



## Can medtech start-ups show us where the industry is headed? Insights from MedTech Innovator and industry leaders

### Executive summary

Medical technologies are often the result of years of research and development. In the US, they are a foundation of a rich ecosystem of innovation. Start-ups offer advanced technologies that hold the promise of producing data, delivering better care, and driving insights that can improve patient outcomes. These products, services, and capabilities show that we are rapidly moving toward our vision of the Future of Health™ where real-time, interoperable data enable prevention and early detection, and shift the focus away from acute intervention.

In spring 2021, Deloitte's Center for Health Solutions collaborated with MedTech Innovator (MTI)—the world's largest health care accelerator for medical devices, digital health, and diagnostic companies—to evaluate trends across the medical technology start-up landscape. We analyzed MTI's database of 1,000 start-ups that applied in 2021 to participate in the organization's global competition for support from MTI's accelerator program. To deepen our understanding and learn about where stakeholders think the industry is going, we also interviewed leaders from start-ups and medtech companies that could be strategic acquirers ("strategics").

Through our data analysis and interviews, we quantified the following trends:

- **Start-ups and strategics are expanding beyond episodic care and procedures:** Companies that have historically targeted specific therapeutic areas defined by a procedure (e.g., implanted devices) are adding products and solutions to their portfolios to help address the full patient journey—from diagnosis to rehabilitation. Nearly half of start-ups (46%) have a focus on prevention and/or wellness or detection/diagnosis, and only 19% include a focus on treatment.
- **Care is shifting away from the traditional inpatient setting:** Ambulatory clinics, at-home care, self-administered diagnostics, and always-on remote monitoring are growing areas of interest. Seventy percent (70%) of start-up companies in the diagnostics sector have a product applicable to the point-of-care setting. These trends have implications for reimbursement and clinical support.
- **Medical technology is getting smarter:** Seventy percent (70%) of start-up technologies include digital capabilities such as artificial intelligence (AI) and machine learning (28%). Strategics seeking acquisition targets might be looking for these capabilities.
- **Start-ups are choosing less burdensome regulatory paths:** A majority of innovators are planning to enter the market with 510(k) (47%) or unregulated (29%) products.

- **Pre-seed rounds have been commonplace, with significant step-ups in average round sizes, and limited runway:** In their most recently closed funding, the average round size for pre-seed (39%) was \$0.25M, seed (42%) was \$1.31M, and series A (13%) was \$4.85M. The average seed stage company has six months of funding before it will need to find additional capital.

- **Series A Investors are looking beyond proof of concept:** Investors have become more astute over the last few years in assessing value, clinical efficacy, and reimbursement potential. Innovators have gotten the message that investors may be less willing to make significant investments without clinical evidence or near-term regulatory approval. Most companies seeking series A are clinical or later in their development stage (66%).

COVID-19 has been both a positive and a negative from the business perspective. Interviewees told us they are largely recovering financially from having fewer elective surgeries in 2020. They have learned how to engage with physicians—and support their products—remotely. Funding for medtech and health-tech innovation has remained strong, reaching record levels in 2020. Moreover, the commitment to developing innovative products that support the whole patient journey appears to be even stronger than it was before the pandemic.

In addition, we found that both start-ups and strategics are addressing diversity and health equity. Nearly all of the company executives we interviewed—and 83% of the companies in the MTI database—have diversity and inclusion strategies for talent, though representation still has room for improvement. While 49% of start-ups have female employees in leadership positions, only 16% have BIPOC leadership, and 35% have other POC leadership. Medtech companies are also working to:

- Make their products broadly accessible
- Keep diversity in leadership in mind as a part of M&A
- Use real-world data to look at outcomes by race and gender

## Introduction

Deloitte's Center for Health Solutions continually evaluates

trends in all aspects of health care, with a focus on the Future of Health™. Over the next 20 years, we expect the health care industry will shift from a reactive focus on care to a proactive focus on wellness and prevention, which will all be centered around the consumer. While we might never completely eliminate disease, we expect that breakthroughs in science, data, and technology will make it possible to identify disease in its earliest stages, intervene proactively, and understand disease progression. These anticipated trends could help consumers more effectively and actively manage their own care and sustain their well-being. Specifically, we expect:

- An explosion of data access and analytics will shift us to real-time, pervasive computing that enables earlier detection and intervention.
- Consumers will no longer be led by doctors but will instead be empowered to bring ideas to the table.
- The health care system will transition from a provider-centric model to a consumer-centric model.
- Well-being and care enablement will eclipse sick care.

To play a larger role in the health system of the future, medtech companies will likely need to expand both their scope and their capabilities. One route may be through partnerships with consumer health organizations<sup>1</sup>. Another could be through new business models that could include managing the entire patient journey around a disease or becoming an ecosystem data and analytics provider<sup>2</sup>. Start-up partnerships and acquisitions might offer another important pathway for strategics to explore new models and remain relevant.

Given that start-up companies reflect the leading edge of innovation, we analyzed MedTech Innovator's (MTI) database of early-stage innovators to determine if start-ups could serve as the backbone for the strategic shift in the medtech industry. The database includes a wide variety of medical technologies that address a wide range of therapeutic areas and needs. The database also indicates whether the start-up community's efforts align with our vision for the [Future of Health](#).

## Background and Methodology

MedTech Innovator (MTI), the world's largest health care accelerator, has a particular emphasis on medical devices, digital health, diagnostics, and life science tools. MTI is a 501(c)(3) non-profit, purpose built to ensure that viable innovations successfully reach patients and with maximum value. Companies apply with no fees or strings attached and are selected solely based on merit.

Incentives to apply are corporate mentorship and access to MTI partners, industry recognition, visibility and exclusive ability to pitch at leading conferences, education via the MTI LIVE webinar series, investor introductions and showcases, access to a peer network, and cash awards in competitions on the "main stages" of The MedTech Strategist Summit, Willson Sonsini's Medical Device Conference, and AdvaMed's The MedTech Conference. Across all cohorts, \$1M in non-dilutive funding will be awarded in 2021 by MTI.

To learn about MTI, visit <https://medtechinnovator.org>

More than 6,000 companies have applied to MTI since 2013. MTI is highly selective, with less than a 5% acceptance rate. Within its portfolio of 340 alumni companies, 95% are still operating and 85% have raised equity funding. Graduates have raised nearly \$3 billion in follow-on equity funding, achieved 17 acquisitions, and brought 85 products to market.

For this report, Deloitte analyzed 1,000 companies applying to participate in MTI's 2021 program. This database reflects applicants who have developed at least a prototype and have not progressed beyond a series D round of funding. Some highlights about this pool of companies:

- 76% of applicants have raised equity funding, collectively raising \$3.9 billion.
- Applicants hail from 43 countries and 48 US states
- 33% percent are pre-clinical; 28% are clinical / pre-approval; 9% are approved, and 22% have customers

For each company in the MTI database, data was analyzed in the following areas:

- Development stage
- Product categorization (clinical and technical)
- Completed milestones
- Completed funding amounts, rounds, and investor sources
- Upcoming fundraising and milestones
- Customer types and healthcare economics
- Market access plans
- Competitive advantage

- Intellectual property
- Regulatory path and status
- Validations, traction, and sales
- Revenue model
- Team
- Diversity, equity, and inclusion

In addition to analyzing the MTI dataset, Deloitte also interviewed 14 leaders from start-ups and executives from established medtech companies that could be strategic buyers. They offered their perspectives on the start-up landscape, trends in the industry, and barriers to successful innovation.

## Research Findings

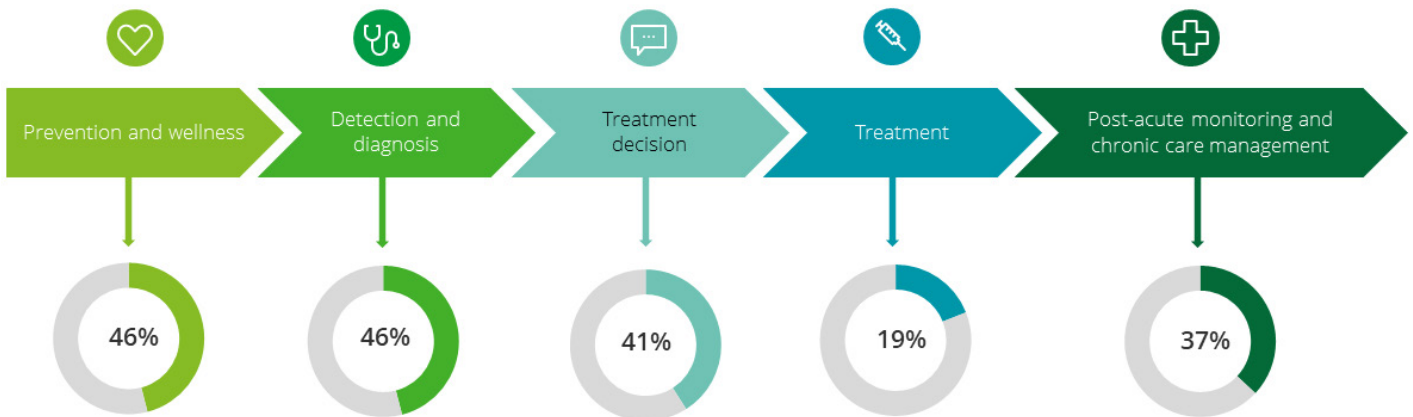
### Most start-ups are focusing on prevention, wellness, and diagnosis, rather than treatment

Among the 1,008 companies in the 2021 MTI database, nearly half (46%) have a focus on prevention and/or wellness or detection/diagnosis. Just 19% of companies are focusing on treatment. Within the prevention/wellness category, companies indicated a variety of clinical areas. Cardiology was the most common.

Our interviews confirmed that the industry is trending toward prevention, wellness, and diagnosis. This is in addition to many innovations that support treatment and post-acute monitoring. Strategics that have built businesses around specific therapeutic areas defined by a procedure (e.g. where the technology is an implant) told us they are adding products and solutions to their portfolios to address the full patient journey—from diagnosis to rehabilitation.

Figure 1

### Medtech start-up companies are focusing on the early stages of the patient journey



**Survey question:** Please select each step in the patient journey that applies to your product. (Check all that apply)

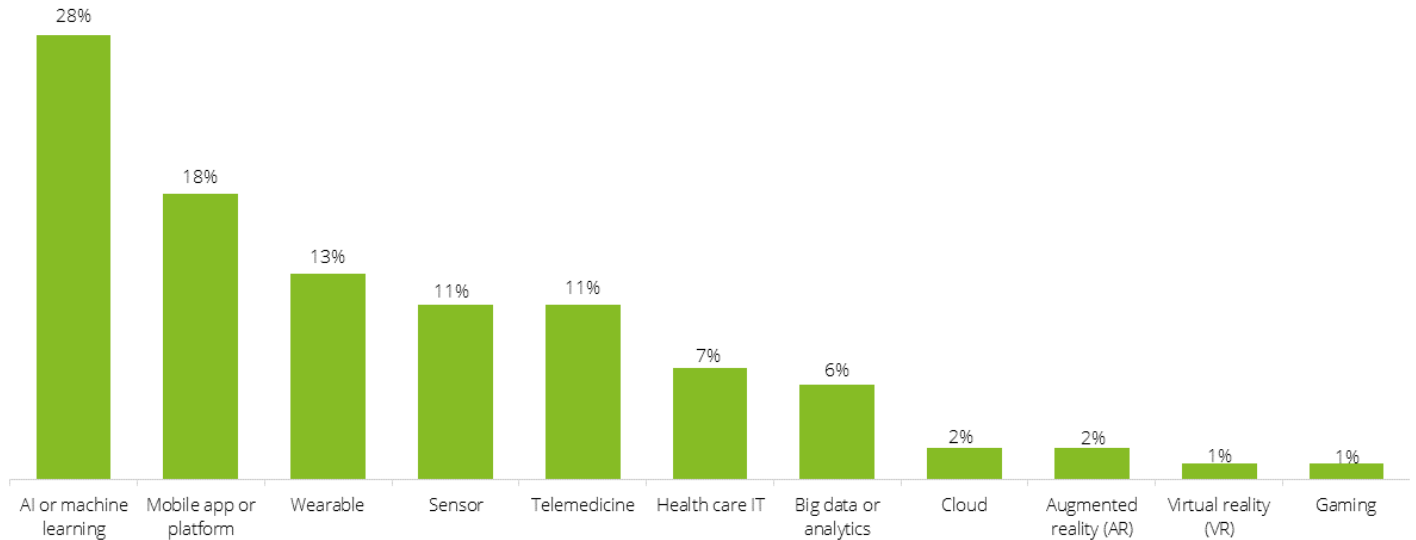
**Notes:** Percentages will not add up to 100%; N=1008.

**Source:** Deloitte analysis of the MTI database, 2021.

In addition, executives from 705 of the 1,006 companies in the MTI database (70%) said they had advanced digital capabilities. The most common type was AI/machine learning (28%). A wide range of other capabilities were also represented, including mobile app/platform, wearables, and sensors, which likely could enable interventions along the patient journey

Figure 2

### About a quarter of medtech start-ups are developing products with AI or machine learning capabilities



Survey question: If your product is digital or has a digital component, which category best defines it? (Single select)

Notes: N=705.

Source: Deloitte analysis of the MTI database, 2021.

### The site of care is shifting away from traditional inpatient settings

Business development leaders at strategics said they are seeing a significant shift in areas where products are used, moving toward less acute settings:

- For cardiology procedures and implants, they anticipate increased opportunities to offer products along the patient journey and sites of care—from traditional inpatient settings to ambulatory care settings.
- For diagnostic products and services, interviewees expect to see more offerings and opportunities in point-of-care and home settings.

The COVID-19 pandemic spurred changes to funding, innovation, payment policies, and strategies that support virtual health across multiple dimensions. Our interviewees discussed the increased emphasis on virtual health, which includes ambulatory care clinics, at-home care, self-administered diagnostics, and always-on remote monitoring.

Detection and diagnostics are a key focus of innovation,

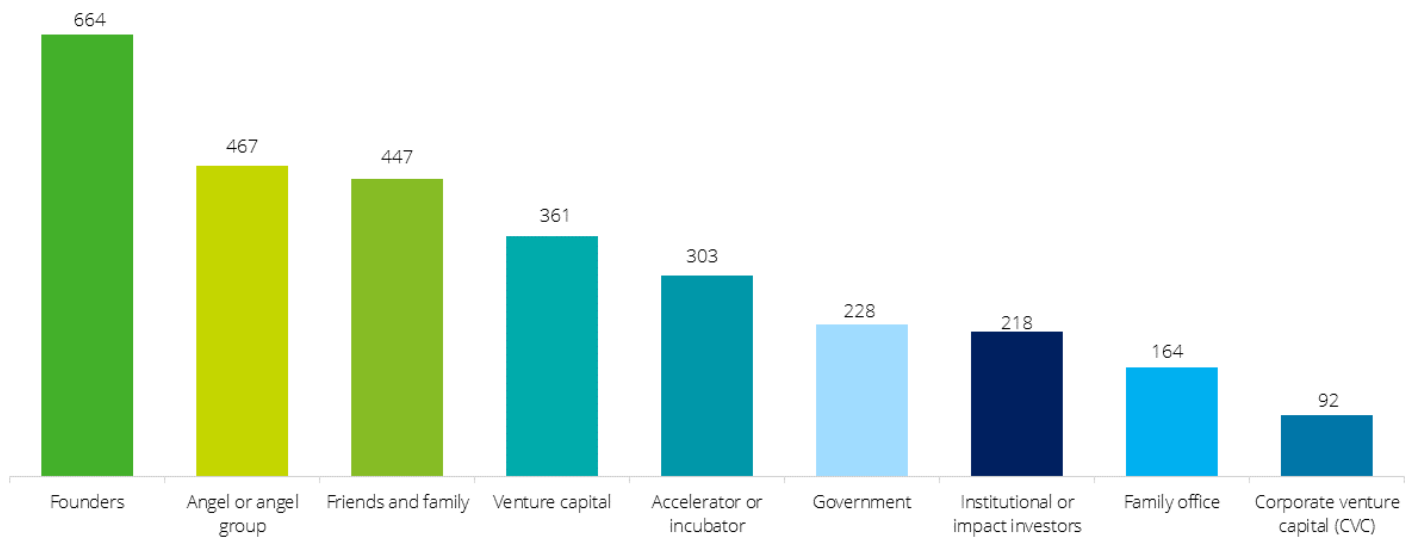
particularly around testing or technology at the point of care. According to analysis of the MTI database, over the last three years (2019 to 2021) the share of point-of-care products has grown significantly—from 62% of companies to 70%—among start-up companies that have diagnostic products. Somewhat fewer companies were focused on genomics/sequencing during the same period. The share of company executives that said this category applied to their product declined from 12% to 7%.

### Investors are interested in medtech, but start-ups may need more money to survive

The MTI database shows that early-stage medtech companies are typically funded by founders, family and friends, and angels (see figure 3). Founder interviewees told us that they have started to turn to high-net-worth individuals and/or family offices for funding when more traditional sources, like venture capitalists, are not ready to invest. This is a continuation of trends we saw in a 2017 [research study](#) that focused on the medtech innovation ecosystem.

Figure 3

### Major investors in medtech start-ups include founders, angels, and friends and family; CVCs comprise a small part of the investor pool



**Survey question:** Select the types of investors who have already invested in your company. (Check all that apply)

**Notes:** Institutional investors consists of foundations and philanthropy, lenders and banks, growth equity, hedge funds, real estate, and private equity; N=981.

**Source:** Deloitte analysis of the MTI database, 2021.

We found a few surprises when we examined which investors contributed the most to companies: (Figure 4)

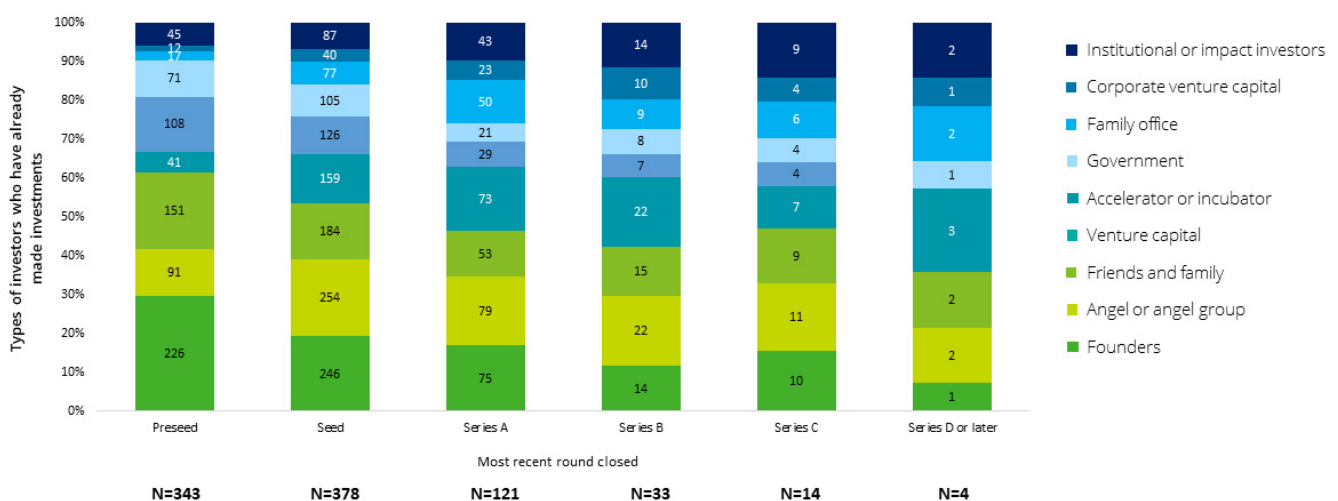
- Only a quarter of companies (228) reported being supported by government grants. This was especially true in the early stages of product development. One possible funding avenue for products at this stage is small business innovation research (SBIR) grants—non-dilutive funding that can help companies get

through product development.

- Corporate Venture Capital groups (CVCs) were listed as a source of funding by early-stage companies, including some in the pre-seed (13%) and seed stages (43%).
- About a third (n=303) of surveyed founders said they have been supported by an accelerator.

Figure 4

### Founders, angels, and friends and family are the predominant early-stage investors in medtech start-ups



**Survey question:** Select the types of investors who have already invested in your company. (Check all that apply); Choose all the rounds that you have already completed

**Notes:** Institutional or impact investors consists of foundations and philanthropy, lenders and banks, growth equity, hedge funds, real estate, and private equity; N=893; Number of companies reporting fundraising for each stage is also shown.

**Source:** Deloitte analysis of the MTI database, 2021.



Looking at investments by medical area (Figure 5), companies that have products in cardiology, radiology/nuclear medicine, or nephrology appeared in the top five, totaling nearly \$400m through Series C funding.

Figure 5

### Medtech start-ups raised \$1.8 billion in funding in their most recent rounds; the top three medical areas were cardiology, radiology, and nephrology

	Pre-Seed		Seed		Series A		Series B		Series C		Series D or later		Total funds secured	Total # of companies
	Funding secured	# of companies	Funding secured	# of companies	Funding secured	# of companies	Funding secured	# of companies	Funding secured	# of companies	Funding secured	# of companies		
Cardiology	\$5M	19	\$45M	25	\$26M	7	\$13M	3	\$70M	2			\$158M	56
Radiology / Nuclear Medicine	\$3M	6	\$30M	14	\$16M	5					\$85M	1	\$133M	26
Nephrology	\$0M	5	\$7M	3	\$6M	1	\$105M	2					\$119M	11
Orthopedic Surgery / Sports Medicine	\$2M	18	\$18M	14	\$50M	8	\$39M	5					\$110M	45
Cardiac, Thoracic, Vascular Surgery	\$3M	10	\$33M	12	\$57M	6	\$4M	1	\$5M	2			\$101M	31
Other medical areas	\$68M	266	\$332M	286	\$383M	84	\$233M	20	\$66M	8	\$86M	3	\$1.17B	667
<b>Grand Total</b>	<b>\$82M</b>	<b>324</b>	<b>\$463M</b>	<b>354</b>	<b>\$538M</b>	<b>111</b>	<b>\$394M</b>	<b>31</b>	<b>\$142M</b>	<b>12</b>	<b>\$171M</b>	<b>4</b>	<b>\$1.79B</b>	<b>836</b>
Average funding secured per round	\$0.25M		\$1.31M		\$4.85M		\$12.71M		\$11.83M		\$42.75M			

Survey question: Most recent equity round total closed (by top five medical area); choose all the rounds that you have already completed.

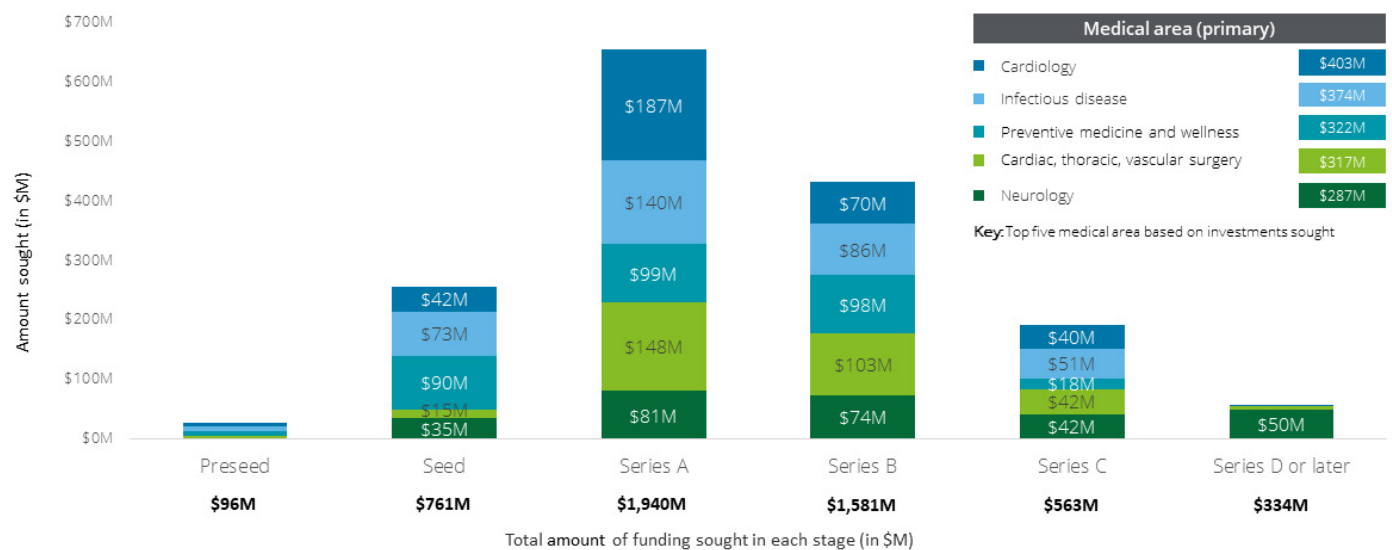
Notes: Blank space indicates no companies reported funding for those phases; All dollar amount are in USD; N=836.

Source: Deloitte analysis of the MTI database, 2021.

Cardiology is the dominant category for funding sought overall (\$403m) (Figure 6). Products related to infectious disease—perhaps spurred on by the pandemic—also appeared in the top five, as did preventive medicine, with funds sought totaling \$700m.

Figure 6

### Most medtech start-ups are seeking series A funds, with cardiology being a prominent medical area of focus



Survey question: If you are not currently raising a round, specify the round that you will next be seeking; How much funding are you seeking?

Notes: Total dollar amounts per medical area reflect additional, smaller, non-series-based fundraising efforts (not shown); N=Bases vary.

Source: Deloitte analysis of the MTI database, 2021.

Most of the start-ups in the MTI database (77%) said they have only enough capital to continue operations through the end of 2021. Without additional cash, 96% of them could run out of money at some point in 2022. This includes companies that currently have paying customers.

Companies that have a product prototype supported by clinical and feasibility data are more likely than companies with concept-stage products to attract attention from institutional investors and strategics. But without adequate funding during the earlier stages of development, it can be difficult to generate the data needed to attract interest from institutional investors. Start-up companies often struggle to make it out of the so-called “valley of death” period between initial investment and the development of a commercially viable product, according to our previous research with AdvaMed. While strategic acquirers depend on a thriving external innovation ecosystem for acquisition targets and new sources of growth, many of them shy away from making investments in early-stage, unproven technologies<sup>3</sup>. Strategics told us that acquisition hurdles are getting higher. They said they often look beyond the technology and whether it fits their portfolio and consider clinical evidence, the likely path to regulatory approval, and reimbursement and sales potential.

Start-ups need money to generate the clinical evidence necessary to demonstrate commercial potential. Initial Public Offerings (IPOs) via the open market can provide start-up companies with public capital while Special Purpose Acquisition Companies (SPACs) can also, in some cases, offer an alternative to both an IPO and traditional M&A.

But like 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—which can take many forms, including:

- **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. These companies typically split 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. 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 companies run their own accelerators for early-stage technologies. Other companies are active participants in accelerators run externally by organizations such as MTI. An additional and perhaps complementary option for engaging with innovators is to take an equity stake in a start-up. This can provide an opportunity to potentially earn a financial return from their investments. These options, coupled with the types of partnerships mentioned above, can reduce the investment risk for strategics. It also can provide start-ups with the capital needed to move forward in the development process, and to generate the evidence required. However, while start-ups increasingly are looking to CVCs as a source of funding, only 20% of founders said CVCs had invested in their pre-clinical stage product, vs. 43% of approved or later-stage products. If start-ups cannot get the funding they need early on, important innovations might never reach a single patient.

## Many new medtech companies are exploring the 510(k) regulatory pathway to approval as well as multiple revenue models

### Regulatory pathways

More than two-thirds of the start-ups in the MTI database are in the pre-approval development stage, and 22% have paying customers.

Nearly half (47%) of start-ups are pursuing a 510(k) regulatory pathway to approval, and 29% said that approval is not required for their product. Under the 510(k) pathway, infectious disease (likely reflective of the pandemic), and emergency medicine were the most common primary medical areas. Preventive medicine/wellness was the top medical area reported under the ‘not applicable’ pathway—likely referring to digital apps. It is possible that products that do not currently require approval might need approval in the future.

Notably, only one fifth of company founders said they are developing products that would require de Novo (13%) or

premarket approval (PMA) (8%). Given the investment dynamics described earlier, this is not a surprise. The de Novo and PMA pathways are more stringent than the 510(k) pathway, for example, and require more clinical evidence to support the application. Consequently, companies could incur higher costs when seeking approval of products via the de Novo or PMA pathways. One start-up founder described being caught in a vicious cycle of not having the clinical data required to attract investors because there was no money to run a clinical trial that would generate the clinical data. This was despite having demonstrated that the novel product could address a significant unmet need in a large market. While higher-risk products can provide a more direct route to payment in the end, fundraising plans (Figure 7) indicate that most companies are not seeking dollars to pursue the more stringent pathways to approval.

## Changing regulations aim to expand access to digital health products

Today, digital medicine products are treated as medical devices or software as a medical device (SaMD) and reviewed and approved through traditional medical device pathways, including the 510(k) and De Novo.

Some industry observers think that these pathways are not optimally suited for software-based digital medicine products, which need to be updated periodically in response to real-world performance and user feedback<sup>4</sup>. developers to go through a typically lengthy and expensive 510(k) process. This can limit their ability to bring new products to market or to make changes to existing products.

In response to this challenge, the US Food and Drug Administration (FDA) created the Digital Health Software Precertification (Pre-Cert) Pilot Program. The program aims to develop an innovative approach for accelerated review and oversight of digital health products by “looking first at the digital health technology developer, not the product.” This involves pre-certifying companies that demonstrate a commitment to a culture of quality and organizational excellence and monitoring real-world performance of their products. Pre-certified companies would likely be able to market their lower-risk products with only a streamlined premarket review or bypass the premarket review altogether<sup>5</sup>. For more, see Deloitte publication [Reimagining Digital Health Regulation](#).

In 2019, the FDA launched a pilot to evaluate the feasibility of the Pre-Cert model. The goal was to determine if this model for premarket review can provide the same quality of information on safety and effectiveness as traditional approaches. Going forward, FDA will continue to test and iterate the model.

Figure 7

### Most medtech start-ups seeking investments are pursuing the 510(k) regulatory pathway

	510 (k)		Not applicable		De Novo		PMA		Combination Product (CBER)		Combination Product (CDRH)	
	Funding sought	# of companies	Funding sought	# of companies	Funding sought	# of companies	Funding sought	# of companies	Funding sought	# of companies	Funding sought	# of companies
Concept to Prototype: pre-clinical	\$559.77M	178	\$211.28M	79	\$184.60M	47	\$251.50M	42	\$55.50M	6	\$19.70M	10
Prototype: clinical to Product: pre-approval	\$570.98M	137	\$127.00M	41	\$614.05M	59	\$332.25M	26	\$23.00M	1	\$41.40M	6
Product: approved	\$338.20M	38	\$102.15M	30	\$51.80M	7	\$25.00M	2			\$19.50M	4
Paying customers	\$808.30M	72	\$660.28M	109	\$101.50M	8	\$18.00M	2	\$22.50M	2		
<b>Grand Total</b>	<b>\$2.28B</b>	<b>425</b>	<b>\$1.10B</b>	<b>259</b>	<b>\$0.95B</b>	<b>121</b>	<b>\$0.63B</b>	<b>72</b>	<b>\$101.00M</b>	<b>9</b>	<b>\$80.60M</b>	<b>20</b>

**Survey question:** Which of the following best describes your product's US regulatory pathway?; How much funding are you seeking?

**Note 1:** "Not applicable" mostly consists of innovations categorized under the digital category.

**Note 2:** The Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) are two FDA centers that regulate combination products.

**Note 3 :** Blank space indicates no companies reported seeking funds for those pathways; All dollar amount are in USD; N=906.

**Source:** Deloitte analysis of the MTI database, 2021. Response options were single-select.

Interviewees told us they understood the regulatory processes and noted that regulatory agencies have worked hard to improve the pace of approvals. They said regulators are also accommodating new forms of technology, such as software as a medical service. However, even as the pandemic begins to wane, the FDA has indicated that backlogs and staffing shortages could lead to delays in reviewing products<sup>6</sup>.

Cyber threats are another emerging regulatory issue. As medtech companies increase connectivity of their products, they also increase their vulnerability to cyber threats. Regulators in Europe have taken a strong approach to this vulnerability, and US regulators might follow. Medtech companies—both start-ups and strategics—should have a thoughtful approach to managing cyber risk.

### Reimbursement

Reimbursement is typically challenging, particularly when a technology is new. This adds uncertainty to whether the technology will be covered by payers, whether there will be a new code for the technology, and how much the payment rate will be. The shifting site of care has reimbursement implications. Medtech companies could see increased price pressure on products used in lower-acuity settings. Interviewees told us that investors have become more knowledgeable about these challenges. This means start-ups might need to provide detailed information about likely reimbursement. Companies should consider taking advantage of the parallel review process offered by CMS and FDA<sup>7</sup>.



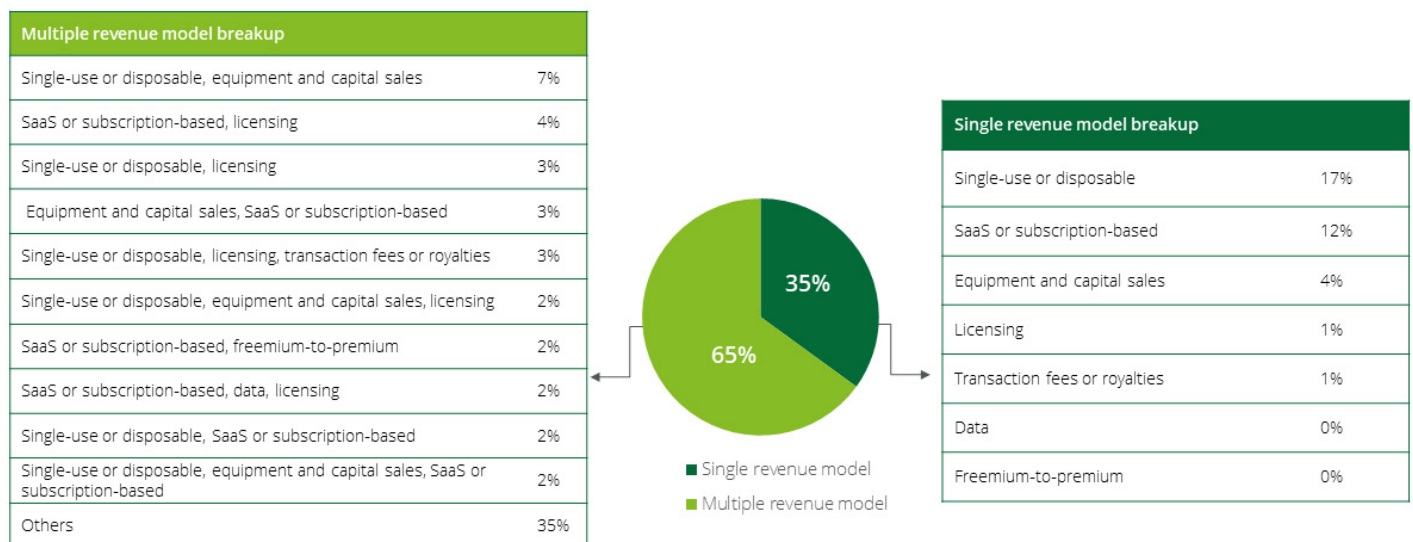
Several people we interviewed expressed frustration at the late release of regulations related to the Breakthrough Device coverage pathway. The Medicare Coverage of Innovation Technology (MCIT) regulation would automatically grant four years of immediate coverage to FDA-breakthrough-designated medical devices concurrently with regulatory approval<sup>8</sup>. In May 2021, the Biden administration announced that it would delay this regulation until December 2021, citing concerns that the Centers for Medicare and Medicaid Services (CMS) would have less authority to revoke coverage if it turned out that the approved breakthrough technologies were harmful<sup>9</sup>.

### Business models

SaaS/subscription-based models (49%) and single use disposables (48%) are the most preferred current/expected revenue models by start-ups; other models such as licensing (37%) and equipment/capital sales (35%) are also well represented. Interestingly, 65% of start-ups reported a diversified revenue model approach where two or three or more models are pursued at once. This could include efforts to monetize digital aspects of new products, including data.

Figure 8

## Medtech start-ups prefer SaaS, subscription-based, single-use, and disposable revenue models



Survey question: What is your revenue model or anticipated revenue model? (Check all that apply)

Note 1: N=950.

Source: Deloitte analysis of the MTI database, 2021.

### The impact of COVID-19 on the innovation ecosystem

The impact of COVID-19 on the medtech innovation ecosystem depends on the types of technologies that companies offer. Some companies were at the forefront of addressing the pandemic. They developed tests, supplies, and protective equipment as well as technology that supported patients who received treatment in the hospital. Many of these companies have experienced unprecedented demand and regulatory flexibility, which made

it possible to bring new products to market more quickly.

Consistent with previous years, the number of companies in MTI's database for 2021 remains high. This suggests there is no lack of ideas for new products or any drop in interest in incubator support. Unsurprisingly, virtual health was a hot investment area in 2021, which was driven by a surge in use during the early months of the pandemic.

#### Earlier Deloitte report finds very high investment interest in health technologies

Although medical technology is the focus of this study, Deloitte also recently analyzed investment trends in health technology. In that study, we found that health tech innovators that are focused on the Future of Health will likely continue to receive the lion's share of funding in 2021 and beyond. Innovators that are focused on well-being and care delivery models received a record \$6.4 billion funding in 2020 in the US. The pandemic accelerated funding for innovators that offer alternative forms of care delivery, such as remote monitoring and virtual health.

This was driven by health systems and health plans that had not already invested in these technologies and had to pivot to them quickly. Interest in virtual health is expected to continue, even as in-person visits have recovered. Finding an effective, scalable balance between virtual and in-person visits could be a challenge. Interviewees suggested that major focus areas for 2021 and beyond include on-demand health outside of traditional health care settings, mental health, and fitness<sup>10</sup>.

Many companies that had been developing technologies to address more traditional and complex technologies used in surgeries saw a drop in clinical-trial enrollment and sales. Interviewees—both innovators and strategics—told us they are recovering financially from the drop in elective surgeries that reduced revenue in 2020. They are now able to meet with physicians and support the use of their products in clinical settings. Some interviewees noted some challenges in recruiting patients for clinical trials. While the threat of the pandemic has diminished, some patients are still concerned about their ability to maintain social distance in a health care setting.

**Incumbent medtech companies and start-ups are addressing health equity in their businesses and products**

Issues related to systemic racism and health equity have been in the spotlight for much of 2020 and 2021. The moral imperative for health equity is undeniable, but there are also business reasons for this focus. Many life sciences and health care organizations have an especially strong interest in improving health equity, which could bolster their commercial success while also saving lives and delivering more value to the individuals and communities they serve<sup>11</sup>.

Many start-ups and strategics are addressing health equity within organizations, products, communities, and ecosystems. Nearly all

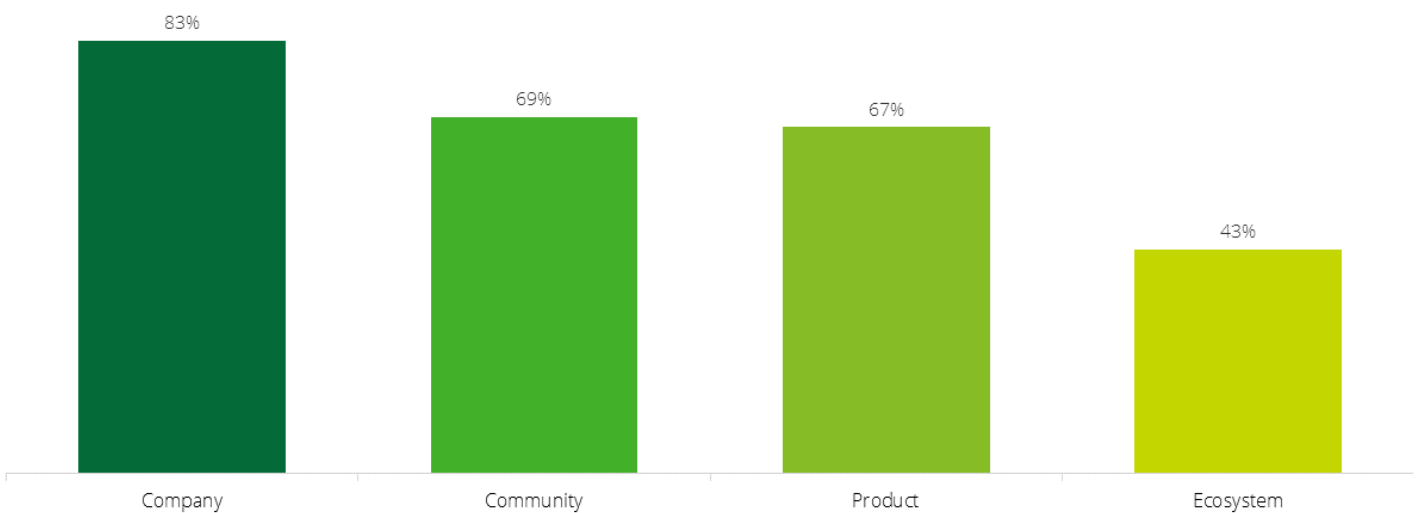
of the company executives we interviewed, as well as companies in the MTI database, have diversity and inclusion strategies for talent. Strategies include a focus on making products more broadly accessible, keeping diversity of leadership in mind as a part of M&A, and using real-world data to look at outcomes by race and gender.

MTI asked this year's applicants to describe how they are approaching health equity along four potential dimensions that Deloitte has been using in its Activating Health Equity approach. The four dimensions (and explanations given in the applications) include:

- **Company:** Advancing internal initiatives to improve diversity, equity, and inclusion in the company and understanding the needs of employees
- **Product designed for diversity:** Assessing and changing core services and/or products to reduce disparities, such as improving access, reducing pricing, and showing diversity in packaging and marketing
- **Community:** Taking a role to improve outcomes, including social determinants of health in geographic and virtual communities
- **Ecosystem, including policy:** Actively reflecting a diversity leadership agenda through aligned suppliers/vendors, establishing ecosystem relationships, and public advocacy

Figure 9

**Medtech start-ups are thinking about health equity and are focused on diversity and inclusion at the company level**



**Survey question:** As applicable, please let us know the status of initiatives in which you are setting policies as it relates to health equity. (Check all that apply)

**Note 1:** N=852.

**Source:** Deloitte analysis of the MTI database, 2021.

Eighty-three percent of companies in the MTI database are focused on health equity at the company level, but many companies also indicated a focus on other aspects of health equity. Almost half (49%) of start-ups have women in senior leadership positions (CEO, President, Founder/ Co-Founder); 35% selected “other people of color” (e.g. Latinx, Asian, Indian) as being in these same roles. However, Black, indigenous, and other people of color (BIPOC) representation is only 16%.

Innovators noted that their companies are small, which often means the range of potential impact is limited. Some innovators have been explicitly thinking about how to support broad access to their products as part of health equity and how the products themselves might help to improve equity. One start-up executive told us that because his product produces real-world data, it is perfectly positioned to support the analysis of disparities in use and outcomes by all types of patient and health system characteristics. However, another start-up executive noted that since his product is specialized, it will likely be adopted by academic medical centers, which could limit most people’s access to the product.

Among business-development leaders at strategics, we heard a range of responses to questions about diversity and equity. While some of these leaders said they were aware of some of the health equity strategies within their companies, their functions were not leading these initiatives. However, other interviewees told us they try to achieve a balanced representation of leadership in the companies they acquire.

## Conclusion

As we have discussed in our Future of Health™ perspective, health care is transitioning away from the historic model of reactively treating illness. By 2040, Deloitte estimates that two-thirds of health care spending will be related to well-being and the early detection, prevention, and curing of disease<sup>12</sup>. This is good news for the medtech industry. Disease detection and prevention will likely rely on sensor-driven, regulated medical devices, which could create a substantial new medical technology market. We see a lot of focus among start-ups on precisely these areas.

How and where health care is delivered is becoming just as important as the care itself. In the future, we expect connected ecosystems to transform where patients receive care, including through virtual and retail channels, and even at home. The transition from episodic care to improving and maintaining well-being will put pressure on the traditional medtech business model.

For strategics, this shift is creating new challenges. A mix of funding strategies is typically needed to optimize the ROI of innovation

### Established medtech companies should prepare for the future by also considering the following:

- **Align to where the market is going:** Embracing new business models will be a key to success. Some models are likely to become more consumer-centric. As health care shifts toward prevention and wellness, for example, medtech companies will likely need to engage consumers before they become patients

(as well as during the patient journey) while also plotting new growth strategies. Executives from start-up companies are thinking about how to move outside of current operating boundaries in health care, not within them.

- **Invest strategically and early:** Traditionally, strategics grow through smaller tuck-in acquisitions. Instead, these larger medtech companies should consider strategic investments earlier in the lifecycle of a product. This includes licensing, co-development, joint-venture arrangements, or taking an equity stake in a start-up company to build portfolios and help foster a robust innovation ecosystem.
- **Revamp the product development process:** Another important focus should be optimizing the product-development process to deliver the right products to the market at the right time. This includes adopting agile processes and other techniques such as rapid prototyping (which are often absent in medtech today) but also refining the organizational culture, structure, and talent strategy to develop new capabilities. This is key to driving market share and offering value to patients and customers—in addition to generating returns on investments. Companies that choose to sustain their existing product line, rather than buy or build new and innovative products, run the risk of missing the needs of the market in the future—and being left behind.
- **Focus on reimbursement opportunities:** Current payment policies can put pressure on medtech manufacturers to differentiate themselves and demonstrate value. Many companies are rising to the challenge by creating new contracting and value-based arrangements, such as sharing risk with providers or payers for the total cost of care or clinical outcomes. Recent updates, such as the now-delayed MCIT rule, which provides same-day national Medicare coverage for FDA-designated breakthrough medical devices, will likely reduce the lag between approval and payment and are step in the right direction. Medtech companies should also pay close attention to cyber issues, as experts say regulatory guidance has not kept up with the advancements in digital technology<sup>13</sup>.

Start-ups that want to be acquired by strategics need to understand the opportunities and the challenges facing the industry. These companies should ensure that their strategies and products are well positioned for these trends. While there are growing opportunities outside of traditional care settings and along the patient journey, reimbursement could be challenging. A keen understanding of reimbursement, site of care shifts, and alignment with existing product lines will increase the likelihood of acquisition or other financial support.

Working with accelerators such as MTI, can be extremely valuable for the start-up community. Newer organizations can learn from more experienced companies on how to position their products and articulate their value. Worth mentioning is the material financial support that winning companies can garner. In 2021, MedTech Innovator and its partners will give out \$500K+ in cash prizes as well as other awards in the US program. Although not the focus of our research, we heard a continued refrain that MedTech Innovator was a well-respected force in the innovation ecosystem.

## Endnotes

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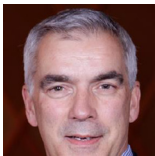
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