

New strategies for medtech startups

Attracting investment from across the innovation ecosystem



Executive summary

Investment in early-stage medtech innovation can be critical in ensuring that patients have access to novel therapeutics and diagnostics. In 2017, the Deloitte Center for Health Solutions and AdvaMed Accel conducted a study on [reinvigorating medtech innovation](#). The study found that venture capital investments in the sector were declining as investors shied away from unproven early-stage technologies, regulatory and reimbursement hurdles, and lackluster returns.

In 2021, we revisited this research to find out how investment and investor priorities had changed over the last five years. We interviewed 16 seasoned medtech investors and entrepreneurs in the early-stage ecosystem (see sidebar 'Methodology') and identified several areas of improvement, including:

- Overall venture financing in medtech increased 67% since 2017. However, most investment is going toward late-stage diagnostic and digital companies.¹
- There is more opportunity to invest in medtech via the public markets. Many entrepreneurs have found increased access to alternative financing options, including family offices.

However, seed and Series A funding has continued to decline since 2017, creating challenges for entrepreneurs entering the space. This is likely primarily due to three factors:

- **Low yields:** Despite offering steady and consistent returns, medtech investments typically generate lower yields than investments in other industries.
- **Time and capital:** Medtech incumbents ("strategics") tend to wait for commercial success before investing in or acquiring medtech startup companies. This can increase the amount of capital required, and the time needed to exit.
- **Reimbursement:** Payment pathways are often unclear and inconsistent. This is particularly true for companies that have developed non-traditional technologies that require new coding or coverage policies or those that are pursuing new markets.

In addition, the COVID-19 pandemic led to a new set of challenges, including negative pressures on the sale of technologies used in elective procedures, delays in clinical trials, and supply chain issues. These issues compounded the fundraising challenges for many medtech entrepreneurs.

Consistent with our prior study, investors told us that they are looking to fund innovative, scalable technologies that offer strong clinical outcomes for patients. They noted several strategies that could improve the flow of early-stage funding in medtech:

- Partnerships (such as build-to-buy) between strategics and early-stage companies could provide attractive opportunities to balance risk and reward for both parties.
- Strong clinical evidence and reimbursement strategies for new products should be developed as early as possible.
- All stakeholders should continue to work with regulatory and other policy-impacting bodies (e.g., FDA, CMS, AMA) to promote consistency and to streamline the review process. This could help ensure that new and innovative technologies face fewer hurdles while obtaining reimbursement pathway approval.

Introduction

Our 2017 [study](#) described how stakeholders could address the capital and commercialization risk challenges that early-stage medtech companies often face. Five years later, we continue to track the declining investments in early-stage medtech innovation. This trend is mostly due to enduring complexities in the regulatory, reimbursement, and commercialization processes for medical technologies and devices. But when coupled with lower returns for investors, the impact could be significant – meaning fewer new startups focused on medtech, and fewer lifesaving innovations for patients.

Of the 15,500+ medtech companies that are actively operating in the US today, 94% are either pre-revenue or have no revenue at all. Only 130 companies reported revenues of \$100M or more.² Additionally, 82% of medtech companies had fewer than 20 employees, according to analysis of 2020 data by Macro Policy Advisors for AdvaMed.³

A healthy early-stage medtech innovation ecosystem, including a constant flow of novel products from start-up companies, can be critical not only to bring new products to market, but also to sustain incumbent medtech company pipelines. Further, as we discussed in our [recent research](#) into the medtech innovation landscape, nearly half of startups were focused on prevention, wellness, diagnosis, and/or detection of disease – not treatment. Investment in these kinds of technologies is essential to realize Deloitte’s vision of the Future of Health® -- where early detection, empowered consumers, and a focus on wellness reduce the need for acute care. Our 2021 research looked into where investments in medtech startup companies stand what has improved over the past five years, what challenges persist, and what impact COVID-19 has had on the market overall.

Methodology

We interviewed 16 founders, serial medtech entrepreneurs, thought leaders, seasoned investors, and industry veterans who have experience scaling and launching medtech companies. We also looked at trends in financial investments made into early-stage medtech startup companies. Using Global Data and Pitchbook, we compared funding trends within different segments of the medtech industry and elsewhere to draw conclusions about where investment dollars are going, both inside and outside health care.

The current state of venture capital investing in medtech

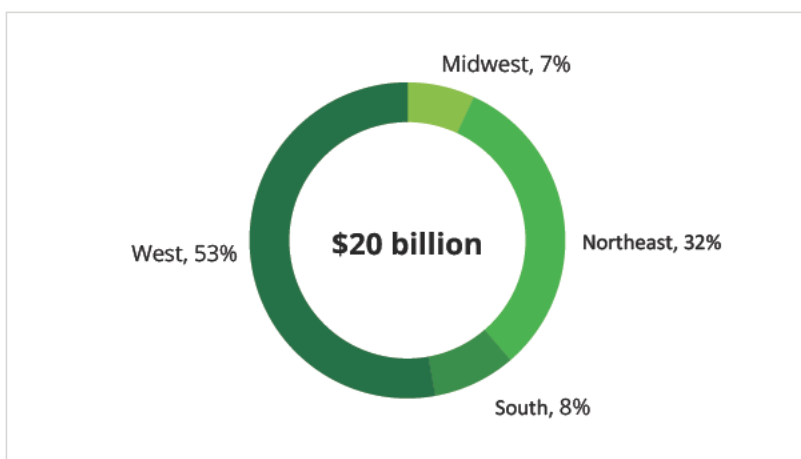
Medtech startups are concentrated in the Northeast, West

Where start-ups are based is largely driven by proximity to academic/clinical research institutions and clusters of entrepreneurial talent. California and Massachusetts are home to the most medtech startups in the country – approximately 3,000 and 1,000, respectively – and the flow of venture capital funds clearly aligns to this data point. Eighty-five percent of venture dollars awarded to US-based medtech companies in 2021 were either in the Western (53%) or the Northeastern (32%) regions of the country (see figure 1).

Among states, California had the highest cash inflow in all the three funding stages (early-stage, growth capital/expansion stage, and later-stage) with more than 225 medtech companies bringing in about \$9.3 billion in funding in 2021.⁴ The state boasts multiple medical-device hubs, and attractive financial incentives including the California research tax credit and the California R&D sales tax exemption.⁵ For example, San Francisco-based Hinge Health says it is building the world's most patient-centered Digital Musculoskeletal (MSK) clinic to reduce MSK pain, surgeries, and opioid use. The company raised about \$900 million in Series D and E in 2021.⁶

Massachusetts was second to California in terms of funding inflow at around \$3 billion. Like California, Massachusetts is home to leading research hospitals and universities and offers a tax incentive program (Massachusetts Life Sciences Center (MLSC)) to companies engaged in life sciences research and development, commercialization, and manufacturing.⁷

Figure 1: Medtech startup companies based in the West and Northeast regions of the US received the lion's share of funding in 2021



Source: Deloitte analysis of medtech VC funding deals pulled out from Global Data

Note: 6% of the total deal value in 2021 was either undisclosed in terms of value or geography, hence that has been excluded from this dataset

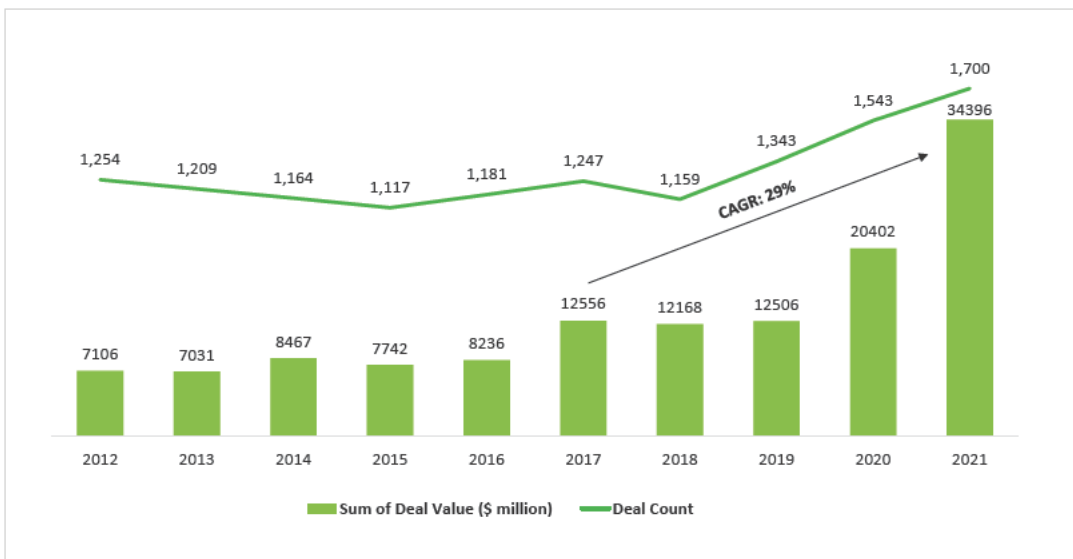
Venture capital funding surged to record levels

Looking at the global funding landscape, the IT sector has received more venture capital (VC) funds than all other industries in the last few years (8x and 4x higher than medtech and pharma/biotech, respectively, in 2021).⁸ One of the major reasons could be the pandemic-accelerated shift to digital and smart-technology solutions, as everyone adopted a more remote working style.

However, the medtech and pharma/biotech industries saw the highest percent increase in VC funding in 2020 (63% and 66% respectively) compared to other sectors. This is likely also due to the pandemic, highlighting opportunities to invest in high unmet needs in health care more broadly.⁹

Medtech companies raised significant sums of VC funding globally in 2020 and 2021 (\$20 billion and \$34 billion respectively), which has grown at a CAGR¹ of ~29% from 2017-21 (see figure 2). Every quarter since 2020 has seen a higher inflow of funding than the preceding ones. Medtech VC funding also broke new ground in terms of average deal size, reaching \$17 million in 2020; 2021 is even higher at \$25 million.¹⁰ These deals were driven in large part by a strong interest in (and an influx of) investment dollars into diagnostics and information technology.

Figure 2: VC funding of medtech companies reached its highest levels globally in nearly 10 years



| Year | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
|--------------------------------|------|------|------|------|------|------|------|------|------|------|
| Average deal size (\$ million) | 6.2 | 6.6 | 8.1 | 7.8 | 7.9 | 11.4 | 12.5 | 11.2 | 17.0 | 25.0 |

Source: Deloitte analysis of medtech VC funding deals pulled out from Global Data

Note: Count does not include deals that have undisclosed value

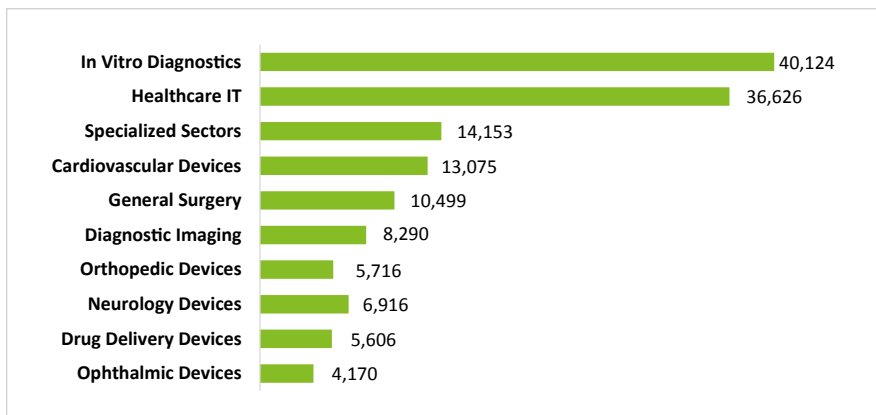
1 CAGR = compound annual growth rate

In-Vitro Diagnostics (IVD) and Health Care IT are the largest VC fundraising segments

In-vitro diagnostics (IVD) and health care IT have dominated fundraising efforts in medtech over the past decade (see figure 3). Over the past two years, as the COVID-19 pandemic took hold and diagnostic testing became a priority for many governments, diagnostics companies became some of the biggest VC fundraisers in the sector. According to Silicon Valley Bank, investments in all types of diagnostics and R&D tool companies reached a record in 2021, up \$2.9 billion over the prior year.¹¹ The IVD segment in particular saw a spike in average VC funding deal size – up from an average of \$14M in 2019 to \$28M in 2021 (see figure 4) – which might be attributed to the rise in demand for fast and accurate COVID-19 tests. Companies focused on other aspects of diagnostic and digital health technology have also seen significant investments:

- The other large diagnostics-focused financings were in companies such as liquid biopsy developers Grail (\$390M in Series D), Thrive Earlier Detection (\$257M in Series B), and Caris Life Sciences (\$235M).¹²
- Some of the biggest funding rounds in the first half of 2021 went to companies active in telehealth, digital therapies, and home treatment, all of which have seen increased acceptance during the pandemic. UK-based, home-based dialysis machine maker Quanta Dialysis Technologies raised \$245 million to scale up manufacturing, sales, and customer service.¹³

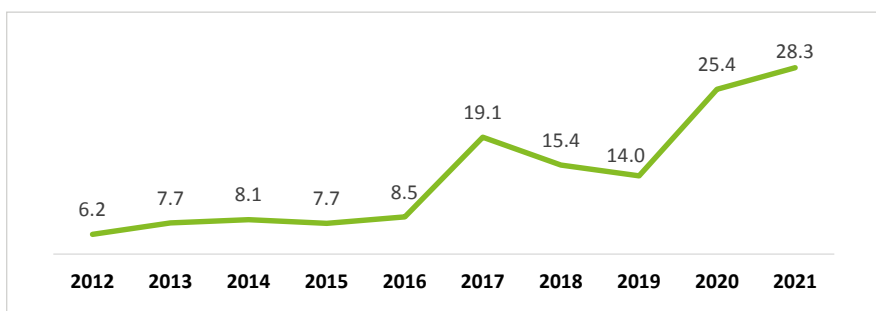
Figure 3: The IVD and Health Care IT segments have seen the most VC funding over the past decade (2012-2021) (\$ million)



Source: Deloitte analysis of medtech VC funding deals pulled from Global Data

Note: 'Healthcare IT' includes devices related to clinical IT systems, medical imaging information systems, provider IT, and home-care IT

Figure 4: The average VC funding deal size for the IVD segment increased significantly in 2020 and 2021 (\$ million)



Source: Deloitte analysis of IVD segment VC funding deals pulled out from Global Data

How has COVID-19 affected medtech innovation?

With the onset of the COVID-19 pandemic, many medtech companies faced operational challenges that negatively impacted the overall ability for a product to get to market.

In addition to delaying or halting clinical trials, the pandemic also led to the deferment of non-emergency procedures, resulting in a major blow to procedure-dependent medtech companies. Several companies saw their revenue streams fall by more than 60% as surgeries were halted and medical device sales representatives were denied access to physicians on hospital premises¹⁴ (See Deloitte's [Clinical leaders' top concerns about reopening paper](#)).

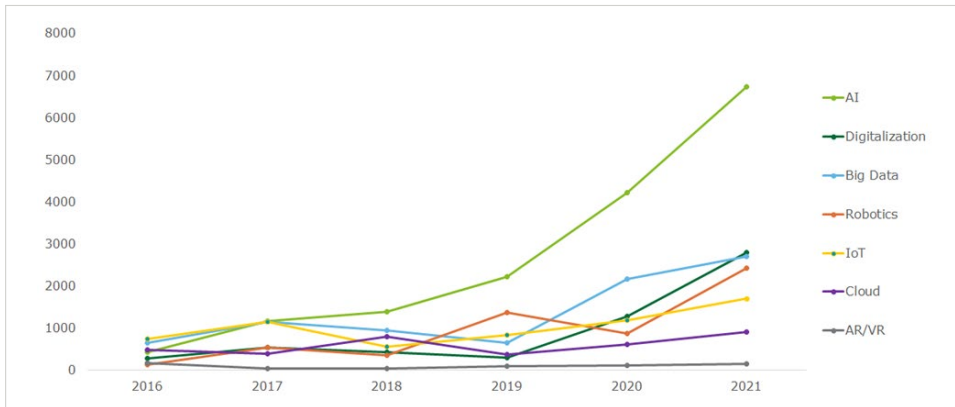
Lastly, the pandemic exposed vulnerabilities in the supply chain infrastructure. Interviewees mentioned that on one hand, the industry saw an unprecedented surge in demand for medical devices, while on the other hand, the severe shortage of semiconductor chips for medical devices – coupled with the shutdown of transportation modes – often led to one-year delays in product launches.

AI technologies lead VC funding in medtech; robotics are on the rise

VC funding in artificial intelligence (AI) has increased significantly in recent years (see figure 5). Paige.AI, one of the highest VC-funded medtech companies in 2021, used the proceeds to expand its geographic footprint as it accelerates the development of AI-based clinical applications, biomarkers, and diagnostics.¹⁵

After seeing modest increases in total investment dollars since 2016, VC funding of robotics decreased in 2020. This could be attributed to the reduction in non-emergency surgeries – for which robotic systems are commonly used – since the pandemic began. However, as demand for non-emergency procedures rebounded in 2021, so did funding activity. The largest recent financing of a robotic surgery platform was in a UK-based medical technology company, which raised \$600M in a Series D round. Caresyntax (\$100M in Series C) was the next largest.¹⁶

Figure 5: VCs are funding AI technologies at their highest level in 5 years (\$ million)



Source: Deloitte analysis of medtech VC funding deals pulled out from Global Data; see Appendix for category definitions

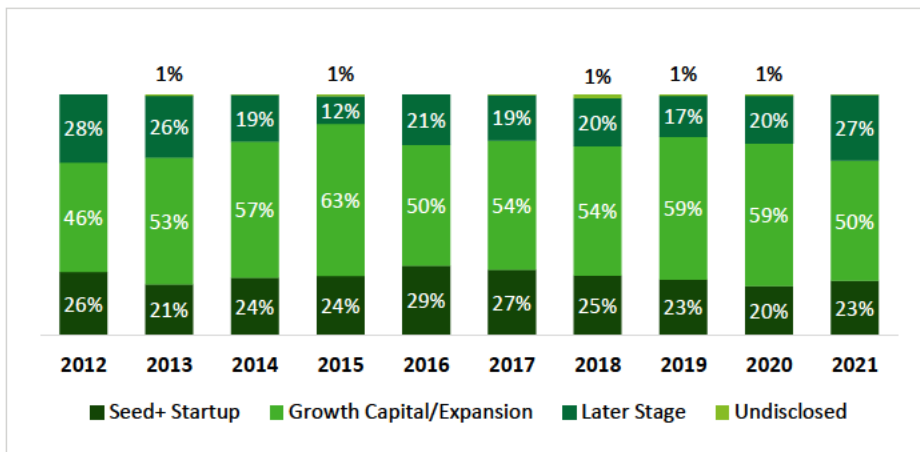


Seed and Series A fundraising saw only a slight uptick in 2021; late stage deals are increasing

Despite all the venture funding pouring into the medtech industry, only a small proportion is going to early-stage companies. Seed and Series A investment declined from 27% in 2017 to 23% of total medtech VC funding in 2021. Over the last few years, mid-stage rounds (Series B-D) have attracted the most VC investment (50% of total medtech VC funding value in 2021). Late-stage (Series D-H) funding activity also increased significantly in 2020 and 2021 (see figure 6).

In general, VCs are investing in later-stage, relatively de-risked, more established companies where challenges related to clinical-trial data, regulatory approvals, and reimbursement are less of an issue. This type of investor sentiment is consistent with some of the observations we made in our [previous study](#). In that paper, we said that medtech startup companies were struggling to make it out of the “valley of death.” This is the period between an initial investment and the creation of a commercially viable product. We noted that declines in early-stage medtech investment could threaten innovation.

Figure 6: VCs offered more later-stage funding to medtech companies in 2021 compared to previous years



Seed + Startup: Seed, Series A; **Growth Capital/Expansion:** Series B-D; **Later Stage:** Series D-H

Source: Deloitte analysis of medtech VC funding deals pulled out from Global Data

Note: In some instances, Series B is captured in both 'growth/expansion' and 'later stage' due to overlap

Medtech investors still struggle to achieve significant returns

Despite an overall increase in medtech funding, many early-stage companies are struggling to get noticed by investors. Just 5% of the global deal value in 2020 went to medtech start-ups, while 13% went to biopharma companies.¹⁷ Although the returns on investment in medtech have been consistent, in the range of 1-2x, the returns in biopharma can be 3-4x or higher.¹⁸ Investors told us that higher returns in medtech usually require a market size of \$500M or more, which is often not the case for medtech products. Investors also said that gross margins for medtech products are generally much lower than for drugs. This highlights the importance of articulating market size, payment, and adoption when securing funding.

According to investors, medtech startups often face a unique set of challenges when it comes to commercializing their products, which can make it difficult to secure early-stage investment dollars:

- **The time to exit is longer:** In 2021, the pharma/biotech industry touted 92 IPOs, compared to just 30 IPOs for diagnostics and R&D tool companies, and 24 IPOs for device companies. In M&A, the total pharma/biotech median deal value was \$513 million in 2021. That same year, the median deal value for diagnostics and R&D tool companies was \$270 million, and \$268 million for devices.¹⁹ Investors generally favor investment prospects that provide the greatest chance of returns, the least amount of risk, and require the shortest amount of time. According to our interviewees, uncertainty about whether technologies will be approved, paid for, and/or adopted drives hesitation to take on investment risks – especially in the early stages of development. If the goal is to realize a return on investment within the lifespan of a fund, for example, a potentially long time-horizon is often a nonstarter. Consider this:
 - **The regulatory process can be inconsistent:** Interviewees described an approval environment that lacks clarity and consistency, making the process unpredictable and time consuming. Regulators recognize the need for flexibility when evaluating newer technologies – especially those that include digital components or Software as a Medical Device (SaMD) – but are still formulating the processes. The Food and Drug Administration recently released its first Artificial Intelligence/Machine Learning based SaMD action plan to advance the agency's oversight of AI/ML-based medical software, for example.²⁰ The FDA Digital Health Software Pre-certification program is still in the pilot phase.²¹
 - **Securing payment can be difficult:** Even after successfully navigating the regulatory process, many medtech companies still have a long way to go to make it in the market. Investors used to be more confident about new product coverage once they received regulatory approval. In the current market, however, regulatory approval is not enough to guarantee success. Investors said the coding and reimbursement pathways for medical devices are much more variable than in biopharma– especially for companies that are pursuing new markets or for companies that have developed nontraditional technologies that do not fall under existing coverage policies (see sidebar “Coverage reform for innovation in medical technologies”). In such cases, companies often must first show adoption of their products before reimbursement has been approved, then apply for a new code, and then hope for payer coverage. This process can increase the cost and the length of time for reimbursement, further delaying the ability of companies to demonstrate commercial success of their product. It also can delay the exit opportunity for investors.

“How can you as a fund that has a 10-year life, invest in something which will take potentially eight years to develop and bring through approval, and will take another five years for it to realize its potential and be sold?”

— Medtech Advisor

“Earlier, exits in medtech would occur in 5-7 years, because big strategics were acquiring just upon FDA approval, and they were willing to fight the reimbursement battle. That has changed over the last 20 years. Now most medical device exits take 7-10 years because acquirers want the reimbursement pathway to be clear and they don't want to invest additional funding to get the revenues up higher.”

— Venture capitalist

- **Medtech strategics tend to be more conservative with investments:** Investors noted a cultural difference between medtech and biopharma, where large players often look externally for early-stage assets to build their portfolios and accept the risk that comes with that approach. Investors told us that medtech strategics prefer companies to have clinically proven products with established payment pathways and/or clear sales channels *before* they will commit dollars.

Coverage reform for innovative medical technologies

Centers for Medicare & Medicaid Services (CMS) understands that updated coverage policies for innovative technologies are needed. However, no new policies have been enacted to date. The most recent proposal -- Medicare Coverage for Innovative Technology (MCIT) -- was repealed in November 2021; its predecessor, Expedited Coverage of Innovative Technology (ExCITE), was scrapped in 2018. While this area remains a priority, several challenges exist that might prevent alignment on this issue:

- Lack of consensus on evidence-requirement thresholds and/or commitments; compliance with such policies can be costly and cumbersome for small companies.
- Budget impacts can be difficult to estimate.
- Safety and efficacy must be balanced with effectiveness and improved outcomes for patients.

A lack of clear and consistent pathways to reimbursement for emerging technologies can pose a threat to the innovation ecosystem. According to a recent study, "since breakthrough technologies are often more challenging to bring through development, clinical studies, and reimbursement, investors and innovators alike are less likely to pursue such projects, impacting important fields such as cardiovascular disease, stroke, and cancer."²²²²



Investors are willing to bank on medtech startups – if they meet certain criteria

Many of the VC investors we interviewed said their passion for the medtech sector often compels them to take financial risks in pursuit of therapeutic benefits for patients. Interviewees agreed that strong management teams – combined with technologies that have relatively low regulatory and reimbursement barriers – are critical to realizing a return. Other common considerations include:

- **A focus on scalable technologies that address unmet needs in large markets:** Some VCs are inclined to invest in technologies that address unmet needs or are in segments that have room for innovation. Some interviewees said that products with even modest improvements over the current standard of care are important. Others choose to focus on disruptive technologies. But most respondents said that adoption of new products at scale continues to challenge small medtech companies well into the commercialization stage, mostly due to complex sales channels, lack of access to customers, and strict institutional rules.
- **Interest in companies that could help reduce the overall cost of health care:** In addition to addressing unmet needs, VCs are also enticed by opportunities that reduce costs and deliver economic impact through innovation. Investors said that medtech entrepreneurs should strive to demonstrate the financial benefits their products offer to their customers. This could include products that improve efficiencies in the health care delivery process, which ultimately reduce the total cost of care.
- **A preference for efficient, forward-looking companies:** VCs want to invest in capital-efficient companies that can build profitable businesses with limited funding. They are looking for company leaders who are thinking strategically about building clinical evidence, protecting their intellectual property, identifying realistic sales channels, and taking action to mitigate risk and other potential barriers to future success.



Some medtech startups are seeking alternative financing

As strategics continue to take a conservative approach to investing and traditional VCs pull back from investing in early-stage technologies, some medtech startups are looking to alternative modes of financing. The good news – some modalities are proving to be fruitful:

- **Access to public markets via IPOs/SPACs:** Traditionally, early-stage startups were limited to private and/or institutional dollars when fundraising. Public funds were only accessible via typical Initial Public Offerings (IPOs) following demonstrated commercial success and growth. In recent years, some medtech companies have started using nontraditional IPOs and Special Purpose Acquisition Companies (SPACs) as vehicles for accessing public markets to secure capital at an earlier stage. While not an easy route, IPOs and/or SPACs can give entrepreneurs an opportunity to access a much broader investor pool and generate broader interest – even in the pre-revenue stage.
- **Build-to-buy:** In this model, a strategic identifies an early-stage company that has a product of interest and negotiates the terms of its investment. This might include evaluating the startup's business plan and key milestones and helping it through the product-development process. The build-to-buy model also involves taking an ownership stake in the company, filling board seats, and retaining the option to buy the company if milestones are met. In the end, startups might choose to trade future valuations – potentially at higher levels – to get the financing and development help they need. For strategics, the build-to-buy model can provide a guarantee on their investment. It can also reduce competition from other buyers if the product comes to fruition. Furthermore, these equity investments often include venture funds. While this may seem like a perfect solution, industry leaders told us that getting strategics to the negotiating table often requires work and careful orchestration. However, this approach has been gaining some traction in recent years.
- **Family offices:** Family office investment groups tend to be less formal than VC funds, are often mission driven, and are usually run by independent families. Furthermore, they may not be limited to exit timelines like traditional venture capital funds. Investors told us that most family offices in medtech have specific interests in certain therapeutic areas and can often offer functional expertise to the entrepreneur – sometimes by taking a controlling stake and/or board seats. The family office investors we spoke with cautioned that experience investing in the medtech sector is critical. There have been several instances of funds that sustained substantial losses after entering deals without fully understanding the sector. This is not only unfortunate for the fund but also for the sector as it could negatively impact future investments from that office.

Suggested steps forward

The medtech startup ecosystem is complex. However, the industry leaders, entrepreneurs, and investors we talked with were optimistic that new and innovative products could be brought to market. The recent significant increase in overall venture funding in medtech supports this optimism.

As mentioned previously, all stakeholders, including medtech startup company accelerators and incubators, should work with regulators to improve and streamline coding, coverage, and payment processes. Mechanisms for the reimbursement of novel products while evidence is being generated should also be prioritized. In the meantime, specific stakeholders could also consider the following:

- **Investors:**

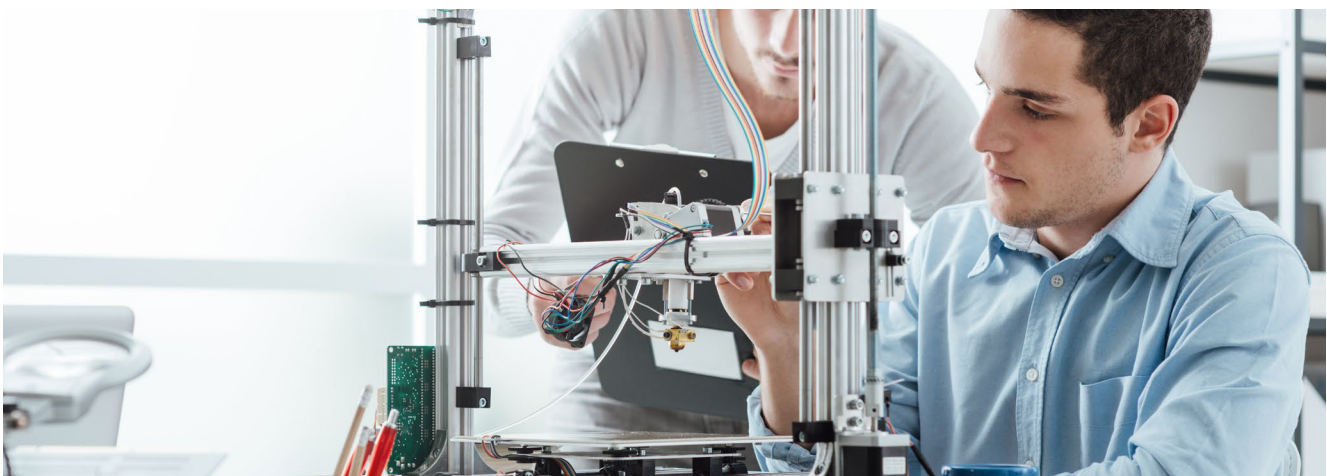
- Consider medtech as a long-term investment opportunity and prepare for syndication with various investors over multiple rounds of funding.
- Help portfolio companies prepare for exits by building strong relationships with multiple strategics.
- Support portfolio companies in building manufacturing quality systems, compliance programs, and in laying the groundwork for regulatory and reimbursement success. Strong governance and diversity, equity, and inclusion efforts should also be supported.

- **Strategics:**

- Invest early in novel technologies to support the innovation pipeline, boost existing business lines, and advance new business lines. In addition, investing early can help prevent being priced out of the market for potential acquisition later.
- Prioritize investments in new products and/or external collaborations. Acquisition opportunities that add transformational products to the portfolio should be considered.²³
- Share expertise and leading practices with startups to help early-stage entrepreneurs accelerate innovation.
- Pilot build-to-buy partnerships to foster innovation while mitigating risk.

- **Entrepreneurs:**

- Focus on developing a strong clinical evidence base and clinical strategy. Demonstrate clinical and economic value to attract investor attention.
- Use investment dollars efficiently to expedite development and decrease capital requirements.
- Create plans to mitigate and address reimbursement challenges. Start this process early.
- Explore multiple exit strategies – such as early IPOs or build-to-buy. Novel approaches could provide interesting opportunities, especially with increased access to public markets.



Appendix:

Technology category definitions for Figure 5

| Tech segments | Definition |
|--------------------------------------|--|
| Artificial Intelligence | The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages. AI technologies includes machine learning, data science, conversational platforms, computer vision, AI chips, smart robots, and context aware computing. |
| 3D Printing | 3D printing is the process of joining materials to make objects from three-dimensional model data, usually layer upon layer. Moving forward, 3D printing is expected to be centered around more personal treatments such as printing custom pharmaceuticals at low cost or printing custom organs and medical devices tailored to patients at their bedside, to be implanted with minimal failure rates. |
| Cloud | Cloud computing is used for delivering IT services in which resources are retrieved from the Internet through web-based tools and applications, as opposed to a direct connection to a server. With the massive amount of health care data shared globally, the cloud has allowed this data to be accessed easily, no matter who you are, or where you are |
| Digitalization | Digitalization refers to the way that the health care industry is being overhauled. This includes patient and physician medical records, appointment scheduling, communication methods, and more. The digital transformation is shifting the way healthcare services is provided, allowing easier communication and focus on patient care. |
| Big Data | Big data is data that is so voluminous and complex that traditional data-processing application software is inadequate to deal with it in its entirety. Big Data competence is vital for health care companies, as it allows them to understand their market better, understand their customers better, identify potential areas of opportunity and uncover internal waste and inefficiency. |
| Internet of Things | An umbrella term referring to the ability of everyday physical objects to connect with other devices over the internet, enabling them to send and receive data. |
| Robotics | Robotics involves the design, construction, operation, and application of robots in healthcare. Robotics plays an important role in medical devices. Surgical robots, the largest market, automate all or part of the process of medical surgery and have revolutionized the way that surgeries are performed. |
| Virtual and Augmented Reality | Increasing health care expenditure and the need for cutting-edge technologies to aid the development of novel therapies and diagnostics have fueled the need for VR/AR in the health care industry. The myriad possibilities for VR/AR technology in the health care sector include medical education, image-guided treatment, the treatment of neuropsychological conditions and visual impairment, as well as use in rehabilitation. |

Endnotes

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AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit www.advamed.org

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