FOLLOW-ON FUNDING RAISED BY MTI ALUMNI

Deal value ($ million)

- 2013: 2
- 2014: 4
- 2015: 72
- 2016: 23
- 2017: 43

Number of events

- 2013: 2
- 2014: 4
- 2015: 72
- 2016: 23
- 2017: 43

- Deal value (U.S. $ million)
- Funding event count
Dear Friends and Colleagues,

“Crisis” is not too strong a word to describe the climate for medical device start-ups in 2011 when the MedTech Innovator program was launched. Though the broader global economy had begun to climb out of the global recession of 2008-2009, venture capital firms were still struggling, and medtech-focused firms struggling more than most. At the same time, the multinational strategics, who might have bailed out start-ups trying—and largely failing—to raise capital were, for the most part, sitting quietly on the sidelines. And don’t even talk about public offerings.

Back in 2011, Paul Grand was himself a venture capitalist in the LA office of Tucson-based RCT, a venture firm focused on early-stage investing, a particular sore spot for small medtech companies, and living daily with the frustrations that those companies were experiencing. Grand believed that the medtech start-up space needed something novel both to assist those early stage start-ups who too often lost in the fund-raising process and to give them greater visibility.

With the help of Casey McGlynn, head of the life sciences practice at Wilson Sonsini Goodrich & Rosati, Grand, who had been an entertainment industry executive early on in his career, came up with the idea for MedTech Innovator, a competition program modeled after American Idol, the mega-popular TV show at the time. The idea: to showcase a large number of very early stage companies at a select number of industry conferences. The first MTI program was held at WSGR’s conference in June 2013, and the winning company primarily got bragging rights. Starting in 2014 winners would receive a small grant from Johnson & Johnson and RCT. But the exposure for all of the participating companies was, arguably, even more valuable.

How far MTI has come from those early days. As MTI’s success took off, reflected in the number of companies applying and participating, in the number of corporate sponsors who’ve signed on, and in the dollars that competing companies now vie for, what started as an entertaining competition outgrew its home at RCT. Four years ago, MTI formed a valuable partnership with AdvaMed, the medtech industry trade association, and in 2016 spun off from RCT to become an independent company.

It’s been our delight to support MTI in its efforts to promote and strengthen the medtech start-up community, both through our conferences—MTI is a major part of our annual Dublin conference—and in the pages of The MedTech Strategist. The technological brilliance and clinical impact of the companies that have come through the competition has truly been impressive and we’ve profiled many of the winners and finalists over the half decade. In addition, we profiled MTI itself soon after its spin out two years ago.

In this special supplement to The MedTech Strategist, we offer an abridged and updated version of that MTI interview, as well as updated profiles of nine of the companies who’ve come through the program that we have published in The MedTech Strategist. We hope that the publication you hold in your hand suggests and reflects, in no small way, not just the impressiveness of the MTI companies but of MTI itself.

Warmest regards,

David Cassak  
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LETTER FROM THE EDITORS

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MTI’s success took off, reflected in the number of companies applying to be Innovator alumni. Grand believed that the medtech start-up space needed something novel both to address the technology and clinical need for invasive and uncomfortable diagnostic and treatment options. Each year for an individual subscription, per year for a corporate subscription.

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MedTech Accelerators

MedTech Innovator: Showcasing Medtech’s Newest Stars

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Each registered participant will have access to our event partnering software: network and interact with other attendees; pre-schedule private one-on-one meetings; post documents/videos about your products, technologies, and company; and much more!

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Special Guest Speaker:
Dr. Adam M. Hill, CMO, McLaren Applied Technologies

Dr. Hill is a senior executive within McLaren Group’s advanced technology, innovation and design company. In this role, Adam is responsible for defining growth strategy, including the incubation of McLaren’s health business.

Program Highlights
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“This has become the go-to medtech conference in Europe offering a good blend of start-ups, large medtech, investor colleagues and other VIP’s organized in perhaps Europe’s most prominent medtech region, Ireland! Happy to see many colleagues from the US as well.”
—Arthur Franken, Partner, Gilde Healthcare Partners

“Great event! Amazing attendance and interesting topics!”
—Diana Saraceni, General Partner, Panakes Partners

“The Innovation Summit in Dublin is now Europe’s premiere medical device event for start-up and early stage companies. The event attracts innovative companies, VC’s, corporate venturing and business development, and a range of service providers, in a well-organized yet informal setting. It’s the ‘must-attend’ event on the European medtech innovation calendar.”
—David O’Flynn, President, Eva Consulting Ltd.

“Without doubt the best meeting in Europe for any med device company seeking investment, wishing to talk to potential industry partners or wishing to network / learn from peer experience.”
—Steve Atkinson, CEO, Atlantic Therapeutics

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MedTech ENGINE
Closely related to the funding crisis that the very earliest stage medical start-ups face today is an equally challenging issue: how to get noticed in a world where dozens—if not hundreds—of companies are competing for the attention of the same small pool of investors and corporate partners?

Six years ago, Paul Grand, then a managing director at early-stage venture fund RCT Ventures, came up with an idea: an annual showcase for promising new companies that would give those companies the kind of exposure that would lead to greater things down the road.

Working initially with Casey McGlynn, head of the life science practice at Wilson Sonsini Goodrich & Rosati (WSGR), Grand devised a program that was serious in its intent but playful in its execution, a program that brought nearly a dozen young companies to the stage at WSGR’s 2013 Medical Device Conference. Companies in the competition pitched their technologies to an on-stage panel of industry executives and investors, but the judging was left to audience members in a popular-vote format consciously modeled after the smash television show, American Idol.

Grand’s MedTech Innovator (MTI) program was an instant hit, and he soon expanded it to include appearances at WSGR’s June conference as well as showcases at Innovation in Medtech’s conference in Dublin, held each April, and AdvaMed’s annual conference in the fall. Together, the three conferences highlight innovation from dozens of companies before determining a winner that receives a monetary prize that has grown over the past several years.

To be sure, the prize money is small—even when compared to a typical seed or Series A round. But more valuable, arguably, is the exposure and mentoring that companies that enter the MTI competition receive. Backed by corporates like Johnson & Johnson and Becton Dickinson, as well as health systems and other industry players, MTI has quickly established itself as a major showcase for emerging medtech companies, fostering a hopeful and enthusiastic mood for a group of companies that rarely experience that.

As the program took off, it grew beyond its role as a sidelight in RCT’s broader investment strategy. Two years ago, MTI spun out as an independent organization, with Grand as its CEO. In the following interview, excerpted and updated from an article that originally appeared in The MedTech Strategist, in December 2016, Grand talks about the growth of the program, its role in the eco-system of medtech start-ups, and MTI’s plans for the future.
The MedTech Strategist (MTS): In 2016, you transitioned the MedTech Innovator program from a kind of in-house project at RCT to a stand-alone operation. Why did you do that?

Paul Grand: The medtech industry has really recognized over the last couple of years that we have a crisis in the start-up ecosystem. Much of that is due to the financing climate, and part is due to changes in decision-making at customers driven by healthcare economics. I was part of a leadership panel and roundtable series organized by AdvaMed Accel, and the discussion was entirely about the crisis in funding for start-ups. The talk at the panel was focused on examining what the industry can do to help the innovation ecosystem, to ensure that the promising start-ups are successful. It was clear to me that MedTech Innovator could be a vehicle to help achieve that goal, that it had to be a partnership with the industry, and that we were going to need to grow the program for it to really contribute to solving the crisis in the ecosystem.

That was the external rationale. Internally, MedTech Innovator had already become too big to continue to run as a program within RCT Ventures. We had a series of discussions about how important MedTech Innovator had become to the industry and the opportunity it had to make an impact, and we decided it was time for it to be a stand-alone company.

MTS: So have you severed ties with RCT? How will the program be set up differently going forward?

Grand: RCT and Johnson & Johnson provided the founding sponsorships to establish MedTech Innovator as a stand-alone non-profit company in July 2016. Additional funds were then contributed by BD [Becton, Dickinson & Co.]. Chris Martin at RCT is on our board of directors, along with representatives from several of our other industry partners. We have a stellar full-time team who manages the program, which runs year-round.

I want to make sure to acknowledge how important our partnership with AdvaMed is. In addition to providing multiple opportunities for our start-ups to network and be showcased at their annual meeting, they provide resources for jointly produced content and events throughout the year. AdvaMed is doing this because their constituency has said the start-up pipeline is really important to them, and a lot of that is now coming through MedTech Innovator. Every company selected for our program is there because they were identified as being of strategic interest to somebody.

MTS: Are those your only revenue sources? Do you anticipate getting money from anyone else?

Grand: As MedTech Innovator is a non-profit, our goal is to be supported broadly by the medtech industry. In 2017, we brought on 5 new sponsoring partners: Baxter, Amgen, BTG, Olympus, and Ximedica. We are currently in discussions with a number of additional leading companies in the industry about joining as sponsors of our 2018 program. J&J, RCT and BD have given us commitments for three years. In addition to our industry sponsors, we also won a grant from the 2016 SBA annual Growth Accelerator Fund Competition where MedTech Innovator was selected as one of the top accelerators in the United States.

MTS: What do sponsors get?

Grand: Sponsors get benefits that include deal flow, with access to our database of thousands of start-ups, influence in selecting companies for our program, and forming close relationships with some of the most transformative start-ups in the world. They also get a good deal of visibility as supporters of the innovation ecosystem, and that is very important to them.

The ability to be part of our selection committee is a key benefit, and we limit the number of selection committee seats to facilitate an open dialogue. We give our higher tier sponsors first preference for the judging panel seats in our competitions at large industry conferences like The MedTech Strategist Innovation Summit, the Wilson Sonsini Goodrich & Rosati Medical Device Conference, and the AdvaMed annual meeting. We also opened up a new ecosystem tier of sponsorship for 2017, which is primarily for service providers, that includes access to our database and participation in our events but does not include seats on our selection committee. We don’t take equity in the companies for participation, and there are no investment rights for the sponsors.
MTS: How do you factor out bias? J&J is pretty broad-based, but BD has a narrower range of interest, while international groups might naturally bias toward portfolio companies or companies located in specific geographies.

Grand: We generally seek out sponsors with complementary expertise and interests, so there is a mix of companies selected that will appeal to the broader industry. We also have participation on our selection calls by representatives from customers to provide their perspective. One of the things that I like best about MedTech Innovator is that we get all these different people from different parts of the industry, and they all sit around the table on phone calls and in meetings and defend and argue for these start-ups. It’s great to hear to the vice president of business development for a medtech company, or the head of purchasing for a particular hospital system saying, “No, no, we need this company. We have to pick this company.” And not just because it’s a strategic fit. They’re saying this company is critical to our business. And people like Renee Ryan [VP, Venture Investments at J&J] will say all the time that it’s not about the next strategic fit for J&J; it’s about helping the ecosystem. They are all cognizant of the fact that this ecosystem is in crisis. Geographically focused sponsors weigh in only on selections in their regional pitch events, not our overall selection.

MTS: How did the idea for MedTech Innovator come about?

Grand: In 2013, I was talking with Casey McGlynn of WSGR at J.P. Morgan, and we were commenting that it was a disturbing trend that so few entrepreneurs were going to J.P. Morgan and other industry conferences. It’s critical for start-ups to attend these events to facilitate networking and relationships with the key people that they need to know to be successful. And it wasn’t solely that they couldn’t afford it, but rather it was the perception that the investors weren’t going either—or if they were going, they weren’t really interested in medtech—and if the investors weren’t going to be there, there was no reason for the entrepreneurs to go.

We started talking about what we could do to get entrepreneurs to go to conferences where they could network and get exposure. I said, “We could do something like American Idol for medical technologies where the audience votes for the winner. Let’s call it Medtech Idol.” And Casey said, “Sounds great. Let’s do it at my conference in June.” That really was the genesis of it.

MTS: I remember when Casey first talked to me about what you and he were planning. I said it sounded more like Shark Tank than American Idol.

Grand: I know my kids would like that, as they love Shark Tank. We didn’t go with that format for a couple of reasons. The sharks are very aggressive, and we didn’t want people tearing companies apart and making them look bad on the stage, which is what sometimes happens in that format. We wanted something with a more supportive and positive feel. The other consideration was that with Shark Tank, the Sharks negotiate and commit to an investment at that moment. And while I know a lot of those deals we see on TV never happen, they make a commitment, and there was no way we were going to be able to do that in healthcare where diligence takes more time.

I like the Idol-style model where the audience votes for the winner because it builds a following of supporters. That doesn’t happen on Shark Tank. Our model engages the audience in a more meaningful way, where they feel invested in the outcome and a personal connection with the company. When you vote for the winner in our competition on your phone and they get a check for hundreds of thousands of dollars a few minutes later, you really feel like you helped make that happen.

MTS: You’re now in your sixth year. Who do you identify as potential MTI participants? Have the criteria changed as the program has matured?

Grand: A core component of MedTech Innovator’s mission is to identify companies that are aligned with the strategic interests of our partners and the broader healthcare community’s goal to deliver improved value. This means that our criteria for choosing our participants are actually different every year, to evolve with the changing needs of the industry. We start with a survey of leading players, including manufacturers and providers, to ensure we are focusing on technologies that are of interest to the industry. Then, our selection committee aggregates the survey results into a collective industry wish list of 10 themes. (See “MedTech Innovator: Showcasing Medtech’s Newest Stars,” The MedTech Strategist, December 22, 2016). These themes guide the selection and review process and are used as the criteria for sourcing each year’s participants.
**MTS:** So what is the recruitment process like? Is there a typical profile of a MedTech Innovator or of a company that applies to become one? A lot of the participants seem to me to be fairly young, as opposed to seasoned serial entrepreneurs who may be starting their fourth or fifth company.

**Grand:** The applicants run the gamut. A lot of them are recent grads in healthcare-related fields, PhD engineers or MDs with a great idea for a new technology—Biodesign types of people, which is great to see. (See “Biodesign at Fifteen,” The MedTech Strategist, June 30, 2016.) Many of the younger people also come from industries outside of healthcare, and that’s exciting because they bring a whole new set of solutions with them. But we also get seasoned healthcare executives who are on their third or fourth company and yet still struggle to raise capital in today’s environment. Some start-ups come out of accelerators; some come from overseas. We’re global now in our reach. There are really interesting companies coming from places like Israel and Ireland and Germany that weren’t on our radar early on.

**MTS:** If you’re tapping into companies that aren’t well known, how do you find them to get them to apply?

**Grand:** That’s part of our secret sauce. We reach out to every pocket of innovation that we can find. Sometimes that’s a university that has a Biodesign-like program or one that has a medtech focus, like universities in the Coulter Translational Partnership program. We maintain relationships with incubators and accelerators all over the globe, and there are hundreds of them. Each of these may have five to twenty projects going on at one time. There are literally thousands of new companies coming out of these programs every year.

**MTS:** You’re obviously soliciting applications from the US, and I know you’ve expanded to Europe, particularly Ireland. Are you reaching innovators in Asia—China, Singapore, or India?

**Grand:** We’ve been approached by a number of organizations about expanding to other places in Europe, as well as Canada and Australia. We haven’t yet done a big push into Asia, but that’s coming for sure. We’re talking to several potential sponsors from Japan as we speak. We’ve also had a number of people approach us about Singapore and China. We plan to selectively and thoughtfully work with partners who can help us reach innovators in new regions.

**MTS:** I know there’s a several step process, but once you start soliciting companies to apply, how many typically apply and how many make it to the second stage?

**Grand:** Our applications for 2018 opened in late November. We had close to 600 companies apply last year, and I expect to exceed that, based on our past experience. In the first round, our selection committee will choose about 100 companies of strategic interest to advance to the next stage where they will be invited to pitch events in cities around the globe. We’ve had many companies tell us that just getting to pitch at these events is an incredible opportunity, even if they don’t make it past that stage, as they get to meet and pitch senior leaders from our sponsors and investors in the medtech industry.

**MTS:** As you put applicants through the screening process, are you looking for anything in particular to advance them to the next stage? Is it about the nature of the technology? The management team? The market size or commercial opportunity?

**Grand:** The management team is often at the top of the list...

**MTS:** But a lot of these entrepreneurs are young. How can you judge their management skills?

**Grand:** The technology and the IP behind it along with the plan and market opportunity are obviously important, but ultimately you need a solid team to execute on the plan.

We don’t place as high a priority on a complete management team, because the companies are often early in their development, but the importance of management is one reason we like to meet with companies in person: to assess the people behind the companies.

“Working with MedTech Innovator has been a great way for Ximedica to collaborate with startups on new ideas, technologies and business models to advance health care delivery.”

—Tracy MacNeal, EVP, Corp. Dev., Ximedica
Prior to those in-person sessions, we have a selection committee that goes through all of the applications and selects companies that we invite to present. In that process, while management is always a key criterion, it isn’t the first criterion. At that stage, we’re looking at the technology, the value proposition, and the benefit to patients.

“What makes MedTech Innovator unique is the sheer number of leading MedTech stakeholders it brings together for the benefit of the innovation ecosystem. Baxter is proud to support the program and to work so closely with other leading industry manufacturers to drive patient-centered innovation.”

—Anne E. Sissel, Vice President, Baxter Ventures

The selection is guided by the ten themes that the industry selects in our annual survey. Any company that is selected has to fit into one of those buckets. There are definitely companies that won’t qualify because they don’t address one of the themes. Once we’re confident a company fits, we look at things like the technology, the intellectual property, the competitive landscape, the market opportunity, and reimbursement. We’ve added categories in consumer health in recent years, based on industry interest. We accept very early-stage companies and some of them have done very well—like Spinal Singularity, or Green Sun Medical, which [the latter] won MedTech Innovator 2016. (See “Spinal Singularity: Improving the Quality of Life for Spinal Cord Injury and Disease Patients,” The MedTech Strategist, August 12, 2015.) But companies that only have a concept and no prototypes or IP can’t apply—they’re too early for us.

MTS: It’s interesting that you mentioned consumer health. It seems to me that one of the things that you’re implicitly wrestling with today is what it means to be a medical device company. I notice a lot more digital health companies on the program. You’re pretty expansive in your definition of medtech. Would you ever consider selecting a wearables company with a FitBit competitor?

Grand: Absolutely. We’ve had companies like Spry Health (formerly known as Echo Labs) in the competition—that’s a wearable technology—not a consumer wearable, but a wearable. Their device looks like a next generation FitBit, but it collects a lot more information. We also had Bloomlife, which makes a consumer-focused wearable for pregnancy.

MTS: What about biotech, particularly for a drug-device convergence play?

Grand: We might include a drug delivery company, but we wouldn’t do biotech.

MTS: So to get back to the selection process. You winnow the 600 or so applications to around 100 companies to pitch in person. What happens in the next stage, because you still need to select your accelerator companies and the ultimate goal is to get those to four companies?

Grand: There are a few important additional stages in the selection process.

The selection committee will choose 50 MedTech Innovator Showcase companies. These are early to mid-stage companies identified as being of strategic interest to the industry, and our Showcase program provides them with exposure and access to our partners. They all receive a full scholarship to attend and present at the Wilson Sonsini Medical Device Conference in June and The MedTech Conference in September. They’ll get to present to the conference audience as well as participate in business development partnering and attend the entire conference.

Additionally, the selection committee will select a subset of the Showcase companies to participate in a four-month virtual Accelerator program from June through September. During that program, the Accelerator companies will receive in-depth, customized mentorship from our sponsors and partners in the medtech industry without having to relocate during the program. They will also have opportunities to present in stage competitions at several conferences where they will compete for cash prizes along the way to the finals.

Finally, in the last round, after getting to know the companies during the Accelerator, the selection committee will choose the four finalists who get to compete for the audience vote in the finals at The MedTech Conference, which is the largest gathering of medtech leaders in North America. We will award over $500K in prizes this year.
**MTS:** How hard is it to say No to companies, particularly the ones that are very early stage and come a long distance in the hopes they’ll get picked?

**Grand:** For me personally, saying No has always been the hardest part of my job. I was a venture capitalist for nearly 12 years, and it was the worst part of the job.

With MedTech Innovator, I get to say Yes to over 100 companies every year, and they get a ton of value out of the experience. Those companies get to present to a group of active investors and key M&A executives at some of the top medtech companies in the world, where we give them real feedback. It’s like being invited to present to the partners at a dozen VC’s at one time.

Even if we don’t pick companies to present in person, there still could be benefits to applying to our program. For example, there have been companies that have received investments purely as a result of being reviewed, even if we didn’t select them for anything. We have over 200 reviewers at leading investors and strategics, and we’re now a significant deal flow vehicle for those companies.

**MTS:** You mentioned before that one of the things you’re trying to accomplish is to give some visibility to companies that may not be well known. Is stage of company a consideration? Is this really for those companies that have just launched or have been struggling to get by on little or no capital? Or can a five-year old company that has already raised a Series A compete?

**Grand:** Giving visibility to companies is a huge value of our program, and I firmly believe that anyone can and should apply, because it gets them on the radar of our industry reviewers, and deals happen because of that process.

**MTS:** Is there any value to a company that has already raised some money, even a Series A? The prize money has gone up in recent years, but it still seems as if it would have materially less impact for a company that’s trying to raise a Series B than one that’s pre-seed.

**Grand:** There’s a great deal of value in being part of our platform, regardless of stage. Our preference is actually for companies that already have some capital, as we want to be sure they have the resources to execute on the guidance they get from our program. The stage of the company helps us determine the selection of the opportunity within the overall MedTech Innovator program that is the best fit for them. Companies that have recently launched and/or raised up to and including a series A are going to be the best fit for our Accelerator. For companies that have already raised a series B or later, we might select them to participate in the pitch events, partnering events, and potentially the Showcase program. It ultimately comes down to choosing an aspect of our program that we think will offer the company the most benefit within our platform.

**MTS:** The first MTI was in 2013. If I applied any time between 2013 and 2017, is there any reason I should apply in 2018 or beyond? Or does the fact that I was already turned down suggest you’ve already made the judgment that I’m not MTI material?

**Grand:** Well, our repeat rate is pretty small in terms of the companies that apply.

**MTS:** Is that because the companies get the message? Or because they go out of business?

**Grand:** Probably a combination of both. Some definitely don’t survive. I have had some people email me and say, “I applied last year and didn’t make it. Why should I bother?”. But just because you aren’t a fit in one year doesn’t mean you won’t be selected in the future. A lot of it has to do with timing. One of my favorite examples of that is MobileODT, which won our competition in 2015 and was a crowd favorite at every one of our conferences that year. They had actually applied and been turned down in a prior year, but the CEO, Ariel Beery, was persistent. He reached out to me for feedback, and then he reapplied. The first time we saw the company, there were a lot of questions on our selection committee about the value of a mobile phone-based diagnostic test. The feeling was that their primary market was going to be the developing world, and we just didn’t get that excited about it. By the time he applied again, a lot of our reviewers had become interested in the developing world and recognized that those technologies could also be a fit in rural settings in the US. Also, interest in mobile phone-based technology had definitely grown. So, we do encourage companies to apply again if they’d been turned down in the past. (See the profile of MobileODT, in this issue).

One of the interesting challenges we face is that as the program has grown, the quality of the companies has gone way up. Not only are we seeing a huge increase in the number of applications, but our reviewers are now coming from companies like J&J, BD, Baxter, Olympus, BTG, and other leaders. They’re the ones giving us feedback that
leads to picking the companies. So if you want to re-apply, you have to take into consideration that you’re being judged by those kinds of companies. And they’re pretty demanding when it comes to quality.

**MTS: Looking ahead, now that you’re a stand-alone organization, are there other places you can take this model? Have you thought about a BioTech Innovator, for example? Is there anyone doing anything like this in other areas?**

**Grand:** We could certainly apply the MedTech Innovator model to other spaces like biopharma, but for now, we plan to stay focused on devices, diagnostics, and digital health. We have been approached by people interested in bringing MedTech Innovator to more geographical regions. The trick is to find ways to expand our reach and scale without sacrificing quality. That’s where I’ve seen other accelerator programs fall apart. They just hand their playbook to someone in a new region or sector and tell them to run with it, and that doesn’t work. We don’t want to make that mistake. Our focus in medtech and our virtual nature is unique, and we’re going to be careful about how we scale.

**MTS: As you think about the future, how will you incorporate digital technology? Is it part of MedTech Innovator? Is it a separate category?**

**Grand:** We certainly include digital technology in our platform now, and I don’t think you can underestimate how important digital is going forward. At least half of our 2017 companies had a digital component to their model. A number of our existing sponsors and partners have expertise in-house in digital, and we are adding new sponsors and partners from the digital sector in 2018 to expand our capabilities and expertise.

We’re still wrestling with whether digital should be a separate category. The reason we haven’t treated it as one until now is that with rare exceptions, every medtech device is going to have to go digital. Whether that’s pure digital, incorporating digital components, or harnessing Big Data, almost every device, from cardiovascular devices to surgical sponges, will become part of the digital world.

**MTS: One reason you might want to treat them separately is that they may differ in significant ways, for example, a different set of investors.**

**Grand:** I’m not sure. Certainly there have been differences in the investors in the past, with more capital available for pure digital health than for medtech, though the amount of money going into digital is slowing down. But I’m finding that a lot of digital companies are now coming to me and saying that they’ve raised a Series A from a more traditionally tech-focused firm and now that they are beginning to do their Series B, they realize they need some healthcare investors. While they thought they could get by with hiring some consultants, they realize now that it’s not enough. They’ve hit a wall and now want investors who understand medtech: the FDA, reimbursement, value, and healthcare economics. They want investors who get it.

**MTS: I know this is a big question, but your experience with digital raises a larger issue: in surveying hundreds of companies and having done this for nearly six years, you must have seen just about everything. Do you have any larger thoughts about how the nature of medical device technology is changing and where it’s headed? I would imagine that the kinds of technologies you saw in your first year are quite different than the stuff you’re seeing now, or is that not true? Would many of the first participants in the MedTech Innovator program make the cut today?**

**Grand:** I know we haven’t seen everything, because I know how many new companies are being formed every year, and there are a ton of them. That said, you’re right in that our vantage point gives us a pretty interesting view about trends both in the US and globally. Digital technologies are everywhere and they are going to radically alter our industry. In my experience, there is dramatic need for education within the traditional medtech industry to understand the capabilities and implications of digital technologies and to influence their rapidly evolving business models.

The technologies of interest to the industry each year and the technologies from the companies applying are definitely evolving. There were no applications with Big Data, AI or machine learning in our first year, and now applications missing those buzzwords are in the minority. Mobile technologies were a curiosity, and now people are often mobile-first. Reduction in cost has gone from a nice-to-have to almost an absolute requirement. Technologies focused on low resource settings were met with a shoulder shrug when we started, and today they are of great interest to many of our partners. Consumer Healthcare wasn’t even a consideration, and it was also a new dedicated theme starting with our 2016 program. Patient safety and satisfaction have become so important that it was also elevated to become a new theme. Services were interesting to only a few of our partners and reviewers in the beginning, and most investors had no interest in the space, but today there’s a huge...
amount of interest in technology-enabled services. When you couple changes like these with the huge increase in the quantity and quality of our applications, it’s absolutely true that many of the participants in our first competitions might not make the cut today.

However, many of the categories have remained the same, such as technologies focused on the management of chronic diseases and infectious disease. There also remains a huge interest in next-generation surgical technologies. One thing that has remained a constant is the criteria that we are seeking companies that benefit patients and deliver improved value.

**MTS:** Now that you’re a stand-alone organization, how will you measure your success? If you were still at RCT, you might measure success in a very straightforward way: how many companies did MTI tee up for investment and what’s been the return on investment? But without that investment vehicle today, what will you point to in five years to prove that the program has been a success?

**Grand:** It won’t be a classic return-on-capital calculation, because we’re not investing directly in these companies. It will be some combination of follow-on funding raised, the number of products that reach the market, revenues, and companies that reach an exit. We have a growing list of companies hitting all of those milestones, and I expect our companies will outperform the portfolios at a traditional fund, because we’re so strong in the broad input that goes into the selection process and mentoring in our program.

In the bigger picture, we’re trying to rebuild and accelerate a healthy innovation pipeline, and we’re doing a very good job at that. With only one or two exceptions, every one of the companies that has graduated from our accelerator programs still has, I believe, a very strong potential to be a successful product. Ultimately, these are companies that have been purpose-built to develop technologies to transform healthcare, and we’re selecting the ones that we think can give the most benefit to patients, and that’s what it’s all about.

**MTS:** As I understand it, MTI is in the process of forming a venture capital arm. Can you supply some details on size and objectives?

**Grand:** Yes, that’s right. We’re raising a fund called Innovator Ventures as a separate entity, with a target size of $100 million. We envision initially making seed or Series A investments in four to five companies each year with a reserve for follow-on investments. The objective is to make a financial return by investing in early-stage companies with a high degree of strategic interest from the medtech industry.

“We strive to bring ideas, products and services to life that profoundly change the trajectory of health for humanity, and MedTech Innovator supports that mission by finding and cultivating the best medtech startup companies in the world.”

—Renee Ryan, Vice President, Johnson & Johnson Innovation – JJDC, Inc.

**MTS:** Why did you do that? What will be the relationship between the MTI program and the venture fund? Will the venture fund invest only in MTI finalists? Will all finalists receive investments from the venture fund?

**Grand:** As I see it, this is the last leg of a three-legged stool. We have a proven platform for sourcing and accelerating some of the most compelling companies in the world. MTI awards non-dilutive grants to the winners, but it’s not enough to get them to the next critical milestones. For that they need significant funding that MTI can’t provide.

In September 2017, AdvaMed released their second report examining the funding crisis for early-stage medtech, and it’s not a pretty picture. Medtech Series A investments as a percentage of total venture investments in the sector dropped from 19% in 2006 to 10% in 2016. AdvaMed concluded that VCs have moved to later stage investing, and the pipeline is drying up. Without a robust pipeline of acquisition opportunities, large, established medtech companies could face challenges in finding new technologies to fuel future growth.

The primary driver for us is to address this early-stage medtech funding gap. As you know, most traditional VC’s have moved to later stage investing. While corporates stand to benefit from the success of these early firms, a variety of issues typically prevent large-cap corporate venture from making early-stage investments themselves. That’s where Innovator Ventures comes in.

Of course, the differentiator is our ability to leverage MTI’s unique sourcing, diligence, and intelligence platform. Our
aim isn’t to invest in all our finalists but rather those that we think will have the greatest chance of success with the help of our capital. We already have a strong track record, with our alumni companies raising more $500 million in follow-on financing since we started five years ago and even several acquisitions. There were 43 funding rounds by our past alumni in 2017 alone, so we certainly won’t be able to invest in all our finalists.

“What’s so great about this program is that MedTech Innovator finds the best start-ups not just for our company, but for the industry as a whole.”

—Al Lauritano, Director, External Innovation & Partnerships - BD Technologies & Innovation

MTS: How will you deal with conflict of interest issues, if any?

Grand: That’s a really important question and one that I’ve thought about quite a bit. The conflict of interest would be using philanthropic dollars to support companies already in the portfolio. In other words, if Innovator Ventures were to invest in a company and then MTI awarded the company a cash prize from the nonprofit, that could be a conflict. The solution is to not invest in companies until after they’ve graduated the MTI program. Also, remember that the MTI selection committee decides who advances to the finals, and the conference audiences ultimately choose the award winners, so by design, our team doesn’t control who receives cash awards from MTI.

MTS: You’ve also significantly increased the number of corporate sponsors. Who are these new sponsors and do you have a sense of why they’re signing on?

Grand: Growing our corporate sponsors was a priority for us in 2017 and continues to be in 2018. Our new sponsors such as Baxter, Olympus, Amgen, Gore, BTG, and Ximedica are signing on to enhance their own external innovation efforts. Our program gives our partners visibility into the landscape of companies developing transformational health technologies. Through our mentorship structure, they are able to provide guidance that can have a significant impact on the trajectory of the start-ups. They’re also all aligned in supporting the innovation ecosystem, because it’s critical to the health of the medtech pipeline.

MTS: As you’ve increased the number of sponsors, has the value proposition changed for them? Does adding more sponsors increase or diminish the value of participation for those already in, and in either case, why?

Grand: The value proposition is to help corporates engage with start-ups in a way that is structured and productive but also non-committal. By that I mean that we provide clearly defined expectations and value to both the corporates and the start-ups. Bringing on additional sponsors won’t diminish that value. If anything, it increases the value, because with more sponsors available for mentoring, we’re seeing higher quality engagements.

MTS: As you expand the number of sponsors, is there a profile of companies you’d like to welcome into the program? Do you have a ceiling in terms of the number of sponsors you might bring on or can you accommodate as many as would like to participate?

Grand: We’re very choosy about the companies we bring on as partners. We want the relationship to be mutually beneficial—a win-win-win for us, them, and our start-ups. We don’t intend to sign up every large medtech company, and we’re not about accepting money just to put a logo on a sign. Ideally, we’ll have 10 or so sponsoring companies in any given cycle that are invested in being true partners and are interested in putting in the effort to get the most out of their relationship with us while providing meaningful value to the Accelerator and Showcase companies.

MTS: Before we end, can you tell us something about 2017’s winning company?

Grand: Day Zero Diagnostics was the 2017 MedTech Innovator of the Year. It’s a company with an ambitious plan to combine genome sequencing diagnostic technology and machine learning to modernize infectious disease diagnosis and treatment. Antibiotic resistance is a global health crisis, and DZD has the potential to offer improved value to patients, the hospital, and the health system, a highly coveted combination for any medtech company. Their CEO Jong Lee is a highly-skilled and experienced medtech executive who dove headfirst into our accelerator process and came out not only with $350,000 in prize money but with insights from mentors that helped shape the direction of the business. Let’s just say we’re watching their progress with great anticipation. (See the profile of Day Zero Diagnostics in this issue.)
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**Day Zero Diagnostics:**
**New Diagnostic Rapidly Identifies the Resistance Profile of Bacteria, Enabling Targeted Therapy Sooner**

Every hour counts for patients at risk of developing sepsis, yet the diagnostic tests that help clinicians determine treatments don’t deliver results for days. Day Zero Diagnostics has taken on this challenge by combining whole genome sequencing, machine learning, and blood sample preparation tools.

At the 2017 meeting of Advamed, the medical device industry’s advocacy organization, young start-up Day Zero Diagnostics was chosen as this year’s MedTech Innovator Global Competition winner. To win this accolade (and prize money of $350,000), Day Zero Diagnostics rose up from a starting pool of 600 early stage companies, made the cut to the final four, and was selected as the winner by a voting audience of 1,500 medtech professionals.

The MedTech Innovator program is an accelerator that brings sponsors from the industry to the table to help early stage medtech start-ups make the right choices on the way to commercialization of technologies that help patients while reducing the costs of healthcare. Day Zero Diagnostics plans to do this with a means of rapidly identifying bacteria and their antibiotic resistance profiles so that infected patients can receive targeted antibiotic therapy as soon as possible.

The company is out to provide such valuable information in hours (on “day zero”) to save patients from life-threatening sepsis, and other infections. In comparison, today’s culture based diagnostics take days to arrive at a microbe’s antibiotic resistance profile. If clinicians could rapidly obtain information about bacterial identification and susceptibility, they could choose the correct targeted therapy days earlier, in some cases, a less toxic agent, and prevent the rapid rise in mortality risk that occurs with inappropriate antibiotics. But Day Zero’s diagnostic would also strike a blow in the battle against the public health crisis of antibiotic resistance, driven, in part, by the unnecessary use of powerful, broad-spectrum antibiotics, a ‘carpet-bombing’ approach to which clinicians resort when they don’t have the information they need to treat patients who are deteriorating rapidly.

The concept for the start-up originated because of the frustration of Doug Kwon, MD, PhD, an infectious disease physician at Massachusetts General Hospital (MGH) and the director of clinical research at the Ragon Institute of MGH, MIT, and Harvard. His research focuses on fighting HIV/AIDS and other diseases of the immune system. As a clinician, Kwon was frustrated that it took so long to get useful diagnostic information while patients were decompensating, says Jong Lee, CEO and co-founder of Day Zero Diagnostics.

Kwon brainstormed with the other co-founders on ways that high throughput sequencing could be used to make the entire process faster and more modern, says Lee.

Whole genome sequencing (WGS), which involves sequencing an organism’s genome and then comparing that to known sequences as a reference, is a well-developed diagnostic method in prenatal care, rare disease and oncology care, and has become the standard in certain cancers such as non-small cell lung cancer, where it is used to determine if a patient’s tumor is likely to respond to a particular oncology drug. (See “Personal Genome Diagnostics: One-Stop Cancer Genome Testing,” The MedTech Strategist, April 15, 2016; “A Boost for the Nascent Molecular POCT Market,” The MedTech Strategist, February 9, 2016; and “In a New Era of Medical Omics, Shift-
ing Roles for Molecular Pathologists, Labs and Consumers,” The MedTech Strategist, May 31, 2016). But, notes Lee, these applications have time on their side. “It is fine for an oncologist to take a sample of blood from a person, send it to a central reference lab, have that lab do the next generation sequencing, and then return a result.” If that takes a week, that is still a clinically relevant timeframe, he says. But in a severe infection, mortality risk increases by the hour. For this application, a test needs to performed locally, in the microbiology lab or as close to it as possible, so clinicians can get a result without all the transfer time and waiting that goes with working with a distant reference lab.

WGS has not yet come into clinical use in the microbiology lab. What is needed there, says Lee, is a straightforward method of sample preparation for sequencing, and an algorithm that can turn the sequence data into clinically actionable information. “We are building our company to solve both of those issues, so it will make all the sense in the world to use whole genome sequencing as a diagnostics method within the microbiology lab.”

WGS is a good place to start, because bacteria genomes are quite diverse. There are far more variations within a species of bacteria than exist in the human genome. Looking at the WGS of a bacteria makes species identification straightforward.

What’s more difficult and more valuable, however, is the determination of the resistance profile. “The mechanisms of resistance are not all known and understood. One resistance gene might drive a certain kind of resistance, but you might find that a combination of resistance genes confers different resistance, or the location of the gene within the genome might alter the resistance profile,” Lee says.

Day Zero believes it has come up with “a modern, rigorous, Big Data approach to solving that problem.” Early on, the start-up forged an agreement with the microbiology lab at Mass General Hospital. For almost 3 years, members of Day Zero’s team have been collecting the culture isolates that the lab is about to discard. “We basically collect their trash,” jokes Lee, who adds that Day Zero has licensed the right to collect these isolates as well as the associated phenotypic resistance profiles generated by the microbiology lab.

To date, the company has amassed more than 30,000 such samples. “That gives us a pretty unique dataset to work off of, a dataset of phenotypic resistance profiles based on the gold standard culture growth assay, combined with genomic sequences. We think we currently have the largest dataset of phenotypic resistance types combined with their genomic sequences in the world.” (The company hasn’t yet paired all 30,000 samples with genomic sequences, that work is ongoing.) These are the inputs for the training of the machine-learning algorithm that will let treating clinicians know what they are dealing with.

The company has targeted bactereemia as its first application, an important therapeutic target that can lead to sepsis and death. The company chose this application because it is one of the areas of greatest unmet clinical need and one of the costliest categories of infection, says Lee. Mortality rates range between 20-50% and treatment costs for sepsis can average $40,000 per patient, and in severe cases, rise to $100,000 per patient. The company believes that the degree of unmet need will create the pull for a newer diagnostic that may potentially cost more than traditional assays, if it can resolve cases of severe infection days sooner, saving thousands of dollars in patient treatment costs.

But that is only the beginning. “Whole genomic sequencing gives you an unprecedented amount of resolution. You will know far more than has previously been available by other methods, for example, what is in the sample and what is causing the infection,” says Lee, and that enables the diagnostic to help accomplish things that were previously difficult to do, for example, investigations of hospital-acquired infections and regional epidemiology.

This will become possible, because every diagnostic that is run by a customer results in the generation of a record that is maintained in Day Zero’s database, which will enable longitudinal tracking as well as tracking across different samples. “We can tell you if things are very closely related to each other, which is valuable in the case of investigations of hospital-acquired infections,” Lee says.

That’s the scientific basis of the company’s platform, but there are many parts to it, beginning with a method of preparing blood samples. Septic blood is one of the most complex clini-
cal samples to work with for whole genome sequencing. Because of the large amount of human DNA in the sample, which can make it difficult and costly to sequence the bacterial DNA of interest, the sample prep process needs to achieve a very high degree of bacterial DNA isolation and enrichment. The company is developing single-use cartridges to accomplish this, an instrument for running the diagnostics, and the computational portion. That’s a lot to bite off, Lee admits, noting that many start-ups would choose to solve only one part of the problem. “We are trying to solve both the biochemistry issue, which is how to do the sample prep, and we are trying to solve the computational issue, which is how you make the genomic sequences informative and impactful to every day decision-making in the treatment of infectious diseases,” Lee says.

But the company’s five co-founders possess diverse skillsets and make up a team that is up to the challenge, says Lee. CTO Miriam Huntley, PhD is a computational biologist with expertise in genomics and machine learning; she has an undergraduate degree in physics from MIT and a PhD in applied math from Harvard. Doug Kwon, whose background was already noted, is an expert in infectious diseases and the microbiome. Melis Anahtar, MD, PhD, who worked in Kwon’s lab through the Harvard MD-PhD program, holds a biomedical engineering degree from MIT, and is now a clinical pathology resident at MGH, with expertise in immunology. With a background in physics and machine learning, Dougal Maclaurin, PhD has developed seminal programs used in machine-learning applications. Lee brings the commercial expertise; he is a Harvard MBA and a former medtech commercialization consultant.

At this stage of development, the company has shown proof of concept; that “all of the things that are part of this diagnostic are capable of being done with the science and technology that we’ve developed,” Lee says. Over the next year, the company’s goal is to demonstrate that all of the proven individual components can be put together and integrated on an end-to-end basis that can “take a complex clinical sample from a patient, and deliver a species ID and antibiotic resistance profile at the back end.”

To date, Day Zero has raised $3.5 million from angel investors and Sand Capital Ventures, as well as additional non-dilutive funding (from accelerator competitions like the MedTech Innovator). The company plans to accomplish another funding round in 2018, which will help it complete the design and development stage, then take the device through the in vitro diagnostic regulatory approval process as a de novo 510(k) product.

Day Zero’s goal is to deliver, to the treating clinicians, a result that looks no different than what they’re using today, except that they will get that information in five hours instead of five days, says Lee. Doing so is by no means easy. “As a company, we have made a choice to do one of the hardest things first. If you look at other start-ups developing diagnostics or molecular diagnostics, they might focus on UTI’s [urinary tract infections], because urine and other clinical samples are easier to work with than blood.” But Day Zero is working where the unmet clinical need is highest. “Solving a diagnostics for sepsis is extremely valuable. We are trying to tackle the biggest unmet clinical need, even though that is one of the harder things to do.”
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Allotrope Medical: A Simple Solution for Protecting the Ureter During Surgery

There are three million surgical procedures each year (in the US) in which there is a risk of injuring the ureter, and rates of injury are highest in minimally invasive cases, where up to 30% of OR time can be spent on trying to identify the ureter to spare it from harm. Allo trope Medical has developed an intuitive, battery-operated, single-use handheld device to help surgeons see the location of this hidden part of the anatomy.

Albert Huang, MD, has always been an inventor. Growing up, he would tinker with cars and motorcycles and rebuild old audio equipment, he says, and that desire to fix things is why he chose general surgery among all medical specialties.

While participating in abdominal and pelvic surgeries as a surgery resident, on more than one occasion Huang became aware of the time and energy it took to identify the ureter, the tube that carries urine from the kidney to the urinary bladder, which is necessary so that surgeons can take steps to avoid inadvertently damaging it. There was constant checking and rechecking, he says, to determine, “Is that the structure? Am I getting close to it?”

The ureter is difficult to find because it is located in the retroperitoneum. It’s behind a layer of tissues at the back of the abdominal wall, where it is very close to organs that are the targets of abdominal and pelvic surgeries; the colon and the ovaries, for example. There are approximately 3 million surgeries that pose a risk to the ureter, including gynecological and colorectal surgeries (and, to a lesser extent, vascular, urological and cancer-related procedures). The risk is highest for minimally-invasive procedures, which prevent surgeons from directly palpating tissue.

Across all of these procedures, the rate of injury is only about 2%, which sounds trivial. However, the consequences of damaging the ureter can be dire, including harmful strictures and scarring, urinary extravasation leading to peritonitis, or even the loss of kidney function. Fundamentally, the threat of ureteral injury is a significant stressor for surgeons.

Huang was assisting one day on a colon resection surgery, “and we were having a bear of a time identifying the ureter, which was impeding our ability to advance the operation.” He says he happened to notice that the anesthesiologist was using a facial nerve stimulator on the patient’s cheek to see if the chemical paralytic agent was working. Driving home that day, he mulled over what he had seen. He thought, “The ureter is smooth muscle. What if we could generate a contraction to help us identify where it is?”

Using off-the-shelf parts, Huang cobbled together a prototype of a handheld electrical stimulator with the idea of inducing a contraction in the ureter and was able to test it in the animal lab at Houston Methodist Hospital, where he was a surgery resident. The device was successful at achieving a visible contraction in the ureter, so in 2016 Huang left the hospital, was accepted to TMCx, the accelerator program of the Texas Medical Center, and founded Allo trope Medical.

Huang notes that the need to identify the ureter during surgery is well recognized, and the placement of stents or catheters is one commonly applied strategy to increase the safety of procedures. However, in and of themselves, stents don’t prevent injury. Although they stiffen the ureter (which makes it easier to find upon palpation), it is still possible to inadvertently nick or even fully transect the ureter. But stents do make it easier to detect injury intraoperatively so the ureter can be repaired. The placement of stents involves calling in a urologist and significantly affects the profitability of procedures. Says Huang, “So stents are not
that effective, they’re not easy to use, and literature shows that it costs about $1200 to place them each time with no reimbursement.” The placement of stents and the addition of OR time and resources spent on other methods of ureter identification (which include time-consuming dissections, stent or catheter placements, or injections of contrast agents like indocyanine green), result in increased costs without properly addressing the issue.

Allotrope Medical’s StimSite is a handheld, single-use, battery operated device that a surgeon can reach for during both minimally invasive and open procedures if it becomes difficult to find the ureter (see Figure 1). The surgeon simply places the tip of the device in the vicinity of the ureter, pushes a button and an electrical impulse causes a characteristic contraction that throws the ureter into relief (it looks like a night crawler, Huang says). “You are able to see the full length of the ureter towards the kidney and the bladder each time you elicit that contraction, even if it is behind other tissues.” The company has filed 8 patents in the US, EU and China, protecting its system and methods for ureter detection and smooth muscle stimulation via electrical stimulation (with expanded clinical and technologic applications).

There are no other smooth muscle tissues in that part of the body, so the device effect is specific to the ureter. Huang also notes that while patients undergoing minimally invasive and robotic surgeries in the abdomen receive neuromuscular-blocking agents, which paralyzes skeletal muscles so that the working space in the body can be inflated with air, smooth muscles are not affected. “You get a zero percent false positive rate with our device. If you see a contraction of this nature in this part of the body, you are certain that it is the ureter.”

The company has developed the alpha prototype of StimSite, and is preparing to work with a contract manufacturer to complete the manufacturing design and aging process required to get the device ready for the FDA. Huang anticipates being able to follow a 510(k) pathway through the FDA using nerve stimulators as predicates. Allotrope is now looking to raise a $3 million Series A round to achieve FDA clearance and advance technology to the market by early 2019.

Huang’s market research has identified gynecological surgery as the best launching point for StimSite, for several reasons. First, it accounts for 50% of the cases of surgical ureteral damage, because the pelvic ureter is the most susceptible segment of the ureter. Also, because general obgyns spend more time in the clinic than they do in surgery, they would be more likely to adopt an adjunctive device that increases their confidence in the safety of a procedure. “Leadership told us they would have a higher adoption rate. They do the vast majority of hysterectomies, but don’t operate every day.” Huang acknowledges that surgeons who do minimally invasive surgery day in, day out are more comfortable working in that part of the body and are less likely to use StimSite. “But they have told me that there are cases where this issue starts to slow them down, because of the presence of scar tissue for example, and that they would like to have it available in the OR.”

Two high-volume procedures that Allotrope will initially target are hysterectomy (750,000 procedures in the US) and colon resections (300,000 cases). While the alpha prototype is a handheld, standalone device, the company also plans on working with robotics companies to incorporate StimSite into their platforms.

The healthcare economics of Allotrope’s device are positive says Huang. StimSite has a projected ASP of approximately $250, a fraction of the unreimbursed $1200 cost of placing ureteral stents. Additional savings will be realized in decreased surgery times (through the elimination of current methods of ureter identification) and increased safety, especially if surgeons don’t have to prolong procedures in order to do slow dissections to identify the ureter, repair a damaged ureter, or worse, address the medical—and legal—ramifications of a damaged ureter that’s not discovered until after the patient leaves the hospital.

Allotrope Medical is at a very early stage, but so far, it has gained positive recognition at every step along the way. It was accepted into the Houston JLABS incubator of Johnson & Johnson, was voted as having the top innovation of the entire event at the annual SAGES surgical conference in March, and at the annual meeting of AdvaMed in late September, Allotrope was awarded second place in the Medtech Innovator competition, out of 600 competing companies across the world.
PROMAXO: A NEW STANDARD IN PELVIC IMAGING

Promaxo is advancing an office-based detection system for prostate cancer with the benefits of MRI in terms of high specificity and sensitivity, but at a fraction of the cost of traditional MRI machines while also eliminating the need for invasive and uncomfortable internal components.

When it comes to the detection of prostate cancer, our current options leave quite a bit to be desired. The standard screening test involves the measure of prostate-specific antigen (PSA), a protein produced by the cells of the gland itself at a higher than normal concentration under cancerous conditions. However, research by the Ontario Ministry of Health has indicated that PSA tests are simply not reliable or accurate enough, returning false positive results for 5% of screened men and even more dangerously, false negatives for another 2%.

These results can have serious consequences, as a mistaken cancer diagnosis inflicts substantial distress on healthy men, and their affected counterparts go without seeking treatment for indefinite periods of time, believing they need none while their disease advances. Thus, it should come as little shock that the US Preventive Service Task Force no longer backs PSA testing with its recommendation.

Biopsy for prostate tissue is also flawed. The average ultrasound-guided biopsy requires 12 needle cores, representing less than 1% of the entire gland sampled. Not only may the needle miss cancerous cells growing between the regularly incremented sections tested, but pathologists are only able to interpret what they can physically see on slides after the extraction. Such tests often necessitate repeat biopsies as follow-ups and are associated with an elevated rate of infection and complications.

Enter Promaxo Inc., a young company headed by seasoned and specialized industry veterans with the goal of improving the process of prostate imaging at the patient, doctor, and administrative levels.

In 2008, CEO Amit Vohra, who had previously honed his biomedical engineering skills with a US Army and Department of Defense funded project at the University of Florida (which was working on counter-bioterrorism measures), found himself joining California-based startup Eigen. At the time, it was the first of its kind, concentrating on MRI/ultrasound fusion prostate biopsy tools before that market had fully developed. Little more than a year later, he served as their vice president of strategy and operations, driving the development of Artemis and ProFuse, a pioneer MRI/ultrasound fusion tool. (ProFuse gained 510(k) clearance in 2012 and is currently available as an add-on to Eigen’s Artemis 3D ultrasound-guided prostate biopsy platform). This would prove to be a defining role for Vohra, as it gave him an introduction to the prostate oncology field.

Then, in September of 2014, as Vohra was working on his MBA at Duke University, he attended the NHLBI Regional Innovation Conference at the NC Biotech Center. There he met Irving Weinberg, who was presenting his MRI platform among a slew of newly debuted technologies. The two started talking and, over the next fifteen months, formulated the structure for the company that would soon become Promaxo. During that time, Vohra’s wife (Abhita Batra, founder and managing director of Advanced Biopharma Consulting LLC) introduced him to Michael Bartholomew, with whom she had done many life science focused strategic deals, and whose forte in commercialization they felt would be crucial to Promaxo’s market success.

The need for a new prostate biopsy application was more than apparent to Vohra. “The whole process is broken,” he says about the diagnosis of prostate cancer. “The incidence rate has dropped dramatically in the last four to five years;
it used to be 220,000 in the US, now it’s dropped to 160,000-170,000, but the number of mortalities has not changed.” In other words, the standard method of detection is becoming increasingly less effective. Though research has shown that MRI has a much higher detection capability for prostate cancer, according to Vohra, “the economics just don’t work out to use a $3 million MRI to guide a biopsy that can takes upwards of 25 minutes inside the MRI gantry.” Cost alone has made the use of MRI impractical for widespread use, prompting scientists to devise an alternative.

With the advent of Artemis and ProFuse, which, as noted, Vohra had previously brought to fruition, a fusion method involving MRI and ultrasound became an effective combination for diagnosing prostate cancer. Fusion has higher detection rates due to the high specificity and sensitivity of MRI. However, the workflow is complex and costs are prohibitively expensive for mass adoption in community settings, according to Vohra.

Promaxo is unveiling an office-based MRI console that not only cuts the cost of traditional MRI machines but also eliminates the need for invasive and uncomfortable internal components such as an endorectal coil. Such features might go a long way towards alleviating the dread that many men associate with prostate exploration. In addition, Vohra assures that Promaxo’s platform is completely safe for patients, causing no bio-effects or peripheral nerve stimulation in a 26-patient safety trial successfully completed on human wrists in 2012. This is accomplished through the use of fast and strong magnetic gradient pulses (“100 times faster than conventional MRIs,” says Vohra) at frequencies above the threshold of nerve excitation. These rapid and strong gradients permit collection of millions of points in k-space (an array of numbers representing spatial frequencies in the MR image) in tens of seconds, yielding images with spatial resolution comparable to histology. The fast pulse sequences reduce artifacts introduced by patient movement, metallic implants, system engineering limitations, and field homogeneity.

Furthermore, Promaxo offers real-time biopsy and treatment guidance under high resolution MRI, two advanced clinical features that no other existing tool or fusion method can achieve, especially at Promaxo’s price range, Vohra claims.

Promaxo has developed an alpha prototype for the first of its kind “single-sided pelvic scanner” and is currently testing it on phantoms and tissue for optimizing its pulse sequences. The company is in the process of developing its beta prototype and plans to perform prostate scans on patients in a clinical setting early next year. Vohra anticipates that the Promaxo system will face a 510(k) regulatory pathway with conventional MRIs as predicates.

The business side of the company is well supported by executive advisors, including Dushyant Chipalkatty, founder of Pack Pharma and former COO of Morton Grove, and Diego Olego, a former chief strategy and innovation Officer at Philips Healthcare, who, Vohra says, are “leveraging their operational and research and development expertise in developing Promaxo’s product pipeline and establishing Promaxo as a manufacturing and production entity.”

To that end, Vohra also hinted at several major corporate partnerships of which he anticipates consummation within the calendar year. He also plans to eventually expand Promaxo’s scope to the field of radiotherapy, orthopedics and sports medicine.

As for clinical experience, Vohra notes that “our clinical advisory team, on the urology and radiation oncology front, has some of the biggest names, most of which are not only advisors but also investors in our company.” With the backing of experienced urologists, radiation oncologists and radiologists, Promaxo is in a good position to solve an unmet clinical and industry need, just as Vohra had done at Eigen years ago.

Currently, Promaxo’s technology, funded in part and showcased earlier this year by the NSF, is the subject of 35 patents filed, eight of which have been issued in the US and China. Vohra believes these patents comprise a robust and defensible IP strategy that will satisfy investors. The company plans to raise a $10-$15 million Series B round in 2018 to support commercialization efforts and to develop products in the pipeline.

In addition to the reduction in the cost and duration of a scan using the Promaxo MRI, Dr. Vohra emphasizes that the ability to perform scans in any given physician’s office, as opposed to having to refer patients to a separate imaging center, takes a substantial amount of stress off of patients’ minds. In what may conceivably be up to ten weeks between the referral and the scan, the possibility of prostate cancer weighs heavily on patients. “It’s human nature,” says Vohra. “If you have a disease, you want to fix it right away. You don’t want to sit on it.”

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EXIMIS SURGICAL:
FILLING A GAP IN LAPAROSCOPIC TISSUE REMOVAL

The notorious morcellator, a tool for the laparoscopic removal of uterine fibroids and other tissues, has largely gone into disuse since the FDA issued a black box warning about the devices because of their potential for spreading cancerous cells. Eximis Surgical is filling the gap with a laparoscopic device that it says will not only be safe, but will also offer procedural advantages and result in higher quality tissue specimens for analysis.

In June 2017, early-stage start-up Eximis Surgical LLC was the winner of a $25,000 award as the top company in the value category of the Medtech Innovator Competition. MedTech Innovator is a global, nonprofit competition and accelerator for companies in the medical device, digital health, and diagnostic industries. Eximis Surgical made the cut—from 600 companies originally vetted—into the final four, and was ultimately deemed to have the best medical value proposition for its laparoscopic specimen removal device, offering a replacement—with improvements—for the tarnished morcellator product category.

It’s counterproductive, says Johnson, if, at the end of a laparoscopic procedure, a large incision has to be made to remove the specimen from the body. Eximis Surgical has developed a device that removes tissue through smaller incisions, reducing the risk of cancer spreading.

The history of morcellators is notorious, largely because of the efforts of Amy Reed, MD, an anesthesiologist, and her husband, Hooman Noorahm, MD, a surgeon. Dr. Reed died in May 2017 from an aggressive type of cancer that was spread as a result of the removal of her uterus four years earlier, which was done with a morcellator, a rotating cutter in common use at the time that was designed to shred tissue so that large specimens could be removed through small incisions. The morcellator was never intended to be used to remove cancerous tumors; however, cancer sometimes lurks undetected, and what are thought to be benign uterine fibroids sometimes turn out to be malignant tumors. In Dr. Reed’s case, she had an aggressive form of uterine cancer that had gone undiagnosed before her hysterectomy, and the morcellation procedure to remove her uterus spread those cancerous cells inside her body, negatively impacting her prognosis. Other women with similar experiences came forward after Dr. Reed’s story was published in the Wall Street Journal. The Reeds campaigned to get industry and the FDA to stop the use of these devices, and were successful. Johnson & Johnson removed its morcellator from the market, and the FDA issued a black box warning against the use of morcellators.

Kristin Johnson, a co-founder of Eximis Surgical, had occasionally encountered the use of morcellators during her 17 years at Covidien, most recently as director of Disruptive Products and Technologies, an internal Covidien incubator. “I didn’t run across them too often,” she recalls, “but when I did, I was surprised that they didn’t follow the model of other surgeries in terms of containment. And I did see the need for a better solution.” Johnson left Covidien at the end of 2013, and the story of Dr. Reed was the inspiration for her and several compatriots—Donna Ford-Serbu, SVP, Lead Management, Spectranetics; William Gregg, who has 25 years of experience in the medical device industry gained at Fisher Imaging and Covidien; and mechanical engineer Dirk Johnson who has co-founded several other businesses across the medical, consumer, industrial, and aerospace industries—to found Eximis Surgical.
Notes Johnson, “It is a very sad story, but Dr. Reed and her husband were successful at getting the morcellator removed from practice.” At the same time, she says, “Now surgeons who were relying on these devices to remove large specimens without creating large incisions did not have a solution to do so.” That meant many more hysterectomies, for example, would be done abdominally, with the extra expenses occasioned by surgery, a longer hospital stay, and the need for more pain management.

“Minimally invasive surgery has gained a lot of traction,” says Johnson, “and a lot of that has been driven recently by the adoption of robotics.” But it’s counterproductive, she notes, if, at the end of a laparoscopic procedure, a large incision has to be made to remove the specimen from the body. “That didn’t make sense to us. We felt there was an urgent need to create a safe and easy way to remove these surgical specimens through a small incision.”

Johnson says that rather than improve upon the morcellator category—and some companies have attempted to do so, by creating containment bags around the morcellators—the company had an opportunity to redefine the problem and address not only the safety issues of morcellators, but other limitations as well. At the top of their list of desired attributes, Johnson notes, were safety, speed, and ease of use. “The specimen had to be contained. That was non-negotiable. Morcellators are time consuming and fatiguing. We could improve upon that.” It can take a surgeon an hour or longer to remove a specimen with a morcellator, and the surgeon’s time and effort isn’t the only issue; this keeps patients under anesthesia for long periods of time, at a cost to the hospital, which might be able to do another procedure in that length of time, she says. “We wanted to develop something that’s fast and easy.”

The company is now finalizing prototypes for preclinical testing of a device called the XCor, which consists of slicing wires (the number varies, according to the product and intended use), preplaced in a containment bag. The surgeon places the bag containing the wires inside the patient, loads the specimen into the bag, exteriorizes the bag opening, and connects it to an instrument that applies mechanical and electrical energy to the wires. The wires pull from the bag through the tissue and into the instrument, leaving behind clean-cut segments of tissue. (On the Eximis website, two side-by-side photos compare XCor specimens, which look like slices of raw bacon, to those of morcellators, depicted by a bowl of what looks like ground meat.) The surgeon then reaches into the bag and removes the segments, all through an incision smaller than 2.2 cm.

“From the surgeon’s perspective, it fits nicely into their clinical workflow,” says Johnson. They are used to placing tissues into—and removing tissues from—specimen bags. “We have just added a step of connecting a connector and pushing a button. It is easy, simple, and instead of up to an hour or longer, we believe we will enable removal in five minutes. And we have optimized the device so that it’s low temperature.” She adds, “From the surgeon’s perspective, the difference between five minutes of pushing a button and up to an hour with a morcellator is big.”

XCor yields an unexpected benefit as well. “When we began showing these clean-cut segments to surgeons, they told us that these were significantly higher quality tissues for pathological assessment than a morcellated specimen, and therefore would likely be used in procedures where a morcellator otherwise would have not.”

Eximis Surgical is at an early stage (as are most of the MedTech Innovator contestants) and is now working on finalizing the device’s design and getting it into surgeons’ hands for preclinical testing. It has also engaged manufacturing partners. The company aims to get to first-in-human studies and a 510(k) de novo submission in the next two years.

Eximis’ initial target markets are the "vacant morcellator markets," says Johnson, i.e., laparoscopic hysterectomy, myomectomy, nephrectomy, and some benign general surgery applications, or “any case where a large specimen needs to be removed through a small incision,” which Johnson believes offers a total addressable market of $2 billion.

The company anticipates that the upfront costs of the XCor will be comparable to those of morcellators offered in containment bags, but with additional economic advantages in terms of shorter and easier procedures, and perhaps the ability to perform more surgeries in a minimally invasive fashion.

In the future, Johnson believes the XCor platform can be integrated into robotic procedures, “enabling a surgeon to complete the entire surgery with the robot.” The company also foresees additional surgical applications for XCor that weren’t necessarily the province of morcellators in the past.

Eximis Surgical has raised $3.5 in seed funding, the majority from Angel investors, many of whom are experienced medical device professionals or executives. The company will be looking for a $4.5 million Series A round at the end of 2017.  

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The task of cardiac imaging and analysis using MRI can be painstaking and tedious, requiring not only a massive amount of processing power to render images of the heart but also the time-consuming manual drawing of circles and contours to measure clinical parameters for analysis.

Such parameters, including the amount of blood pumped per heartbeat (known as ejection fraction), depend upon the accuracy of the contours drawn for endocardial, epicardial, papillary and trabecular muscles. Furthermore, due to time constraints, the manual delineation process is often limited to the end diastolic and end systolic phases, which don’t yield sufficient data to fully analyze the motion of muscle walls or compute peak ejection and filling rates. Thus, countless hours are spent by clinicians every year on a process that is suboptimally effective and due to time constraints, the manual delineation process is often limited to the end diastolic and end systolic phases, which don’t yield sufficient data to fully analyze the motion of muscle walls or compute peak ejection and filling rates. Thus, countless hours are spent by clinicians every year on a process that is suboptimally effective and highly subjective, varying from doctor to doctor. Now, software start-up Arterys Inc. is offering a streamlined modern solution.

When the company’s four founders met at Stanford, they pooled their collective knowledge of business, medicine, and high-performance computation, believing that cloud technology and machine learning could transform the healthcare industry. Beginning operations with a focus on cardiac imaging and using MRI as a means of acquisition, Arterys entered the field with two initial goals for the development of their cardiac suite: enabling new ways of looking at the heart and automating the intricate segmental delineation workflow. With respect to the first objective, current MRI applications produce files that are too large for hospitals to read and process, so the minds behind Arterys set out to leverage that challenge to observe blood flow with a new type of waveform analysis. The technique, dubbed 4D Flow, provides a more comprehensive view of the heart compared to an echocardiogram, the current industry standard. Using 4D Flow, cardiac radiologists can track the flow of blood to see any deviations from expected paths that might indicate a shunt, leak, or ventricle inversion, and diagnose patients accordingly. The software also boasts cloud capability to lessen the burden on hospitals’ systems incurred by the large files that MRI generates.

To further their second pursuit, automation, Arterys’ founders integrated into the platform deep learning, an advanced computing model that relies on distributed graphics processing units (GPUs) and complex neural networks to actively learn through extensive input. GPUs, which are also used in automotive cameras to detect road markings and other objects, are fed thousands of cases from which to develop an algorithm with millions of rules to help it recognize regions of the heart. After rendering an image from a scan, a remarkably quick step at just ten minutes, the deep learning automatically draws in the ubiquitous contours with clinically reliable accuracy, though physicians can always overwrite them.
manually. As founder Fabien Beckers explains, “Physicians and radiologists are generally used to looking at a 3D plane. That’s what they train on, and they do their computation on a 3D element because they want to determine the volume that the ventricle is pumping.” With the introduction of 4D Flow, the additional analytical dimension of time expedites the calculation of ejection fraction, filling rates and other statistics crucial for diagnosis.

Before the cardiac suite was ready for marketing, it had to receive regulatory clearance from the FDA for both the blood flow visualization method and the deep learning component. In order to earn the FDA’s approval through its 510(k) premarket pathway (the most common regulatory path for software), Arterys used previously approved manual techniques as a predicate, a comparator for evaluation purposes.

So far, Arterys is the first and only company to receive approval for cloud-based deep learning technology, and Beckers believes that their operational speed will help them protect their first-mover advantage. He also hopes that because they were both first and early to the field of medical AI, physicians will be more familiar with the brand and subsequently more comfortable with the platform, encouraging loyalty as competitors emerge down the line. Since the founders began working together in 2011, they’ve built a platform ecosystem by integrating with imaging machine vendors and getting into hospitals’ systems to connect them to the cloud. In fact, Arterys is one of the information providers on the Siemens Healthineers ecosystem and has agreed to enable them to offer 4D Flow analysis and has also partnered with GE Healthcare to offer the AI component.

The two most significant concerns facing Arterys at this juncture are skepticism toward deep learning’s reliability and the security of the cloud platform on which sensitive patient information is stored. Beckers and the other founders stand firmly behind the capability of their products, believing that the variety of cases that constitute the algorithm’s input thoroughly train the program to perceive the parts of the heart as precisely as a seasoned professional would. What’s more, because of the cloud’s connectivity across healthcare networks, the software can continue to learn as it’s utilized by sharing and incorporating data from users (absent of all identifying information, of course). The cloud itself is fully compliant with HIPAA standards of protocol, meaning the privacy of the patients scanned using the Arterys cardiac suite is completely protected.

Looking to the future, Beckers says that real-time surgical applications might be on the company’s radar, though they’re currently remaining focused on the realm of radiology and clinical diagnosis. He also credits the Arterys team dynamic with its momentum thus far, elaborating, “It is not like financial software; it is the world of healthcare, which has been very siloed. The medical device world is here, healthcare IT is over here, and we are bridging those two worlds.” Having managed to assemble a staff who can operate on the regulatory front, act as medical device and AI experts, and sell to hospitals while solving a clinical need, all fairly seamlessly, there’s no reason not to be optimistic about the prospects for Arterys.
Linear Health Sciences has recently unveiled its flagship product, the Orchid Safety Release Valve, an innovative answer to an issue that impacts the satisfaction and safety of patients and nurses alike, as well as the bottom lines of hospitals across the country.

In the years following the completion of his residency, hospitalist Ryan Dennis, MD, the founder of Linear Health Sciences (LHS), took note of a fairly common problem among his numerous patients; their IVs were becoming dislodged in the middle of the night. He would receive calls from nurses who were unable to reestablish access without a PICC line (Peripherally Inserted Central Catheter), which can be unavailable at those late hours, or a much more invasive central line, which would require placement by a doctor. Furthermore, even if a dislodgment occurred during the day, gaining peripheral access was particularly difficult with certain patients, and a central line would need to be implemented.

One case in particular stands out to Dennis as part of the inspiration for his solution to the problem, the Orchid Safety Release Valve. “I had a patient in the emergency room,” he recalls, “who had a chest tube in for a pneumothorax caused by a collapsed bulla.” Though she was experiencing some pain, she was doing fine that evening, so Dennis went home, only to return the next morning to a distressing report of the night before. The patient had gotten up to use the bathroom when her chest tube caught on her bed railing, pulling out the tube and surrounding sutures. Her lung recollapsed in the process. Before Dennis’ arrival, she had spent hours in excruciating pain because no available personnel could reinsert the tube.

As he listened to her story, Dennis was convinced that there must be an alternative with less pain and less trouble. He thought of another device that was easy to reconnect after accidental disconnection—the magnetic charger of his laptop. It only made sense to him that IVs should be just as hassle-free, ensuring the connection while minimizing the risk of damage to either side of the connection when removed. He decided then and there to develop an out-of-the-box solution for securing medical tubing with these priorities in mind.

Initial brainstorming yielded the idea of a breakaway valve analogous to that on a gas pump which releases the hose and stops the flow of gasoline should a car attempt to drive away with the nozzle still inserted. Dennis reached out to Adam Waters, with whom he had developed a friendship stemming from the fact that both their wives worked together as nurses. Waters had previously shown him some industrial projects he had worked on in valve technology for the oil industry, and making a natural connection, Dennis asked if Waters could design a nonmetallic, miniaturized solution for the dislodgment problem he described.

The next step was to commercialize. Dennis turned to his college fraternity brother Daniel Clark, who had been working with some major strategics in infusion disposables and seen several products brought to market, and whose business experience would round out the core team. The founders began working nights to quantify the market and get some initial interest from functional users in the form of surveys. Once they had the numbers to work with,
Waters, the engineer of the group, took on the task of iterating their original design, which proved both practicable and cost-effective.

Bearing a visual resemblance to a standard needle-less connector, the Orchid Safety Release Valve is applied by nursing staff in the same fashion between the IV administration set and the IV extension set. If the line snags on something, the device breaks away and seals off on both sides, protecting the infusion (which could range from cheap saline to precious chemotherapeutic agents) from leaks and backflow. It also sends an alert signal to nursing staff once it registers the break in the connection. The responding staff need only replace the Orchid valve by screwing off the broken halves and placing a new valve in between (see Figure 1). Thus, for just two dollars, the cost of the Orchid valve, a peripheral line that might have otherwise cost $30 in time and resources can be salvaged.

In Dennis’ experience, clinicians brought up two points of concern when the Orchid was pitched. First was skepticism of existing IV dislodgment data. No definitive study exists on the subject yet, though Dennis ultimately aims to carry one out once LHS secures its place in the market, generating data via the pilots that make up the bulk of their commercial launch process. For now, he and his team have been holding focus groups, using some of the existing data to get a baseline for dislodgment rates and gathering their own from records of dislodgment specifically due to tension kept by daytime nurses at Dennis’ hospital, which reflected the figures encountered in the literature. Current data shows that dislodgment is one of the primary IV failure modes, occurring with 10-25% of all lines placed. With 300,000,000 peripheral lines in the United States, those costs add up. If it’s an expensive IV drug or a central line being protected, the savings increase exponentially with the use of the Orchid valve.

The second concern surrounded the integration of the Orchid into administration sets currently on the market. Moving forward, strategic partnerships with existing IV set manufacturers would eliminate the problem of Orchid valves being left on the supply shelf simply because they’re a separate, individual component. “We want this to be on every line, every time,” says Dennis, believing it to be “a standard-of-care-shifting” technology. He cites companies like Becton Dickinson, 3M, Baxter, B. Braun Melsungen, Hospira, and Medtronic among those with whom he has interest in exploring partnerships. Furthermore, though they began with valves for IV tubes which have lure closures on both sides, Dennis’ goal is to apply the platform technology to the chest tubes that originally helped inspire the product as well as portable insulin pumps and other devices for active, ambulatory patients for whom dislodgment presents a risk.

For patients, the Orchid means less pain and a reduced chance of having to resort to more invasive lines. For nurses, it means exposure to fewer sharps and bodily fluids, not to mention workflow efficiencies in terms of not having to spend time placing new IVs. Perhaps the most dramatic impact of all, however, is that upon hospitals’ bottom lines. Using the base case numbers of a $30 line restart (factoring supplies and labor) and a $2 unit cost for the device, the average 160-bed hospital would be expected to see $240,000 in annual savings. Extrapolation over all US hospitals would translate to nearly $1 billion in nationwide savings. Plus, according to Dr. Dennis, the device could significantly reduce potential for infiltration, phlebitis, and line-associated infections.

The development team is currently undergoing final design, verification and validation in preparation for 510(k) FDA clearance. Because of the FDA’s special framework for infusion disposables, they expect an expedited clearance process and anticipate a release date in the third quarter of 2017. At that point, Dennis hopes to establish relationships with strategics in order to sell to hospital buying committees. Initially, he says this will mean demonstrating commercial traction by following a direct sales model with pilot protocols in place to generate data to quantify and prove the savings he projects.
Gal Salomon had already made a name for himself in Israel's high-tech consumer electronics industry as a tech developer, company founder, and investor (as a Partner at Pitango Venture Capital) when he decided, a few years back, to embark on a new path and start a company in the healthcare arena. At the time, he knew he wanted to do something meaningful; he wanted to solve a big problem that would really make a difference in patients’ lives. So he visited hospitals for a first-hand look at the challenges and treatment gaps that were creating their most pressing unmet needs.

For Salomon, this was exactly the type of problem he believed could be solved with “big data” solutions—specifically, a combination of sophisticated data analytics (predictive modeling) and machine-learning algorithms. In 2015, he founded Intensix Ltd., with the aim of developing a real-time predictive analytics platform that could collect and analyze these indistinct signals and identify which patients were at risk of a life-threatening event hours before there were any obvious signs or symptoms. A reliable, accurate way to identify acute-care patients at risk of an impending serious event in order to facilitate early intervention, improve outcomes, and increase hospital efficiency/reduce costs was needed.

Founded in 2015, Israeli start-up Intensix is putting its unique predictive data analytics/machine learning platform to the test in acute care settings, with an initial focus on the ICU. The goal is to identify patients at risk of life-threatening events, such as sepsis, and to do so hours earlier than is currently possible.

One hospital department in particular stood out to him as an area in great need of technology-based solutions. “What really caught my eye,” he recalls, was the ICU [intensive care unit].” The ICU is the most resource-intensive area of the hospital, with monitoring and high-acuity care going on continuously, 24/7, and a massive amount of data being collected on each patient. Moreover, in the ICU, every second counts. Patients who are admitted to the ICU are in grave condition to begin with, and they can very quickly take a turn for the worse that sends them into a death spiral of multi-organ failure. “You can lose a patient in the span of minutes,” Salomon notes.

The problem is, he continues, there is no early warning system that lets doctors and nurses know when an ICU patient is likely to deteriorate and why. Many of these patients are sedated and ventilated, and they can look stable—their vital signs can be within the normal range—but they could actually be in the early stages of deterioration. In fact, he explains, there are subtle signals—a slight upward trend in the patient's temperature, perhaps, or a subtle change in blood pressure, heart rhythm, or liver enzymes—that if detected and deciphered early enough, could enable life-saving intervention.

Intensix closed an $8.3 million Series A funding round led by Pitango Venture Capital in February 2017, and announced a rebranding to CLEW Medical in December 2017.

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Intensix’ platform technology was designed with input from a group of well-respected critical care physicians, including Daniel Talmor, MD, Professor of Anesthesia at Harvard Medical School and Chairman for Critical Care Medicine at Beth Israel Deaconess Medical Center in Boston; and Michael F. O’Connor, MD, Director of Critical Care Medicine at the University of Chicago Medical Center. It is intended to work collaboratively with clinicians and fit easily into their existing workflows. “We’re not telling the doctor what to do,” explains Salomon, “we’re telling them which ICU patients are likely to crash in the next several hours, and we’re telling them the source of the problem” (for example, the liver, or infection, or heart disease, or a combination of things). “In that way, we’re providing them with the missing link [they need for better patient care].”

“In a sense,” he adds, “we’re changing the mindset of medicine.” Physicians want evidence in order to take action, he explains, but in the ICU, by the time you have clear evidence, in the form of outward signs and symptoms, it’s already too late. “So if we come to the ICU team and tell them ‘in the next few hours you will have a [patient] crash in this order, in this sequence,’ we can save a lot of lives and we can reduce costs.” Even highly experienced clinicians can benefit from this type of help, he asserts. “You can be the smartest doctor imaginable, but when you are under heavy stress and working with too many patients [as in the ICU], it’s very hard to see early warning signs; it’s very hard to predict the future. Machine learning can do a much better job.”

The company’s predictive analytics platform takes physiological data gleaned from each patient, converts it into a mathematical formula for analysis, and then provides an assessment in a form that the physician can quickly see and understand—essentially, notes Salomon, the company is transforming “clinical intuition into a mathematical formula” that can be used to provide an accurate, timely alert of an impending patient crisis. That,
Intensix is currently testing the platform at hospitals in Israel and the US, including Tel Aviv Medical Center and the Mayo Clinic. Researchers at Mayo’s Multidisciplinary Epidemiology Translational Research Intensive Care Group presented a poster during the 2017 HIMSS (Healthcare Information and Management Systems Society) conference last month, detailing their experience with the technology for the early detection and prediction of sepsis, a leading killer of hospitalized patients worldwide. The 782-patient study found that the system had a positive predictive value for sepsis of 71.5% and a negative predictive value of 96.7%. According to the researchers, the predictive model “demonstrated high reliability with no down-time” and “detected other events that have signs similar to... sepsis.”

The company has plans to begin studies at four additional US facilities this year and has also begun the process of obtaining FDA clearance, which it hopes to achieve by year-end. The firm plans to open a US office in the Boston area later this year as well. Intensix raised $8.3 million in a Series A funding round that closed in February and was led by Pitango, whose Managing General Partner, Ittai Harel, joined the firm’s Board of Directors. Together with an early raise from company founders and angel investors, that brings the company’s total funding to date to about $11.3 million.

Although Intensix is concentrating the bulk of its early efforts on an analytics system for use in the ICU, Salomon says that is just the beginning—the eventual goal is to capture data throughout the patient’s hospital experience—from the emergency department (ED) to the ward to the OR to the ICU—so that problems like sepsis, acute kidney injury, respiratory distress, cardiac arrest, and other life-threatening events can be detected early and addressed (and hopefully prevented) before the patient needs to go to the ICU. “Our vision is really to try and connect the dots, and the ICU for us is the starting point,” he explains. The ultimate aim is to capture the data as early as possible, he continues, and that would begin with the patient’s first point of entry: the ED.

Clearly, Intensix is taking a big-picture approach to this opportunity. As Salomon notes, “At the end of the day, we’ll have one company that is monitoring everything; we want to be that company.”

The algorithms continuously track and adjust the data as it comes in and analyze it to determine the patient’s current condition and predict his or her health trajectory.
Building on a technology developed at Bayer Material Sciences, Adhesys offers new medical adhesives with improved properties that help them safely close surgical wounds on both the outside and inside of the body.

Surgical sealants and adhesives were once regarded by surgeons as expensive, adjunctive technologies that, in their own skilled hands, weren’t necessary. That’s no longer the case, as advanced surgical hemostatic and wound closure technologies with better handling properties and increased strength are now recognized as solutions for the safe and economical management of surgical patients. The right surgical sealants can reduce blood loss during surgery, an increasing concern for hospitals under new blood management protocols, as well as reduce complications such as air or anastomosis leaks. They’re more needed than ever as healthcare providers increasingly move procedures to lower-cost, outpatient settings where it’s crucial to avoid blood loss, and as hospitals try to avoid the costs of infections and other complications and readmissions, particularly under bundled and value-based payment frameworks. (See “US Hospitals Shift Cost-Control Priorities as Bundled-Payment Programs Ramp Up,” The MedTech Strategist, June 30, 2016.) Numerous large and established players—including Baxter International Inc., CryoLife Inc., CR Bard Inc., Johnson & Johnson, Medtronic plc, Sanofi Group, and B. Braun Melsungen AG, among others—dominate the market for surgical sealants and hemostats with a variety of products, but there still remain unmet technological and clinical needs in this space, and start-ups are working to close the gap.

One of the newest—but by no means inexperienced—players is Adhesys Medical. Founded in 2013, the company is developing a broadly applicable platform of topical and internal surgical adhesives based on medical grade polyurethanes. Development of the company’s core technology began in 2007 within the Bayer Materials Science division of Bayer AG, but when that division underwent a reorganization (it’s now an independently traded company known as Covestro AG), the surgical adhesive project was mothballed.

As Alexander Schüller, president of Adhesys Medical explains, the initial project grew out of an effort by the large company to match its core capabilities to medical business opportunities. Bayer Materials Science is an expert in polyurethanes, which have a long history of use in adhesive applications, and the challenge was to combine the industrial capabilities of a glue—flexible, strong and rapid-sealing—with the requirements of a medical product—safe, non-toxic and fully biodegradable. The inventing team accomplished these goals, developing one
topical product and another for use inside the body.

In 2012, the technology’s inventor, Heike Heckroth, informed the surgeon who’d been working with the product in animal studies that the project was to be discontinued. Surgeon René Tolba was so convinced of the value of the adhesive that he approached Malte Brettel, a professor of entrepreneurship at the RWTH Aachen University. Brettel recruited two PhD students in his program—Marius Rosenberg and Alexander Schüller—to head up a new company, and in 2013, Adhesys Medical was founded.

The company started out by acquiring the patents from Bayer Material Sciences and its significant investment in the platform. In 2014, the founding team won the Rice Business Plan Competition in Houston, which granted Adhesys $500,000 in prize money. The start-ups subsequently gained entry to TMCx and Johnson & Johnson’s incubator JLABS @ TMC, located in the Texas Medical Center in Houston, after winning the JLABS Quick Fire competition. As a result, Adhesys is co-located in the US, where its commercial and financing operations are headquartered, and Germany, where R&D and production reside.

As noted, surgical sealants fall into two categories: topical, used for the closure of external, easily approximated wound edges (in cases of low skin tension); and internal, where surgical sealants and adhesives are useful at stopping bleeding, shoring up suture lines over resected tissue, or approximating subcutaneous layers of tissue.

Adhesys Medical operates in both spaces with the topical product, Cutis, likely to reach the market first. There are many topical skin adhesives on the market and most of them (Dermabond from Ethicon Inc., SwiftSet from Medtronic Plc., SurgiSeal from Adhezion Biomedical LLC, and TissueSeal from B. Braun, for example) are based on cyanoacrylate, the main component of consumer super glue products. Current products have a number of disadvantages. As they polymerize, they harden into a relatively rigid film, which makes them subject to breaking and limits movement of the wound area. They’re also watery and can seep into the wound during application, which can incite inflammation, and they create an exothermic (heat) reaction as they polymerize.

By contrast, Adhesys Medical’s Cutis product has great adhesion; is flexible—you can bend it by more than 85 degrees without breaking it, according to Schüller; and is easy to use because it has honey-like viscosity and can be applied with an applicator brush, since it cures rapidly. The glue sets in 30-60 seconds and is completely tack-free within three minutes. But most importantly, says Schüller, it sets without creating any exothermic reaction. “In our animal studies we observed great healing and minimal scarring because of the physical properties of the product.” Because it is viscous, he explains, it doesn’t seep into the wound, minimizing the risk of an inflammatory response. It is also permeable to air, so it allows the wound to breathe to a certain extent. The company has almost completed testing on the topical adhesive and plans to submit for a CE mark by the end of this year. In the US, the company is preparing the pre-submission for the 510(k) regulatory pathway and clinical trials are scheduled to start in 2017.

In May 2016, Adhesys gained an important validation on its first product. It signed an agreement with Grünenthal GmbH whereby the large company will distribute the topical skin adhesive in Europe and Latin America. “It comes with some perks,” says Schüller, “since they bring resources that a small company such as ours cannot muster.” For example, he says, “They will conduct clinical studies with our topical product that we hope will enable us to make the claims to outshine the competition.”

The company’s blockbuster, however, is its internal product, Vivo, Schüller notes. It will be the first “hemostatic sealant. It can both seal tissue and stop bleeding, even an arterial bleed,” he says.

Products in this market currently fall into two categories. First, there are bio-logically activated thrombin- or fibrin-based surgical sealants, made of a key component in the body’s clotting cascade, which are often used to control diffuse bleeding, but aren’t strong enough to seal tissues under tension. These also can require up to 40 minutes of preparation time since they need to be unfrozen or mixed prior to application.

The second category covers surgical sealants, which includes, for example, products like BioGlue from Cryolife, Coseal from Baxter, and Johnson & Johnson’s Omnex. Schüller points out that those products don’t work well in a wet environment, “exactly when you need them the most.” The Adhesys product, he says, excels in a wet environment, because the polymerization speed of Vivo is increased by the presence of humidity. “Our product can close the bleeding suture holes by mechanical sealing, not by relying on the clotting cascade of the patient.”

Schüller notes that the company’s studies have shown that its glue can withstand pressures twice as high as arterial pressure. “We are even able to seal an arterial bleed in 30-60 seconds,” he says. “It can be a lifesaver.” Finally, the Adhesys product comes ready to use and is stored at room temperature, a high convenience factor. Indeed, the Adhesys Medical hemostatic sealant lends itself as well to battlefield as surgical situations, and the company has been approached about military uses of its product.

For any company with a broadly applicable platform, choosing the right place to start—where the regulatory pathway is not too burdensome yet there is a
significant clinical need—is a challenge. Vivo could potentially be used in a wide variety of procedures, to close arterial punctures, for example, Schüller says. “We have shown that we can close a femoral artery in 30 seconds. Vascular access procedures are on the rise, but there is still an issue with closure, and if you apply our adhesive to the proper delivery device, it wouldn’t take much to disrupt that market. It’s a billion-dollar opportunity with strong growth, and our product fits right in.”

However, the development expense and regulatory hurdles for this application are relatively high, so the company will begin in applications where the product is used to reinforce suture lines to stop bleeding. It has chosen vascular reconstruction (for example, the reinforcement of sutured anastomoses) as its point of entry. The cardiac market represents high procedure volumes, great demand (since current sealants don’t work well in many instances), and a regulatory path that is paved.

Schüller says the company expects to complete preclinical work for the internal product by the end of the second quarter next year and aims to begin clinical work at the end of 2017, for a potential market launch in Europe in 2019.

Adhesys Medical faces competition in a growing market and two in particular stand out, as they target the same set of disadvantages of current products. TissuGlu from Cohera Medical Inc. is the first synthetic surgical adhesive to gain FDA approval. It’s a lysine-based urethane cleared for use in the internal approximation of tissue in abdominoplasty (tummy tuck) procedures. Gecko Biomedical SAS is developing a synthetic sealant that is polymerized by ultraviolet light. It will begin clinical trials on its first application, vascular reconstruction, in late 2016. Both work well in wet environments. Competition is a good thing at this stage in the field, serving to expand the market to new procedures that can benefit from surgical sealants and adhesives.

The company is currently looking for $6 million in funding to support clinical studies. To date, it has raised $5.5 million, $3 million coming from US Angel investors, many associated with the GOOSE (Grand Order of Successful Entrepreneurs) Society of Texas, which was created by Jack Gill, the founder of high-tech venture capital firm Vanguard. Adhesys has also benefitted from seed funding from regional investors in Germany, including Seed Fonds II.

Schüller has readied his elevator pitch for new investors. “We have a unique tunable platform technology with a wide range of potential applications that is capable of revolutionizing the market for wound closure. Workshops with surgeons and incumbents confirmed the novelty of the idea and interest is high. We have shown the product to work in topical and internal applications, built an industrial-scale supply chain and formed a team with a track record of delivering on milestones. We aren’t an early-stage start-up, we’re at the verge of commercialization, having signed with a strong distribution partner, and we’re launching our first product in 2017.

The company is offering substantial upside while having significantly de-risked all aspects of the business.”

Cervical cancer is a highly preventable disease, but it represents a huge public health burden in developing countries. When found early, the disease is highly treatable and associated with favorable long-term survival and good quality of life, especially in developed countries, where screening tests and a vaccine to prevent human papillomavirus (HPV) infections are readily available. However, it is the second most common cancer in women than 85% of these deaths occurring in low- and middle-income countries. A Tel Aviv, Israel-based start-up, Mobile Optical Detection Technologies (MobileODT; formerly MobileOCT), has developed a smart phone-based optical imaging technology that it hopes can have a dramatic impact on cervical cancer detection rates in low-resource settings such as Africa, India, and across Asia.

To truly defeat cervical cancer, about 1.2 billion screenings are required per year worldwide; however, women in low-resource areas have poor access to health technology. Visual inspection with acetic acid (VIA) by a relatively untrained community nurse is the current screening method used in most of the world, as it is low cost and easy to administer. However, the test has a low (17%) positive predictive value. MobileODT’s Eva (Enhanced Visual Assessment and Photodocumentation) System, which resembles a point-of-sale scanner, is currently being marketed throughout the world as a solution to this large unmet need. Comprised of a compound lens and powerful LED light source, enclosed in a medical grade case, and attached to a mobile phone (it is currently only compatible with the Android operating system), the Eva is held 10 to 30 centimeters away from the patient’s body during a physical exam, and images of the cervix are taken. The images are then saved to the user’s smart phone, and also encrypted and relayed securely to a special mobile app for interpretation. The CervDx app is connected to a central website that facilitates remote image storage and analysis, integration into electronic medi-
cal/health records, and multi-clinician collaboration.

Ariel Beery is co-founder and CEO of MobileODT. Before co-founding the company in 2012 with David Levitz, PhD (the company’s Chief Technology Officer), Ariel co-founded and served as the Global CEO of the PresenTense Group, an accelerator for social ventures that has launched over 600 social ventures, and now has franchise operations in 16 cities around the world. Beery has a BA in Economics and Political Science from Columbia University, a Master’s in Public Administration from New York University in Management, and an MA from NYU in Jewish Studies. Ariel teaches at the Inter-Disciplinary Center in Herzliya and lectures in workshops about social business and start-up development around the world. Levitz earned his Bachelor’s degree in biomedical engineering/optics from the University of Rochester in New York in 2002, after which he spent three years working with Riso National Laboratory (Roskilde, Denmark), and Lund University (Lund, Sweden), developing an image-processing algorithm to measure optical scattering properties from optical coherence tomography (OCT) images. Using this method, Dr. Levitz identified differences between normal and atherosclerotic arterial tissues. Following his years in Scandinavia, Levitz joined a leading research group in biomedical optics at Oregon Health and Science University, where he refined the method developed in earlier work and discovered a relationship between enzymatic matrix remodeling in collagen gels and its scattering properties, which could be measured noninvasively. The two decided to start a combined medical device and digital health company focused around cancer screening based on Levitz’s research, for cervical cancer in particular, with the aim of using the technology to help save as many lives as possible, as quickly as possible.

The start-up’s patented Eva System, CE marked in April of this year, has met with enthusiastic response in 14 pilot markets around the world, including Mexico, Haiti, Kenya, Botswana, Nepal, Guatemala and others, with more than 3,000 patients screened since its rollout in April 2014, says Beery. MobileODT is working in close partnership in 14 countries with leading organizations and medical institutions, including Partners In Health, the Center for Global Health at Massachusetts General Hospital, the Botswana-UPenn Partnership, PROSALUD, and the Scripps Medical Center, and also plans to work with established medical device companies in the diagnostic imaging space.

The Eva System is being sold via three main marketing channels, primarily to bulk purchasers such as East African governments, at the county and national level, along with global health organizations, health systems, and private practitioners. In the coming months, MobileODT will also be seeking US FDA 510(k) clearance (as a Class II device), and plans to expand its marketing efforts into the US starting later this year, primarily into rural areas (comprising 20% of the population), along with teaching hospitals, in order to help decrease US healthcare costs. It competes primarily with existing traditional video colposcope technology, available from a wide variety of manufacturers worldwide. These devices sell for approximately $8,000 to $14,000, while MobileODT’s price for its Eva screening system is about $1,800, or $800 each at a bulk rate, plus a monthly fee for access to the company’s data services.

The company has won a number of contests and competitions, including Vodafone’s Wireless Innovation Project, presented at the United Nations’ Social Innovation Summit in 2014, and Grand Challenges Israel. It was also selected as one of 20 semifinalists by the audience at the MedTech Innovator 2015 venture/virtual accelerator competition, held during the Wilson Sonsini Goodrich and Rosati (WSGR) Medical Device Conference in San Francisco this past June. “We are incredibly thrilled and humbled to be chosen as the audience pick at the prestigious WSGR Medical Device Conference,” says Beery.

The MedTech Innovator 2015 competition, designed to identify and support innovative early-stage medtech companies, features 20 semifinalist companies selected from nearly 300 applications that address one or more of the transformative themes identified in a survey of 26 leading manufacturers and providers. The 2015 accelerator program will culminate with the MedTech Innovator 2015 Showcase and Finals competition during AdvaMed 2015, being held October 5-7 in San Diego, CA. All 20 semifinalists in the competition will receive a scholarship for the AdvaMed Innovation Showcase and will be among the 48 innovative emerging growth medical device and diagnostic companies presenting at AdvaMed 2015. During a plenary session in front of the entire industry audience, four finalists will be selected to compete for $300,000 in prizes and to be named the audience-chosen MedTech Innovator of 2015.

MobileODT, which has raised $3 million in funding to date—$2 million from angel investors and the remaining $1 million in grants—is now raising another $4 million in a Series A funding round that will be used toward commercialization of its technology in the US. The company envisions its core technology as being adaptable to other disease states and medical needs, wherever better approaches to imaging soft tissue can make a difference, including applications for other cancers of the mucosa, such as oral, anal, and dermatological disease, and sexual assault and forensic documentation. Pilot studies are underway in several of these areas.

AdvaMed and MedTech Innovator – Helping Startups Define their True Value

Amid all the complex policy issues and partisan disagreements, one thing members of Congress from both parties can agree on is the need to get maximum value out of our health care system. This drive for value comes as the U.S. health care system continues to undergo rapid transformation: purchasing and utilization decisions increasingly are being made by large health systems instead of individual doctors; insurers are demanding more and more evidence before they cover new products and services; and cost pressures are greater than ever.

This translates to a need for manufacturers to clearly and evidently demonstrate the value of medical devices, diagnostic and digital health products to a variety of stakeholders. This is particularly challenging for transformative new technologies, and companies of all sizes are building strategic value propositions from the earliest stages of product development.

On behalf of its member companies, the Advanced Medical Technology Association (or AdvaMed) is advancing payment, coding and coverage policies that ensure greater certainty and predictability in reimbursement for medical technology. We encourage and support our members, which are majority small and mid-sized companies, to establish a clearly defined value proposition from the outset that will deliver patient benefit, encourage uptake and ensure reimbursement in today’s health care system.

This resonates with MedTech Innovator’s mission to improve the lives of patients by accelerating the growth of companies that are transforming the healthcare system. The direct participation of providers like UCLA Health, Mayo Clinic, and Providence with MedTech Innovator, offers critical feedback to startups seeking to define their value on topics like healthcare economics, customer requirements and integration issues.

The Value Framework

The difficulty is that there is no standard definition of what constitutes value among health care stakeholders. To fill this gap, AdvaMed, working with the health experts at Deloitte Consulting, developed Value Frameworks, one each for medical devices and diagnostic products, to provide stakeholders across the health care spectrum – patients, providers, payers, innovators etc. – with a comprehensive approach to objectively assess the value of a medical technology or diagnostic test and the evidence needed to support its use. AdvaMed members have demonstrated application of the Value Framework in several use cases, and reported an increased ability to raise capital, form partnerships with healthcare systems and negotiate exits with strategic partners. The Framework is centered on four key “value drivers”:

- The clinical impact on patients.
- Non-clinical patient impacts.
- The cost impact of the technology, including its impact on the costs and revenues of the provider or payer.
- The broader impact on public health and overall economic impact through increased productivity and reduced dependency.

For more information on the AdvaMed Value Framework visit https://www.advamed.org/issues/payment-health-policy/value-initiative

About AdvaMed

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

AdvaMed is committed to revitalizing the medtech innovation ecosystem through public policies and programs aimed at reducing risk and decreasing time to market.

AdvaMed Accel, the small company division, supports the world’s most innovative emerging and early-growth medical technology companies.

For more information visit: www.advamed.org
**MedTech Innovator 2017 Accelerator**

AdvaMed supported the 2017 MedTech Innovator Accelerator and participated in its Kickoff event to welcome the 2017 class of companies and introduce the newly released Value Framework.

Don May, Executive VP for Payment and Healthcare Delivery Policy at AdvaMed, led a workshop that explained the value drivers, the underpinning evidence guidelines and use cases of AdvaMed member company applications of the Value Framework.

MedTech Innovator and its network of mentors and supporters provided collaborative input to assist each accelerator company to examine its own value proposition and gather immediate feedback from peers and industry experts.

> The AdvaMed Value Framework exposed the 2017 MedTech Innovator Accelerator cohort to a broader set of stakeholders and their value drivers, which enabled 2Morrow to focus more tightly on the metrics and marketing messages driving buying decisions for our Digital Therapeutics.

**Brandon Masterson, Founder and CEO, 2Morrow**

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**AdvaMed Accel & MedTech Innovator**

As the medical technology industry’s leading trade association, AdvaMed is proud to partner with MedTech Innovator, the industry’s venture competition and accelerator.

AdvaMed recognizes the vital role entrepreneurs and transformative startup companies play in the medtech innovation ecosystem, and applauds MedTech Innovator for providing the most promising early stage companies the opportunity for interaction and learning with experienced corporate strategy executives and leading investors.

AdvaMed contributes to the MedTech Innovator accelerator program by providing insights on regulatory and reimbursement policy and processes at FDA and CMS, insights on digital health and tools to assess and define the value of medical technology.

AdvaMed Accel welcomes the MedTech Innovator accelerator companies as members of the association, providing access to information and resources to navigate regulatory, reimbursement, legal, compliance and global market access issues.


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Through AdvaMed’s Value Framework and the MedTech Innovator workshops, Nanowear learned how to effectively articulate a complementary, value-based rationalization to providers and payers for technologically advanced solutions to manage the increasing prevalence of chronic diseases such as heart failure, obesity and hypertension.

**Venk Varadan, Co-Founder and CEO, Nanowear**
MedTech Innovator unites industry leaders with a shared interest in strengthening the innovation ecosystem. We seek partners with the knowledge and expertise to foster the next generation of transformative medtech companies. Join us today.