicate when intervention is needed. Sensors and other digital health technologies—wearables, telehealth, and advanced analytics, among them—are converging with medtech to create innovative products and new business models.

Digital health technologies also are attracting more venture capital investment than traditional medtech in Series A (Figure 5).

Figure 5. Series A investments in digital health outpace traditional medtech



Source: Deloitte analysis of Global data and Rock Health

The convergence of digital and medtech is spurring new types of organizations to invest in the sector, including health care providers and consumer technology companies. Case in point: among the top 15 corporate investors in medtech over the last 10 years are Kaiser Permanente, Ascension Health, Amazon, and Google.[13] One medtech investor noted that "innovation in the industry is likely to continue to come externally. Not just startups, but companies outside of health care looking at how their capabilities fit inside of health care."

Nontraditional investors such as consumer technology companies can bring technological expertise to medtech startups as well as a focus on the consumer. "Their predisposition is starting with the consumer and understanding their behavior and what they can do to drive the consumer to their platform. Medtech companies start with a disease state and a product as opposed to a consumer." By partnering with consumer technology companies, medtech players can add digital, design, and marketing prowess to their own regulatory knowledge, health care industry experience, and credibility with clinicians.

From our research, it is clear that two fundamental issues are facing the medtech industry: the lack of capital available for early-stage investment, and the increased reimbursement and commercialization risks for new products. These issues are not mutually exclusive. Early-stage medtech companies could benefit from significantly more capital, but investors may be more willing to invest in technologies that can demonstrate differentiated value, quickly gain coverage, be commercially successful, and generate a sufficient return.

Partnerships with large medtech companies, alternative funding sources, and tax policy changes could help solve early-stage innovation's financing problem

Increasing the financing available to early-stage companies is a critical component to advancing medtech innovation. Interviewees say that additional funding could come from non-VC sources, primarily large, established medtech companies. Consider the following:

- Large companies would benefit from a robust, early-stage medtech innovation ecosystem, as it provides opportunities to acquire new products and services that could anchor a growth platform.
- Large companies could help shape the development of innovation and reduce financial risk by engaging in strategic partnerships.
- The cost of capital for large medtech players is typically much lower than for VC investors, which need to generate returns of at least 20-30 percent to continue to attract funding. In contrast, many large medtech companies have costs of capital in the high single digits, as well as generally strong balance sheets and ready access to capital.

Interviewed VC and business development executives suggested that investment by large medtech companies is likely to make the biggest impact in advancing early-stage innovation, but that alternative funding sources and tax policy changes could also play a role.

By partnering with consumer technology companies, medtech players can add digital, design, and marketing prowess to their own regulatory knowledge, health care industry experience, and credibility with clinicians.

Strategic partnerships could be a win-win for large companies and startups

Business development executives suggested that large medtech companies could engage in strategic partnerships with startups as a way to access and fund early-stage innovation. Historically, large companies have accessed external innovation primarily through acquisition, usually after the target company has received regulatory approval or payer coverage. Alternatively, a strategic partnership could involve some financing, shared incentives and expertise, and an option to acquire the startup once certain milestones have been achieved.

Strategic partnerships vary in type and scope (see sidebar), depending on the innovation's development stage and the startup's goals. Early on, startups may look to large companies for capital to continue development of a promising technology. As the startup matures, it may approach large companies for funding and capabilities to bring products to market—including sales and marketing skills and global reach. This later-stage partnership could potentially help startups avoid building a costly infrastructure that, in the event of a future acquisition, might prove duplicative.

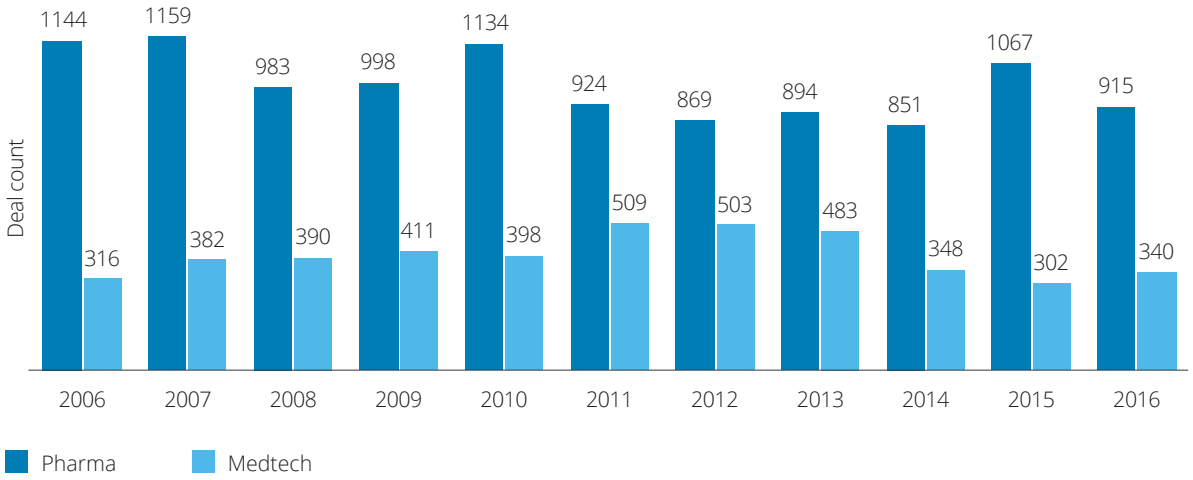
These types of strategic partnerships are common in biopharma, but not medtech. Why? Roundtable participants said it could be due to biopharma's more predictable R&D process, along with more corporate willingness to take on risk. In biopharma R&D, well-defined value inflection points can be tied to development milestones. In medtech, by contrast, the development process can vary and be iterative. In addition, biopharma companies generally are also more comfortable accepting the high risk associated with R&D: they tend to invest with the understanding that not all partnerships will lead to a successfully marketed product. Some medtech companies, however, prefer to wait to invest until successful product commercialization.

Strategic partnerships can take different forms:

- **License agreement:** One party gives another party the rights to use its technology, intellectual property (IP), and brands in their business and operations.
- **Co-marketing:** Two or more companies jointly market each other's products. Each company's team shares sales responsibility, and typically splits roles by market geography or customer type. The companies do not create new products, services, or brands.
- **Co-development:** Two or more companies jointly develop a product, technology, or service.
- **Joint venture (JV):** Two or more parties form a legal entity to undertake economic activity together. The parties agree to create a new entity by contributing equity and/or assets. They share revenues, expenses, and control of the enterprise. The venture can be dedicated to a specific project or it can be an ongoing business relationship.

Some large medtech companies are starting to experiment with strategic partnerships (see case study on the following page), but the level of partnership activity does not compare to that in biopharma (see Figure 6). There has been a noticeable decline in medtech co-marketing partnerships over the last ten years, suggesting that startups are increasingly left to commercialize products on their own. There has, however, been an uptick in medtech co-development partnerships over the past decade (see Figure 7). While the increase in co-development partnerships might suggest that the landscape is changing, the majority has been focused on diagnostics and health IT rather than therapeutic devices (see Appendix A).

Figure 6. Biopharma has almost three times the partnership activity as medtech



Note: Strategic alliances include JV, co-development, co-marketing, and licensing deals
Source: Deloitte analysis of Global Data

Figure 7. Medtech co-marketing partnerships are declining and co-development partnerships are increasing

Source: Deloitte analysis of Global Data

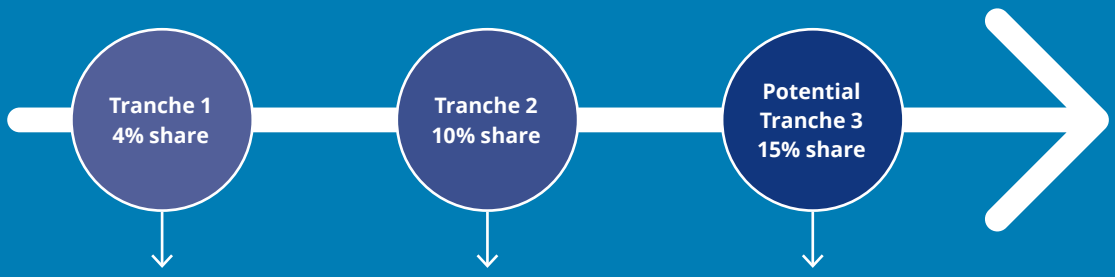
Case study: Global medtech manufacturer partners with small company to co-develop and co-market innovative surgery systems

Recently, a global medtech manufacturer and a small company entered into a two-stage strategic partnership for the co-development and worldwide marketing of the small company's innovative surgical systems.

- **Stage 1:** In the United States, the two companies are co-developing synergistic products and applications and are working together to meet designated sales targets. The small company added representatives from the global medtech manufacturer to its own sales force, who have been raising awareness about the product surgical systems among US surgeons. Additionally, the companies have jointly invested in co-marketing and promotion efforts
- **Stage 2:** If certain sales targets are met by the end of 2017, the agreement will enter the second stage, in which the global medtech manufacturer assumes exclusive global rights for the sale and distribution of the systems. The agreement also includes quotas for the global medtech manufacturer to purchase set numbers of the systems between 2016 and 2020.

Simultaneously, the global medtech manufacturer entered into an agreement to buy an equity stake in the small company (see details below). This investment structure enables the larger company to raise a significant stake in the small company while keeping the investment on its balance sheet and off profit and loss (P&L) reports.

Global medtech manufacturer to make three tranches of equality investment based on achievement of certain milestones



Tranche 1—Invested $11.9M
Equity investment in newly issued securities of small company by global medtech—no milestones

Tranche 2—Capped at $10M (+6% share)
Equity investment to buy newly issued shares of startup based on operational milestone achievement

Tranche 3—Capped at $10M (+ 5% share)
Equity investments based on achievement of a global distribution agreement and certain milestones. Investment at the discretion of small company

A focus on build to buy

Roundtable participants also talked about equity investments with an option to acquire, or "build-to-buy" models, as a way for large companies to invest in startups earlier and help shape product development. Large companies would make an equity investment, take an ownership stake, and retain an option to buy the company if certain milestones are met. These equity investments could be made alongside venture funds' investments (see sidebar). Such models would allow for early partnerships and a closer goal alignment.

"Build-to-buy" in biopharma: A model for medtech?

Early investment with the option to later acquire is a common strategy in biopharma. Below are two examples of how such deals can be structured.

Biopharma company and venture capital fund builds alliance to finance multiple early-stage biopharma startups
Applying a "build-to-buy" strategy, a global biopharma company allied with a venture capital firm in 2013 to invest close to $500 million to launch multiple life science startups over a short time frame. In exchange for its investment, the biopharma company holds the option to acquire these startups upon reaching pre-determined milestones.

The startups are housed at an incubator facility, where each startup receives operational support and benefits from a fully equipped R&D facility and a leadership team. The alliance is leveraging the venture capital firm's experience working with academic scientists and the biopharma company's R&D expertise, which can aid in building early-stage startups.

Within three years the partnership had launched several startups, two of which had identified paths to potential drug application.

Biopharma company makes a Series A investment in startup with an option to acquire
In 2014, a biopharma startup focused on developing treatments for a neurological disorder secured a Series A investment commitment worth nearly $20 million from a global biopharma manufacturer and a biopharma-focused venture capital firm. The startup's early-stage research could also hold the key to treating related neurological conditions.

In addition to the Series A investment, the global biopharma manufacturer provided non-dilutive R&D and other funding to the startup with the option to acquire. Acquisition terms were pre-negotiated, with the startup set to receive upfront and milestone payments upon successful completion of phase 1 studies.

Corporate venture capital takes center stage

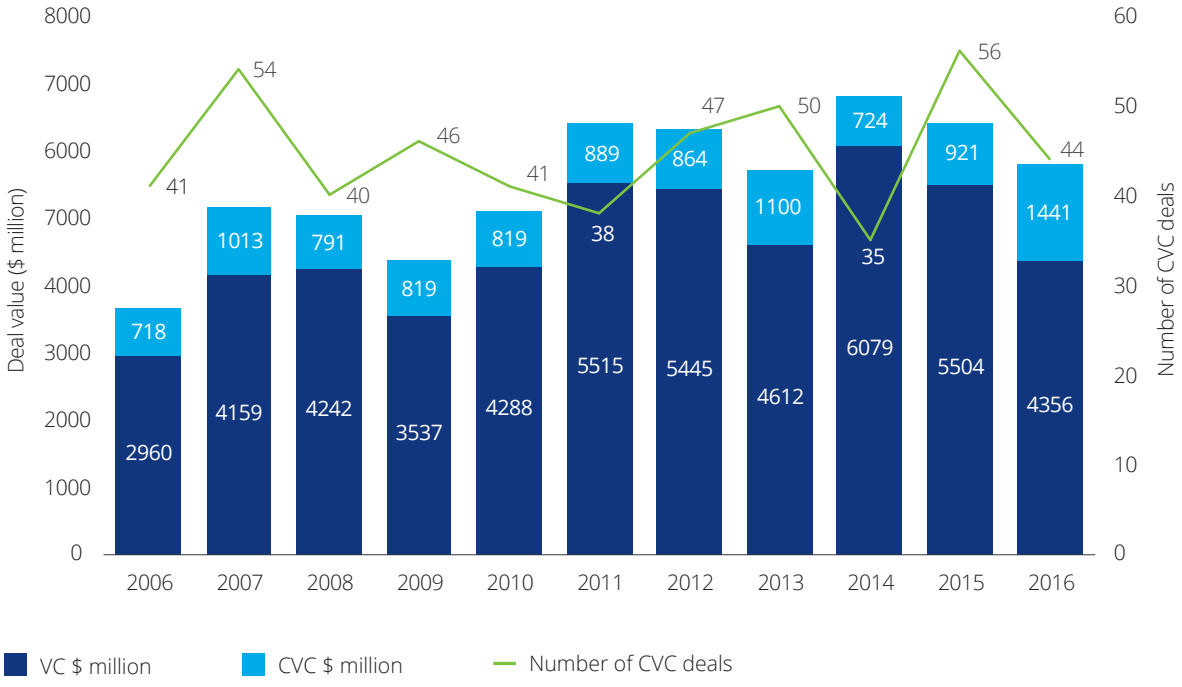
Some medtech companies are making equity investments in pre-revenue companies, often through internal venture groups or Corporate Venture Capital (CVC). CVC funds at large medtech companies most often invest in companies that align with their strategic objectives.

CVC investments rose in 2016—and increased as a percentage of total VC funding—but CVC deal volume has stayed relatively flat over the past decade (see Figure 8). Average deal value increased to $34 million in 2016, and the majority of CVC funding continues to help more-established companies achieve regulatory, reimbursement, and commercialization goals.

Interviewees cited greater CVC funding as a way to advance early-stage innovation. According to a CVC investor at a large medtech company: "Corporate investors can take more risk, given the lower cost of capital. It's more important to us to have a continuous pipeline of innovation, across organic and inorganic approaches. We need a rich, diverse pipeline to provide for a successful future."

Interviewees also remarked that CVC is the preferred avenue for making equity investments compared to working through other parts of the business. CVC funds can take a portfolio approach rather than focus on one particular investment at a time, and spread risk across several investments. Further, if strategic priorities change down the road, and acquisition is no longer desirable, CVCs are in a better position to generate a return on the investment.

Figure 8. Corporate venture capital investments comprise a significant portion of overall VC investment, but their focus is on bigger, later-stage investments



Source: Deloitte analysis of Global Data

Why aren't large companies investing more or engaging in strategic partnerships with small companies?

Large medtech companies stand to benefit from increased early-stage investment in and partnership with external innovators, and while some companies are getting more creative with deal structures, we have yet to see much of this activity in the market. Why? Our interviews pointed to the following potential operational barriers:

Accounting impacts: Taking an ownership stake in a small company triggers an accounting change for the large company that could negatively impact its income statement, which many companies would like to avoid. As a result, large companies that participate in early rounds of investment might be unable to participate in later rounds because additional investment would accrue a bigger ownership stake. This self-imposed limitation typically results in large companies investing later, when the small company has been de-risked and is closer to product commercialization.

Difficulty aligning financial incentives: The medtech product development process can vary and is often iterative, making it difficult to determine key milestones that would be tied to additional payments or increased ownership control. For example, there have been challenges in using earnouts, a structure intended to mitigate financial risk in M&A transactions. Earnouts set post-acquisition financial targets for the seller that would trigger additional compensation. One business development executive talks about how in the past, some small companies were not able to meet these financial goals and, therefore, payments were not made. In many cases, each party blamed the other for the miss. One way to potentially overcome these misalignments is to define milestones thoughtfully and realistically, and include the business leader responsible for managing the transaction in milestone-setting discussions.

Another hurdle that large company business development executives may face is securing an internal champion for white space or emerging opportunities.

Misaligned incentives within the large company: Corporate business development teams may view external innovation as a top priority, while business unit leaders may see it as less important. Several executives we spoke to from a large company described "not invented here" syndrome, which refers to the phenomenon where internal teams perceive products invented externally to be of lower quality than those developed internally. Some teams within the business units might see newly partnered or acquired innovation as a threat to existing products or R&D investments. As a result, internal teams may not commit the same level of time and effort to make sure that programs sourced externally are as successful as those developed internally.

Organizational structure: Another hurdle that large company business development executives may face is securing an internal champion for white space or emerging opportunities. Many large companies are organized by business units, each with specific goals. This structure does not allow much flexibility to change focus or goals as market needs change. It also makes it difficult or even impossible to identify someone to champion business-building ideas that exist outside the established structure. Lacking a champion, those ideas are likely to wither and die. Furthermore, leadership turnover within business units can pose a challenge, since champions may change roles or leave the organization entirely.

Lack of dedicated resources: One large company business development executive describes a lack of internal resources as a common reason for post-transaction deal failure. During the diligence process, this executive says, it is critical to gain an understanding of the key risks associated with a specific program. Once there is a commitment to move forward with an investment or a deal, the company should dedicate the internal resources needed to reduce those identified risks. If the large company does not commit to de-risking the program alongside the small company, there can be greater potential for failure.

Recommendations to increase large companies' innovation investments

Ramping up investment by large companies in early innovation will require organizations to align internally around inorganic innovation goals, and create a process to seamlessly transition transactions from business development into business units. Interviewed business development executives from large companies proposed that such organizations should:

- **Secure top-down commitment.** The CFO could set capital and P&L budget aside to invest in external innovation, and be willing to take on long-term investments in innovation that is attractive but may not yet be accretive. In addition, the executive team should encourage corporate development, business development, and CVC teams to enter into structured financing deals with early-stage companies. External innovation should be a corporate goal that starts at the top and trickles down through the organization (see case study: a corporate innovation incubator).

- **Identify a champion in the business units for each investment.** Given the potential for leadership turnover, it may make sense to find multiple champions who recognize the value a new technology or company could bring. Without a committed champion, the investment, partnership, or acquisition likely will not move forward. One business development interviewee suggested that this can be one of his biggest challenges—even more than gaining alignment with the target company's management team.

- **Engage functional experts early in the diligence process to help evaluate early innovation and generate buy-in and support.** One interviewee suggested targeting business unit team members who have a passion for and business goals targeted at innovation. Also, closely manage diligence requests so that business unit team members' efforts do not exceed one-to-two hours a week over a few months. Further, functional experts could serve as mentors to startups to help shape product development toward mutually beneficial goals. Co-location of internal experts and external innovation teams can bring greater collaboration and idea-sharing (see case study on the following page).

- **Consider pilots to minimize risk.** One business development executive referenced executing pilots to test promising innovation or address a potential market need. For example, technology with a patient engagement focus could be tested with consumers. The large company typically finances the pilot and holds the rights to acquire the small company pending a successful outcome.

- **Transition innovation to the business units when it is ready.** Deals should not be thrown over the fence from business development into the business units without careful planning and buy-in from the internal resources responsible for making the new technology a success. One roundtable participant cited the challenges of integrating a new product into the existing commercial organization, where metrics do not yet reflect product sales goals. The company built a dedicated business accelerator to focus on supporting the product until it could be fully integrated into the commercial team's portfolio and goals.

Business development executives also talked about structuring deals with external partners in a way that aligns incentives across both organizations. Specifically, they suggest that companies:

- Emphasize pre-deal diligence to identify the key risks of the partner or target company. Such risks vary by company and may include technical, regulatory, insurance coverage, commercialization, or management risk.

- Structure the deal around critical milestones that would mitigate the identified key risks.

- Identify and dedicate the right internal resources to pair with the partner or target company to help mitigate risks during diligence and afterwards. Make certain that business leaders responsible for the transaction's success are included in discussions of deal terms.

- Align both companies on the value each is bringing to the table to advance the product.

Case study: A corporate innovation incubator as a model for commitment to external innovation, mentorship, and co-location

Many interviewed executives cited corporate innovation incubators as a potential model for a large company supporting external innovation.

Recently, a global medtech company announced a program to leverage external innovation by providing space, mentorship, and infrastructure (including equipment), to startups with potentially breakthrough ideas. The model stops short of promising investment beyond the initial support, but allows startups tools with which they can develop both their technology and the industry relationships necessary for eventual commercial success.

Executives point to three reasons why this could be an industry model: commitment from leadership, an emphasis on mentorship, and co-location of resources. The Chief Medical Officer of the organization sets the tone and emphasizes the need to look externally for innovative ideas. Executives also note the importance of mentorship: one explains that an entrepreneur's conversation "with a big company's health economics and reimbursement expert can save a small company tens or even hundreds of thousands of dollars." Co-location helps to build these mentoring relationships and facilitates sharing of expertise.

Alternative funding sources for early-stage investment

Along with traditional VC and large company investments, interviewees spoke about the increasing use of alternative funding sources that can help young companies get through early-stage product development. Alternative funding sources can include Small Business Innovation Research (SBIR) grants, state programs, family offices, philanthropic investors, and accelerators (see sidebar on the following page). Collectively, alternative funding sources could help startups move from an idea to proof of concept, in the process de-risking the technology and reducing the capital investment that large companies or VC firms might need to make to move products through FDA approval and commercialization.

In addition to alternative funding sources, startups may want to consider non-medtech companies as investors or strategic partners. Consumer technology companies, health systems, and health plans might be viable options. Many of these organizations already are investing in medtech and could offer complementary capabilities to help advance innovation, especially for products that combine medtech and digital health. For example, consumer technology companies could bring expertise in consumer engagement; health systems could provide insights on population management; health plans could share knowledge of data and analytics. In fact, of the top 15 CVC investors in digital health, three are consumer technology companies, three are health systems, and one is a health plan.[14]

Consumer technology companies, health systems, and health plans might be viable options for startups to consider as investors or strategic partners.

Leveraging alternative funding sources to support early-stage innovation

Representatives from small companies and VCs suggested leveraging the following funding sources:

Small Business Innovation Research (SBIR) Grants: One entrepreneur we interviewed used SBIR grants to get through Phase 1 research and employed that non-dilutive money to build as much of the device as possible. Her company was also able to hire a head of Quality Assurance and set up its ISO certified quality system. However, she pointed to subsequent challenges in securing funding to support FDA approval and to build a sales team to support commercialization. This could be an ideal inflection point for large companies to invest in or partner with early-stage companies: existing infrastructure could be leveraged to support development of technology that has made it through proof of concept.

Angel investors or family offices: Angel investors—wealthy individuals who invest in companies in exchange for debt or equity—and family offices—private wealth-management advisory firms that serve ultra-high-net-worth investors—could be an additional avenue for early-stage investment. Angel investment could help transition products from idea to proof of concept, increasing their attractiveness to venture investors. Roundtable participants were concerned, however, that angels and family offices might lack the depth of industry knowledge needed for medtech investments to succeed. They feared that just one failed investment could deter subsequent investment in the sector. Participants suggested that medtech-focused venture funds could partner with family offices to combine funding sources with medtech expertise to verify that capital is used efficiently.

Philanthropic investors: Philanthropic investors, including family foundations and patient advocacy groups, could also be a source of early-stage capital. For example, the Bill & Melinda Gates Foundation has been making equity investments in for-profit companies that align with its mission and are driven by "impact" rather than returns.[15] Beyond capital, philanthropic investors can attract a network of experts and provide access to additional resources, such as government funding. Similarly, patient advocacy groups often offer grants to companies that are developing technology aligned with their mission.

State funding: Several states—including Massachusetts, New Jersey, Texas, and Ohio—have created additional investment incentives for medtech. Ohio created Third Frontier in 2002, cashing in a $2.3 billion bond to invest in early-stage life sciences startups. Similar to SBIR grants, the state's funds support development of early-stage technologies, and are distributed through a network of investment funds.[16] New Jersey's Economic Development Authority offers low-interest financing through matching loan programs, tax incentives, real estate, and networking opportunities within the investment community.[17] Massachusetts recently proposed a renewal of its Life Sciences Initiative, which would add $500 million to an already invested $1 billion for life sciences innovations over the next five years.[18] Texas reinstated its research activity tax credits in 2013, extending benefits through 2026; these tax credits work alongside the Texas Enterprise Fund, which has awarded $109 million to life sciences-related companies since 2004, and has helped to create more than twelve thousand Texas jobs.[19]

Accelerators and incubators: Accelerators, incubators, and prize competitions could be a viable source of early-stage funding. Entrepreneurs need to apply to participate, and selected companies are often provided with funding, office space, and additional educational resources to help advance a product through the early-stages of innovation. MedTech Innovator, an accelerator and prize competition that offers access to investors, large device companies, providers, and customers, was commonly mentioned in interviews.[20] Educational opportunities and networking connections are consistently identified as the most valuable benefits for entrepreneurs.

Tax policy changes might lead to greater investment

Tax incentives and reforms could spur greater investment in medtech. Interviewees and roundtable participants consistently point to the ACA's medical device excise tax as having a negative effect on investment. They also listed lower tax rates for repatriating cash held overseas, tax credits for angel investors, and other tax breaks for startup investors.

The medtech industry should consider supporting the following aspects of tax reform that could motivate greater investment in innovation:

Repealing the medical device excise tax (MDET): MDET creates a two-fold challenge for medtech startups. It can deter company growth because it is imposed on the first dollar of revenue earned. In addition, by limiting the amount of available funds, it restricts the ability of established medtech companies to invest in or acquire startups.[21] MDET went into effect at the end of 2012, but in 2015 was placed on hold for 2016 and 2017. Recently, policy discussions on health reform and tax reform have included bipartisan proposals to permanently repeal MDET.[22]

Repatriation of overseas cash: Allowing the repatriation of cash held overseas at a lower tax rate is expected to increase M&A activity in the life sciences industry in general.[23] Many multinational medical device companies hold significant cash overseas. If that cash was brought back to the United States, it could be used to support early-stage innovation.

Angel investor tax credit: Tax credits for angel investors could incentivize early-stage investment and facilitate the transition of pre-revenue companies to profit-making status. Twenty-four states have enacted angel investor tax credits for technology companies; eight states have done the same for bioscience investors. AdvaMed Accel has worked to draft an angel investor tax credit legislative proposal that could build upon the success of these state programs at the federal level.[24]

Net operating loss (NOL): When a startup company begins to generate revenue, it may benefit from tax credits on NOLs and R&D. Policy changes involving NOLs could support early-stage medtech entrepreneurs directly, and make these businesses more attractive to investors and established medtech players. By lifting the tax-exempt rate for accumulated NOLs from two to seven percent, the National Venture Capital Association suggests that startups could increase their ability to write down losses and improve their bottom lines earlier. Other changes along these lines could help—for example, exempting R&D credits from this limitation, as start-up expenses can lean heavily toward R&D; and exempting capital contributions, including early-stage corporate and venture investment, from ownership change calculations.[25]

MDET creates a two-fold challenge for medtech startups. It can deter company growth because it is imposed on the first dollar of revenue earned. In addition, by limiting the amount of available funds, it restricts the ability of established medtech companies to invest in or acquire startups.

A compelling value proposition, partnering for evidence-generation, and novel contracting approaches could alleviate coverage and commercialization challenges

Receiving insurance coverage (public and private), being adequately reimbursed, and successfully commercializing products are high on the list of challenges for medtech innovation. In the words of one experienced medtech investor, "being reimbursable is a ticket to the dance."

Interviewees and roundtable participants' proposed strategies for obtaining coverage and reimbursement, and achieving successful commercialization fall into three categories: pitching the value proposition, seeking innovative partnerships for generating evidence, and using novel contracting approaches.

Pitching the value proposition

"You need to prove that your numbers work on day one," stated a business development executive from a large medtech company who participated in the roundtable. Other roundtable members, as well as executives we interviewed, agreed that it is not just about developing a compelling product anymore; the value of a product is defined by the outcomes that product creates—either health or economic.

A compelling story around a product's ability to improve outcomes is essential for funding. Companies need to understand the many levers of value for payers, providers, and patient populations and incorporate them into product development plans. Especially important: understanding how a product or solution's value will be differentiated from the current standard of care.

When it comes to defining value, companies should consider a broad set of stakeholders— physicians are no longer the sole medtech customer. "For years we sold to physicians," said one venture capital investor.

> "Some companies, as good as they are technologically, should never have been funded. Know whether you can really prove your value."
>
> —Venture capital investor

He added that the needs of hospital administrators and payers, along with a broader set of stakeholders, should now be taken into account. Hospital administrators and physicians typically work together on purchasing committees that are responsible for determining which products to keep in inventory. Similarly, payers, employers, and patients are considering cost and other non-clinical benefits when deciding whether to pay for or use medical technology.

While a focus on value is common among health care stakeholders, knowing how each stakeholder group defines value can be critical to commercial success. Deloitte and AdvaMed worked together to develop *The Value Framework*, a roadmap for medtech stakeholders to define and determine product value. The initiative provides an assessment framework with categories that extend beyond traditional clinical efficacy to include patient-focused considerations and a technology's impact on care delivery effectiveness and efficiency under new value-based payment models (see Appendix B).[26]

Discussions about quality measurement in value-based payment models increasingly focus on incorporating metrics such as patient experience, quality of life, improvements in functional status, and evidence-based behavioral interventions. Entrepreneurs may benefit from working with patient advocacy groups to understand how they define value and which patient-centered measures might be relevant to include in product development.[27]

In addition to changing how physicians and health systems adopt new technology, the shift to value-based care presents new opportunities for medtech companies. Payment models that tie coverage to outcomes can allow physicians to try new technologies that might improve outcomes and lower costs, even if they are not included under an established reimbursement code. For example, under global capitation, providers are paid to manage the health of a population, regardless of the services provided. This could create an opportunity for new medtech to be adopted into clinical practice even if a specific coding and payment pathway is not evident (see sidebar on the following page).

MACRA accelerates opportunities for innovation adoption under value-based care

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is likely to accelerate the transition to value-based care by incentivizing physicians to participate in alternative payment models (APMs). Under MACRA, clinicians participating in advanced APMs will receive a five percent increase in their Medicare payments. This increase would be in addition to any potential shared savings or performance bonuses for which APMs may qualify. On average, Medicare payments account for almost a third of physician practice revenue.[28] These financial incentives are expected to spur greater adoption of value-based payment models. Medtech that improves outcomes for metrics physicians will be measured under MACRA and APMs are more likely to be adopted.

It is also imperative to understand the timeframe in which each stakeholder measures value. For a health plan, eventual changes in membership, or churn, could translate to lost value over the long term. If a particular technology generates savings after 10 years, for example, the health plan would want to retain that member over the entire period in order to recoup the savings. Roundtable participants noted that a three-year turnover is more likely, which makes such a long-term investment difficult for health plans to justify. One venture investor put it more succinctly:

> "If payers have a three-year churn in membership, and you're selling a 10-year benefit, that's a hard gap to address. So talk to them in their own terms."

Entrepreneurs should also understand how the value proposition will be developed throughout the R&D process. Medtech R&D can take a long time—sometimes up to 10 years. Investors usually want to hear detailed plans about the value proposition and how it will be developed over the R&D timeline. One medtech investor cited the importance of outlining the development of the value proposition as the product itself develops: "Be able to articulate stage-specific value propositions." In addition, entrepreneurs should think through elements of a successful commercialization plan. For example, if the product aims to change the standard of care, what will it take to educate and train physicians on the new approach to help ramp up widespread adoption?

Partnerships for evidence-generation

Once an innovator understands how different stakeholders prioritize measures of value, the next step is to generate evidence that demonstrates this value. Industry executives cited new models for medtech innovators to generate evidence in ways that could help get them to market faster and more efficiently. Specifically, they saw an opportunity to partner with customers who are focused on improving population health, including providers and employers. Customers could help shape the direction of technology by testing it in their patient populations and by providing input about how the technology could better suit their needs.

To help pilot innovation, roundtable participants specifically pointed to integrated delivery networks (IDNs) as potential partners, and suggested building IDNs to support clinical trials. This could allow innovators to test their product and prove that they can create value outside of controlled clinical trials. Such trials are often conducted at large academic medical centers (AMCs) and participating patients might not reflect a health insurer's membership or the patient population of large IDNs. One roundtable participant said this kind of evidence can be important to regulatory agencies. "Prove you can create real-world value outside of AMCs so when you approach FDA, you already have a solution proven to work" in a given population.

Self-insured employers also could help innovators target new technology. Along with the cost of medical care, these employers must bear costs related to lost productivity. Many might be willing to partner on technology that could reduce lost time and improve workforce productivity.

Research participants also talked about a scalable model. As one participant advised, "Don't look at pilot projects or models as 'one and done.' Look to start small and develop, and then you can also address issues within patient populations." Another roundtable participant noted that large medtech companies have a disproportionate number of relationships with large providers and IDNs. These companies could help the innovation community as a whole by sharing access to these providers, which could forge new relationships and allow new innovations to thrive.

Case study: Joint payer and provider innovation assessment[29]

In 2015 Highmark Health, an integrated delivery system and health insurer, launched VITAL (Verification of Innovation by Testing, Analysis and Learning). This program gives innovators an opportunity to have their products jointly assessed by payers and providers. VITAL works with innovators whose products are FDA-approved but not yet covered by most commercial insurers.

The program is similar to CMS's coverage with evidence development, in that it provides its affiliated clinicians—and their patients—with access to innovative medical technology, while allowing the manufacturer to collect additional scientific data to gain wider commercial coverage. VITAL also allows Highmark's payer business to conduct in-depth reviews of emerging medtech innovation, which it may use to inform changes in its methods to determine coverage.

One of the technologies being tested and validated under VITAL includes a minimally invasive, image-guided device that allows a physician to see inside the artery during an artherectomy. Claims data for patients who have undergone this therapy are being compared against conventional cardiovascular interventions to determine overall benefits to patients.

Getting paid

Research participants suggested that new ways of contracting might accelerate incorporating innovation into clinical practice and, subsequently, getting covered and paid. Payers could provide coverage contingent on innovator companies gathering additional evidence, or coverage with evidence development (CED). Much of the CED dialogue concerns public payers but some private payers are requiring additional evidence in exchange for coverage, as well. In at least one case—a study of at-risk mammographic screening—private payers played a large role.[30]

In the private sector, value-based contracting is another promising approach that allows risk-sharing between companies and payers, making payment contingent upon evidence that a product works in a specific patient population. In other words, companies are paid for technology if it works.

Some medtech companies have worked closely with providers to develop risk-sharing agreements that benefit both. Medtech companies gain market access and providers get the latest treatment options without taking on the full risk of paying for them. Each agreement is different and depends on the needs and interests of the provider and the medtech company. Some recent examples include a medtech company that shares the cost of hospital readmissions in cases that involve its product. This includes guaranteed credit with the manufacturer when cases involve a repeat procedure within a year.[31] In another example, medtech companies bid for a percentage of a hospital's revenue from procedures involving their product. This enables hospital savings and greater medtech company sales volume and market share.[32] Still other models involve the medtech company applying proprietary analytics to hospital processes, resulting in hospital savings and improved patient outcomes.[33]

Policy considerations to advance coverage

The policy environment could be a limiting factor for payer coverage of breakthrough innovation or products that could leverage value-based contracts. The proposed policy changes described below could help to encourage flexible coverage by enabling close stakeholder collaboration and allowing medtech companies to participate more actively in generating real-world evidence and sharing risk and information.

Coverage of breakthrough innovation: Advocacy efforts are underway that support early-stage medtech innovation with provisional or accelerated approval and coverage. AdvaMed has put forward proposals that could increase patient access to new innovation through changes related to coverage, coding, and reimbursement.[34]

Building off of the 21st Century Cures Act, which establishes a regulatory pathway for breakthrough devices, AdvaMed's breakthrough coverage proposal would establish a program of immediate transitional Medicare coverage and payment for FDA-approved or -cleared breakthrough technologies. Evidentiary development requirements normally considered a precondition for coverage would be shifted to the post-coverage approval period, which lasts three years. This could give patients access to breakthrough innovation and CMS the flexibility to make longer-term coverage decisions as evidence is generated and reviewed during the initial period.[35]

AdvaMed is also supporting ongoing efforts by CMS to define additional proposals to improve the process of obtaining coverage for innovation.[36]

Education to overcome reimbursement and commercialization hurdles

"No entrepreneur has knocked on the door of a venture capital fund and not heard that they need the health economics of their idea worked out. But there's no roadmap."

—Startup executive

In interviews and at the industry roundtable session, the need for education was a common theme. It is critical to understand the changing commercialization process, and both large companies and entrepreneurs could benefit from sharing information. AdvaMed could serve as a forum to educate entrepreneurs about the hurdles to receiving payer coverage. Through its Value Framework for Assessing Medical Technologies, AdvaMed aims to help entrepreneurs define the elements of value that are important to key stakeholders. Capturing and sharing case studies about what has and has not worked could also be valuable. One way to start, according to a roundtable participant and medtech innovator, would be for AdvaMed to compile and share "a roadmap, or case studies, of successful reimbursement." Large companies could also contribute by making their internal experts available for mentorship, seminars, and educational sessions at industry events.

Safe Harbors for the Anti-Kickback Statute (AKS): As it now stands, the Anti-Kickback Statute does not allow medtech companies to engage in some risk-sharing agreements; specifically, those in which a warranty guaranteed by the medtech company does not exceed "the cost of the item itself." Under AKS, a medtech company cannot guarantee a patient outcome above and beyond a device that is free of defects. This regulatory barrier may prevent beneficial, value-based arrangements. AdvaMed has been working on behalf of the medtech industry to create a Safe Harbor for agreements under which a medtech company could more easily offer a warranty covering patient outcomes and share risk with providers.

Regulatory guidance that expands the ability of medtech companies to communicate economic information:[37] Current FDA requirements place restrictions on medtech company communications to providers and payers. These restrictions prevent medtech companies from sharing health care economic information (HCEI) that could be crucial to payers' and providers' decisions about when to use one product versus another. Such information also could help determine which patients in which circumstances are most likely to benefit from long-term savings of one product versus another. Particularly in the case of value-based payment arrangements, providers and payers need access to economic information about medtech innovations to enable early access to innovative, safe and effective devices. The FDA has issued draft guidance aimed at lifting restrictions on communications between medtech companies, provider, and payers. As long as it meets standards of scientific evidence, AdvaMed supports medtech companies' ability to collect and provide this information to payers, providers, and related entities for their evaluation.

Suggested steps forward

To re-invigorate medtech innovation, industry stakeholders should consider taking several action steps:

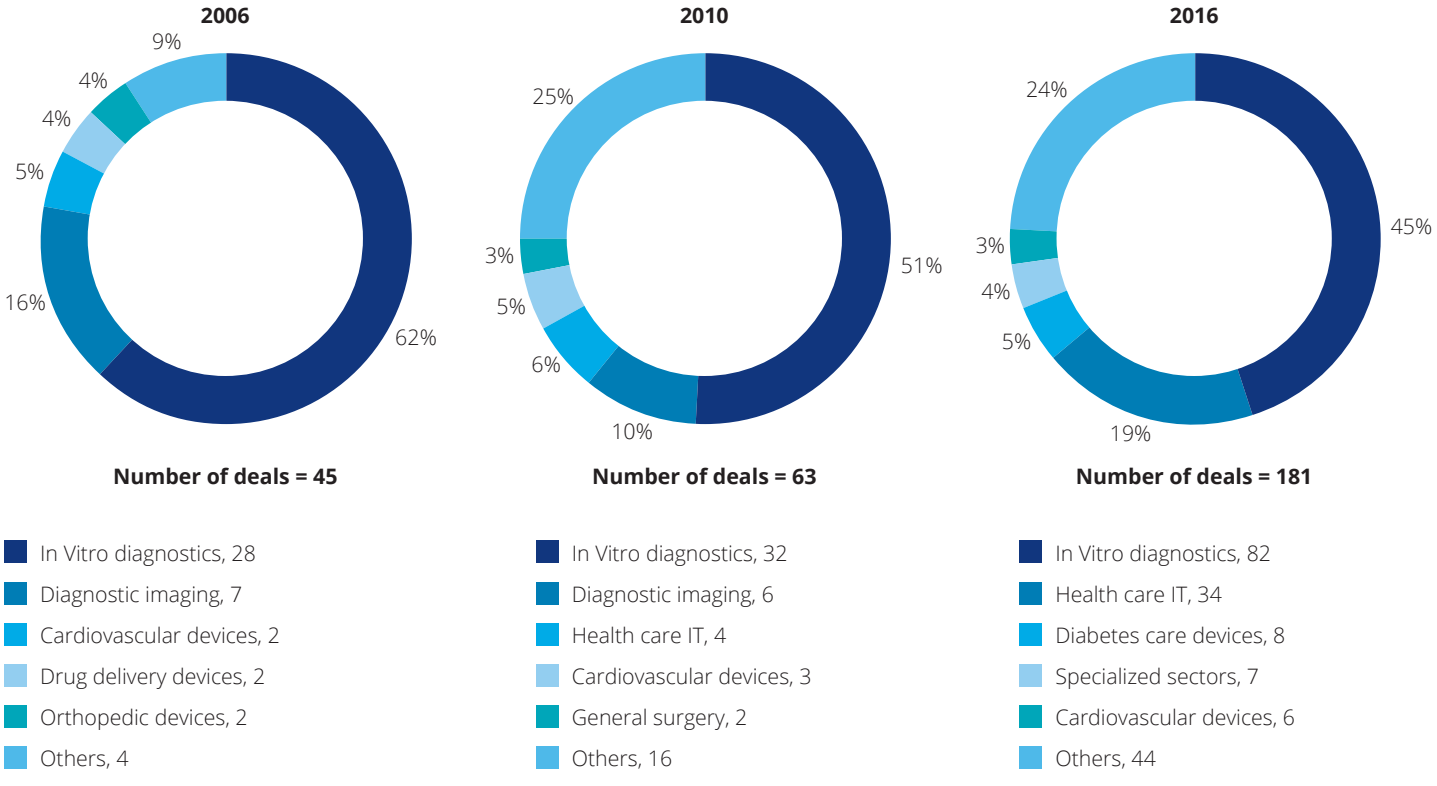
- Large companies:
  - Set aside capital to invest in early innovation, ideally through corporate venture capital arms that are best-suited to managing a portfolio of investments;
  - Consider alternative deal structures (build-to-buy) or partnerships (co-development, co-marketing);
  - Put the right governance model in place and align incentives across business development and the business units that will support these deals;
  - Consider partnerships with non-traditional players (e.g., consumer technology companies) to access new capabilities; and,
  - Mentor early-stage companies on how to develop a compelling value proposition, differentiate products commercially, and tackle key coverage hurdles earlier in the development process.
- Small companies/entrepreneurs:
  - Take advantage of nontraditional funding options: state programs, SBIR grants, family offices, philanthropic investors, and incubators;
  - Consider consumer technology companies as potential investors or partners;
  - Spend additional time understanding potential customers and how they define value early in the product lifecycle; and,
  - Enter into partnerships with employers and payers to test value propositions, or co-develop products.
- Venture capital investors:
  - Co-invest with large companies in early innovation;
  - Set a funding hurdle for products or business models that can demonstrate value, generate coverage, and be commercially differentiated; and,
  - Consider partnering with family offices and other investors to evaluate medtech investment opportunities.

As one large medtech company business development executive remarked, "It's not just about innovation. It's about innovation that fits." Finding the right opportunity, the right people, and the right partners is essential to getting to "the innovation that fits," and creating a robust pipeline of valuable medtech innovation in the United States.

Appendix A. Strategic partnership activity in medtech

Many recent co-development deals are focused on Health IT products and diagnostics (Figure 9). The remaining co-development deals are fragmented across therapeutic areas. This represents a diversification from 2006, when the vast majority of co-development deals were focused on diagnostics. It does appear that there is room for more therapeutic-focused co-development deals.

Figure 9. Co-development activity has diversified from in-vitro diagnostics to include Health IT in recent years



Number of deals = 45

- In Vitro diagnostics, 28
- Diagnostic imaging, 7
- Cardiovascular devices, 2
- Drug delivery devices, 2
- Orthopedic devices, 2
- Others, 4

Number of deals = 63

- In Vitro diagnostics, 32
- Diagnostic imaging, 6
- Health care IT, 4
- Cardiovascular devices, 3
- General surgery, 2
- Others, 16

Number of deals = 181

- In Vitro diagnostics, 82
- Health care IT, 34
- Diabetes care devices, 8
- Specialized sectors, 7
- Cardiovascular devices, 6
- Others, 44

Source: Global Data

Appendix B. The Value Framework

AdvaMed and Deloitte worked together to develop a common framework for assessing value in medical technology. The framework is appropriate for use by stakeholders involved in medtech value assessment throughout health care: payers, providers, government, employers, quality organizations, professional medical associations, potential investors, health technology assessment (HTA) bodies, patient advocates, and medtech companies themselves. Eight principles make up the framework, and they address four broad categories of value drivers. The principles cover specific aspects of determining the types of value and costs to include, as well as the assessment process itself. The value-driver categories are meant to capture newer patient-focused considerations of value-based performance systems. **More detail about this framework can be found in the paper published by AdvaMed and Deloitte, *A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystems*.**[38]

Table 1. Sample key questions for the four value drivers[39]

Value drivers	Clinical impact	Non-clinical patient impact	Care delivery revenue and cost impact	Public/population impact
Sample questions	How does the technology affect clinical outcomes compared to other treatment options?	Does this technology create more/less preferable options for the patient?	How does the technology enable the right choice of treatment, for the right patient, at the right time, at the right place?	How does the technology impact overall public and population health measures?
	How does the technology impact patient safety relative to available alternatives?	How does the technology enable patients and their families and caregivers to navigate, coordinate, and manage their care appropriately and effectively?	How does the technology affect costs related to system throughput, workflows, and care efficiency (site of care, staff)?	How does the technology help lower unnecessary private and public spending?
	How does the technology impact quality of life in the short- and/or long-term?	How does the technology impact affordability of treatment/out-of-pocket expense for different patients?	How does the technology help reduce costs associated with variance in clinical outcomes across individual physicians/sites of care?	How does the technology impact ability for caregiver to provide care, and address productivity and attendance?

Figure 10. Deloitte and AdvaMed's approach for effective value assessment: A schematic

Source: Deloitte and Advamed, A Framework for Comprehensive Assessment of the Value of Diagnostic Tests, May 2017

Endnotes

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