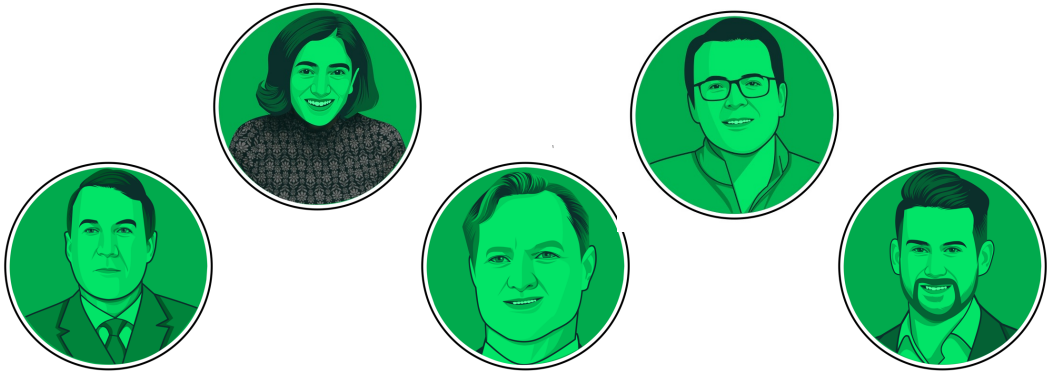
MEDSIDER

VOLUME II

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF VIRTUAL INCISION, GLYMPSE BIO, ACCESS VASCULAR, MOVANO, OSSOR VR, & MANY MORE



SCOTT NELSON

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Introduction

Over the past few months, I've had the privilege of talking to some of the brightest minds in the health technology and medical device arenas. Many of you have joined in by listening to those conversations on our Medsider podcast.

To add even more value, we've distilled the key insights from these founders and CEOs into this volume of Medsider Mentors. Feel free to use these learnings as a reference guide to the podcasts you've already enjoyed. Or, you can use it as a sampler to decide which episodes you're most excited to download.

Some of you will have read and enjoyed our first volume of Medsider Mentors. For you, this edition adds new perspectives to some of the ideas we started exploring there. If you missed it, consider going back to get the most out of both volumes.

Here's a taste of what's to come:

Marcus Gerhardt

Research is at the core of success in medical technology. If you want to develop a brain-computer interface, it's critical. That's why Blackrock Neurotech intentionally forged relationships with 500 leading neuroscientists. In our interview, CEO Marcus explains how this helps them stay at the bleeding edge of the field.

Kevin Goodwin

In 2015, Kevin Goodwin put his 30 years of experience to use by co-founding EchoNous. The company is developing a portable point-of-care ultrasound (PoCUS) powered by machine learning. It's since raised $120 million in private investment. Kevin credits the success to finding investors who are also partners.

Robert Kline

Robert Kline has a long list of successes. He sold Medivance for $260 million in 2011, ViroCyt in 2016 for $16 million, and Bolder Surgical for $160 in 2021. He's now the Chairman of ThermoTek. His advice is to focus on building sustainable businesses rather than optimizing for an exit. Even if you do sell, buyers will want to buy a company with a future.

Holly Rockweiler

For Madorra CEO Holly Rockweiler, building a successful start-up is all about passion. Working in the medical space can wear you down. But, seeing how your product improves the lives of patients will give you the motivation to keep going.

John Murphy

John Murphy leads Virtual Incision, which builds portable surgical robots. The surgical robotics space is getting noisier by the year, but Virtual Incision's systems are only two pounds and can be set up in ten minutes. In our interview, John provides insights on their strategies for navigating regulatory hurdles.

Rosina Samadani

Rosina Samadani is the CEO of Oculogica. She's also a judge for Stanford's StartX Accelerator and MIT's $100K Entrepreneurship Competition. Her philosophy is to get to market quickly. She lovingly refers to Oculogica's first prototype as as "the duct tape prototype." It was literally held together with tape during clinical trials.

Caroline Loew

As the CEO of Glympse Bio, Caroline Loew is pioneering biomarker diagnostics. The company analyses proteins in a blood sample to identify disease states. We discussed her philosophy on working with FDA, which she describes as "early and often." The trick, according to Caroline, is to keep things moving forward from the start.

Jim Biggins

Under Jim's leadership, Access Vascular recently closed a $20 million Series B round. This will help them develop a new base material for vascular access devices that promises to reduce complications. He believes too many entrepreneurs miss the opportunity to speak directly with practitioners throughout all stages of development.

John Mastrototaro

John serves as the CEO of Movano, a company making smart devices that inform users about their health. Before that, he pioneered the world's first ambulatory continuous glucose monitoring system. In our conversation, he stressed the importance of building diverse teams and designing products customers will actually want to use.

Justin Barad

Most medical technology founders don't think of their products as fun. But Justin Barad does. As CEO of OSSO VR, he's redefining how surgeons are trained and assessed. For him, medical start-ups should think more about the physician experience. In other words, design products that doctors love using.

David Neale

During our interview, Argá Medtech CEO David Neale shared two pieces of advice for founders. First, don't neglect the international market. Build diverse teams that reflect the global nature of the healthcare industry. Second, pay attention to healthcare economics. How will your product affect the patient, surgeon, nursing staff, and hospitals?

Justin Zenanko and Greg Molnar

Justin and Greg could save the medical industry $20 billion a year and break the pain-surgery-opioid highway. Their product, a dorsal root ganglion stimulator, could ease pain after spinal surgery without the use of opioids. But building a successful product is all about understanding economic incentives. As Greg says, "payments make the world go around." In our conversation, they spoke about making products work for every stakeholder and the importance of investing in themselves.

Laura Yecies

Laura is leading Bone Health Technologies in developing a vibration belt to prevent osteoporosis. Recently, the National Institutes of Health awarded the company with a $2.7 million grant. In our conversation, Laura stressed the importance of going above and beyond with clinical research. For her, securing FDA breakthrough device designation was key for building customer trust.

Olivier Delporte

Olivier is the CEO of Miracor Medical. Under his guidance, the company is developing an innovative PiCSO treatment for severe myocardial infarction. We spoke about the importance of continuing clinical research even after FDA approval. For Olivier, scientific evidence further substantiates your value to doctors and patients after you've hit the market.

Sina Habibi

Cognetivity Nuerosciences develops digital cognitive tests to identify dementia and other impairments. In our interview, co-founder Sina Habibi, stressed the importance of driving value versus reducing costs and highlighted why your product should aim to increase revenue for healthcare practices

Cody Simmons

Cody is the CEO of DermaSensor, and Forbes featured him in their 30 under 30 list for healthcare. His company is commercializing a novel skin cancer detection tool. In our interview, Cody emphasized the importance of finding an ally investor. Someone who believes in you and your technology.

Eugene Malinskiy

Lazurite develops surgical technology, including a wireless camera for minimally invasive surgeries, and has raised over $25 million. Its founder, Eugene Malinsky, is a Forbes 30 under 30 inductee in manufacturing. When Eugene and I spoke, he advocated for developing a regulatory plan as early as possible.

Bryce Klontz

New View Surgical's CEO Bryce Klontz places an emphasis on communication. He makes transparency a priority in his relationships with investors and FDA. Many regulatory hurdles, he contends, are the consequence of miscommunication. And he should know. New View has secured $14 million in funding and 501(k) clearance. Capital Expo 2020 named it the "Most Valued Company."

Heather Underwood

EvoEndo CEO Dr. Heather Underwood says you should analyze the reimbursement landscape early. For her, reimbursement makes or breaks a startup medtech company. FDA clearance or approval is only the beginning – real success starts with a great reimbursement strategy. Heather also echoed that too many founders focus on shiny new technology rather than what users really want.

Yoav Kimchy

Colonoscopies can be as uncomfortable as they are vital. That's why Check-Cap developed a capsule that patients can swallow like a pill. It scans the inner lining of the colon and delivers a digital reading. In our discussion, founder and CTO Yoav Kimchy shared the wisdom of knowing what your role should be in a company and when its best to hire someone else to be CEO.

Dan Clark

Dan and his company Linear are reducing IV dislodgement with The Orchid, a valve system that reduces waste and improves the patient experience. One of the key challenges he and his team overcame was that IV dislodgement is a widespread problem but it's hard to quantity the prevalence. In our discussion, Dan shared insights about crossing unnecessarily high regulatory hurdles and the challenge of transitioning from early-stage bootstrapper to full-time fundraiser.

Jennifer Ernst

Direct to consumer medtech products are among the most challenging to commercialize. They come with the additional difficulty of producing a product that resonates with consumers and that they can use safely. In our interview, Tivic Health co-founder and CEO Jennifer Ernst highlighted why it's key to understand how consumers will intuitively use your product and why you need to design them with a form and function that aligns with customer expectations.

There's a reason I look forward to these conversations. I always find a practical nugget of insight that I can apply to leading my own team at FastWave Medical. My hope is that this volume will be as helpful to you as it has been to me.

We appreciate your readership, and as always, let us know who you'd like to hear from in the next edition of Medsider Mentors.

Best Wishes,

Scott Nelson

Founder of Medsider

Founding Partner and Managing Director of Big Sky Biomedical

Co-Founder and CEO of FastWave Medical

Why Building a Community is Crucial for Medical Device Startups

Summary

Blackrock Neurotech CEO Marcus Gerhardt discusses the power of community in developing his company's brain-computer interface (BCI) technology. He shares Blackrock's innovative commercial model, and explains why traditional venture capital-backed strategies aren't always the best approach in the medtech industry.

Marcus Gerhardt

About Marcus

Marcus Gerhardt has started multiple companies, including an eCommerce platform and international consulting firm. In 2008, he co-founded Blackrock Neurotech, a pioneer in brain-computer interface (BCI) technology, and the world's leading collaborative partner for developing approved medical devices at scale for neurological therapies. He currently serves as CEO and is on the company's board.

Key Learnings

- Venture capital funding isn't the only path forward for medtech companies. Marcus successfully applied an innovative model for raising funds that leveraged current technologies to finance the lengthy research and development period Blackrock needed.
- Cultivating community is a worthwhile priority. Forming authentic and meaningful connections with researchers in the neuroscience space helped Blackrock become a major player in the industry.
- Regulatory bodies have important responsibilities within the chain of production for medical technology. Embrace the requirements and work with, not against, these agencies.

Why Building a Community is Crucial for Medical Device Startups

A common thread runs through Marcus Gerhardt's career: If a company involves technology and disruption, it's probably calling his name.

Marcus co-founded Blackrock Neurotech in 2008 with his long-time friend and business partner, Florian Solzbacher. Blackrock's MoveAgain brain-computer interface (BCI) system is a breakthrough medical device that uses brain implants to allow immobile patients to control electronic devices, wheelchairs, or prosthetics with their minds.

The two founders contribute complementary skill sets. Florian provides the scientific knowledge: In addition to being co-founder and chairman of Blackrock, he's an adjunct professor in biomedical engineering at the University of Utah. And Marcus spent years honing his entrepreneurial skills, participating in 14 venture projects before turning his attention to Blackrock.

Marcus admits that when his old friend first reached out about his idea for Blackrock, he thought Florian was crazy. But after doing his research, Marcus was intrigued -and he arrived at somewhat of a contrarian business strategy.

Together, they took a leap of faith not just with the technology but also in their funding methodology, creating a model different from traditional venture capitalist (VC) financing options.

In this episode of Medsider, Marcus explains why Blackrock's business model works for medtech companies, how the approach gave the company an "in" with the neuroscience research community, and why medtech companies need to work with -and not against -regulating bodies like the Food and Drug Administration (FDA).

An Alternative to VC Funding

Although he's raised over $250 million through venture capital funding during his career, Blackrock was Marcus' first foray into healthcare startups. So when Florian first approached him, he did his due diligence and researched the medtech sector.

Marcus didn't like what he found.

With more medtech companies failing than succeeding, he was wary of the risk. Additionally, he knew that medical devices require significant investment before a product goes to market, which inherently conflicts with the VC demand for quick turnarounds on investments.

Why Building a Community is Crucial for Medical Device Startups

Marcus knew the business model couldn't rely on fundraising cycles. So he went back to the drawing board, and researched established European medtech companies, like German-based B. Braun. He started to see a pattern: Successful medtech companies were family-owned, and often run by stubborn founders.

> I knew Florian could be very stubborn, and I can be very stubborn, so I thought, OK, maybe we're onto something, says Marcus.

Instead of taking the traditional VC approach, Marcus brought in private investors. He acquired existing technology that could drive revenue and fund other projects that required extensive research and development.

Florian quickly identified a worthy investment: Cyberkinetics Neurotechnology Systems, a Utah-based company. The team, along with a small group of eager investors, bought the company.

With fresh eyes and a new perspective, Marcus and Florian started selling the technology as a tool for those in the neuroscience research community.

They turned a profit in their first nine months.

> It happened much faster than we had projected, says Marcus. Within a couple of years, we were the market leader, providing tools and solutions to neuroscience researchers.

The format allowed the company to stand on its own two feet. By consistently generating cash, Blackrock could pursue additional research and development without relying on fundraising cycles.

The Power of Community

While the rationale for the company's business model was built on a financing strategy, additional benefits quickly became clear.

By providing reliable tools and services for neuroscience research centers worldwide, the Blackrock team was quickly welcomed into the small but influential community of leading neuroscientists.

Why Building a Community is Crucial for Medical Device Startups

Blackrock now has over 500 strong working partnerships with scientists who use its electrodes, stimulators, and data acquisition systems (to name a few examples) in their research.

“Every single one of [our customers] has challenged us and given us ideas to help us come to this point that we’re at now,” explains Marcus.

Through these close relationships, the company was able to keep its finger on the pulse of innovation in neuroscience, which then translated to clinical applications. Marcus believes Blackrock’s behind-the-scenes view is the secret to his company’s success.

Marcus credits the power of the research community for helping Blackrock become the number one BCI player in the market, despite competition from goliaths in the field that are funded by deep-pocketed billionaires.

“We are a product of the BCI research community,” he says. “There is a strong identification with what we do and how we’ve done it, whereas there’s a borderline antagonistic approach from that community towards more commercially-minded endeavors.”

Blackrock’s research roots have also helped the company to scale successfully. Marcus’ team has grown from 50 to 130 people in less than seven months. Despite the many recruitment challenges that companies face today, Blackrock has been able to tap bright minds from within the neuroscience community to support hiring efforts.

“It’s been a fantastic interplay, and we’ve benefitted hugely,” Marcus reflects.

By surrounding themselves with great minds, great connections and great promise, Marcus and Florian find themselves unlikely leaders within the BCI industry.

A Vision to Get People Moving Again

The team at Blackrock is on a mission to help people suffering from neurological disorders to walk, talk, see, hear, and feel again.

As a result, Marcus and his team are driven less by financial indicators, and more by patient success stories and continuing technological advancements.

Why Building a Community is Crucial for Medical Device Startups

For example, Nathan Copeland was one of the first patients to participate in studies with the cutting edge technology. He has two small brain implants in his motor cortex, and two in his sensory cortex. The implants allow Nathan to not just move his neuroprosthetic hand, but to also *sense* touch -a particularly valuable experience when shaking hands (and fist-bumping) with President Barack Obama.

Placing value on the sense of touch was an important focus for the developers, as their research overwhelmingly indicated that people living with paraplegia are more eager to regain their sense of touch than the ability to move.

Blackrock continues to follow both the patients and the technology.

Future areas of focus for the company include cochlear implants that allow deaf individuals to hear again, and technology that supports the re-development of speech skills for those with amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease).

Working With (Not Against) Regulatory Bodies

Blackrock's technology was recently identified as a breakthrough innovation by the FDA, a designation that will speed up the approval process from the United States' regulatory body.

Marcus shares three pieces of advice for how medtech companies can work better with regulatory agencies:

1 Communicate early and often.

Working with the FDA can be a long and arduous process. Open communication lines early, and understand what challenges you will face based on the device or solution you plan to propose. By doing so, you'll be better positioned to provide a thorough proposal that addresses the FDA's concerns.

2 Don't be afraid to challenge the status quo.

When developing disruptive technologies, you'll inevitably push boundaries. This means that all organizations involved (including regulatory organizations) may need to adapt with you.

Why Building a Community is Crucial for Medical Device Startups

2 Don't be afraid to challenge the status quo (cont'd)

Marcus knows that Blackrock's technology is ahead of its time. He understands that part of his job is to help the FDA embrace technological innovations like his company's BCI solutions.

"We're going to be pioneers," he says. "And we're going to have to get the FDA on board to be pioneers with us."

3 Remember that you both want the same thing.

Too often, medtech companies view the FDA as an organization that prohibits or stalls growth. But Marcus believes that's the wrong perspective.

It's important to keep in mind that both the medtech company and the FDA want the same thing: safe and effective products that improve the lives of the people who use them.

Accepting that the FDA plays a vital role in the product development process will minimize your frustration, while also opening the doors for finding practical solutions that support patient needs.

Ultimately, for Marcus, it's all about integrity. He believes in staying true to himself, which is just one of the reasons he's passionate about creating a business that puts patients first, and values researchers within the industry.

> "We have always been very focused on the patient story —the patient impact and the application, Marcus says. That's what we were led by. It wasn't as if we said, OK, that is the biggest financial market: It was, Here is proof this can work.

Why Finding Investors Who Understand Your Product is Critical

Summary

EchoNous founder and CEO Kevin Goodwin explains why he focused on pleasing the biggest skeptics first, refusing to lower his standards to compete with buzzy competitors, and the challenges and opportunities of finding the right private investor to champion your medtech startup.

Kevin Goodwin

About Kevin

Kevin Goodwin has specialized in ultrasound for over 30 years. While at ATL Technology, Kevin founded spin-off company Sonosite, which launched the first point-of-care ultrasound (PoCUS) device in 1999. Unlike other ultrasound devices, it could be used anywhere in a hospital, instead of sitting in the radiology department. Sonosite was acquired by Fujifilm in 2012, and in 2015, Kevin co-founded EchoNous, with the aim of creating a portable PoCUS device powered by machine learning (ML) and (AI) to give even more accurate and detailed results.

Key Learnings

- Know your worth and stand by it. Investors who don't have a deep understanding of the medtech space can be blinded by buzzy companies with flashy, low-quality products. Don't let them force you to lower your price or compete directly.
- When you're looking for customer feedback on your prototypes, find people who are open to new ideas but take a lot of convincing. If you can make something that even the skeptics buy into, you'll know your product has a market.
- There are pros and cons to both public and private investment. Public investors can sometimes work faster, but they also expect quarterly revenue predictions, which can be hard for a startup. Finding private investors is a slog, but if you can bring in people who understand your product and give you the space to work, the opportunity is worth it.

Why Finding Investors Who Understand Your Product is Critical

Kevin Goodwin has already been part of a medical first. In 1998, he founded Sonosite, which released the first point-of-care ultrasound device (PoCUS) the following year. It was a classic startup story: Sonosite hit NASDAQ immediately after launching, with no product, no approval from the Food and Drug Administration (FDA), and no revenue.

But Kevin knew that the technology was ready, and it had the power to change medicine. Instead of having to schedule patients for a scan and transport them to radiology, healthcare workers could bring the device to their hospital beds.

Sonosite was acquired by Fujifilm in 2012, and Kevin left the company in 2014. By that point, he felt that the PoCUS device market that he had helped originate had grown stagnant.

Just as Moore's Law predicted, computers were getting smaller and less expensive to build, while also becoming more powerful. At the same time, artificial intelligence (AI) was making machine learning (ML) a reality. Yet PoCUS devices were still large and expensive, and the images were not all that detailed.

In 2015, Kevin co-founded EchoNous, to make a handheld PoCUS device that cost significantly less than the models used as the standard in hospitals. Even more ambitious, it would use AI and ML to not only deliver more accurate results, but to improve the detail and accuracy of those results over time. The company's AI-powered Kosmos platform was approved by the FDA in 2020.

In this episode of Medsider, Kevin explains the pros and cons of public versus private investors, what happens when a competitor with an inferior product dominates the headlines, and why the toughest potential customers are the ones you should try to win over first.

Own Your Place in the Market

Investors can sometimes be shortsighted when it comes to assessing market fit for medtech devices. You have to understand where you fit within the competitive landscape, and stick to your guns.

For example, EchoNous' Kosmos PoCUS device and platform costs approximately 10x less than the ultrasound machines commonly used in hospitals. Kevin says that this price difference is why some medical device companies showed no interest in developing the technology further.

There's no incentive to make a product that can do more but sells for less, when you can keep selling your existing technology at a higher price. "The problem in this industry is that everybody is loath to self-cannibalize," Kevin says.

Why Finding Investors Who Understand Your Product is Critical

Choosing a lower price point put EchoNous at odds with those established companies, and exploited a gap in the market for a high-tech, low-cost PoCUS device.

However, it also had the unintentional consequence of aligning the product - in the eyes of some investors -with what Kevin views as lower quality ultrasound technology. Specifically, a handheld smartphone-connected device called Butterfly, which has been causing a flutter in the venture capital world.

Like Kosmos, Butterfly is marketed as a lower-cost, high-tech evolution of PoCUS devices. Butterfly's probe costs $2,399 (at time of writing), approximately 4x less than the Kosmos, although users also have to pay a license fee. But despite constant comparisons, Kevin believes that the two companies belong in totally different categories.

"Butterfly has a very low-cost, cheap product... It sits above the stethoscope, but it's not diagnostic grade: it has limits that are very obvious," he says. In contrast, he adds, "We're selling to a whole different cadre of users who don't use Butterfly."

Between the stagnant established medtech companies, and the cheap-and-quick startups turning investors' heads, EchoNous has been consistently under pressure to either raise or lower its price point. However, Kevin has stood his ground, because he knows that there's a true market for what his veteran team at EchoNous is making.

> "My team is very deep in this field...we really know what we're doing, and the key variables, he says. We don't have to do this. We could do other stuff and we'd be cruising. But we're doing it because we see the business opportunity. Investors should take note of that.

Get Input From Skeptical Customers

When you're years into developing your product, and desperate for light at the end of the tunnel, you might be tempted to look for "soft" focus groups, made up of users you know will be gentle with their feedback.

Don't give in to that impulse. If you incorporate feedback from your hardest-to-please customers from the beginning, you'll know for certain that your product delivers on even the most demanding criteria.

Kevin recommends looking for potential customers who have two specific traits: "You go to people that are tough graders, but open-minded about innovation," he says.

Why Finding Investors Who Understand Your Product is Critical

In the case of Kosmos, that meant cardiologists, who had previously been sidelined when it came to PoCUS devices.

> They would buy the cheap products - the old ones -just to take a quick look, Kevin says. But those are non-diagnostic, non-reimbursable. They're better than a stethoscope if you're an expert, but if you're not an expert, you have to actually know what you're doing to use these devices.

Kevin determined that if he could convince doctors who were used to relying on their own expertise to diagnose heart problems that his product was a valuable tool, he could definitely bring people who were already using PoCUS devices on board.

He found doctors who were willing to give Kosmos a try: Roughly 30 physicians in the U.S., in multiple disciplines, and more at a big hospital in Greece. “They were very skeptical whether the hardware would perform at the level predicted,” Kevin says of the Greek doctors.

He listened to the participants’ feedback and iterated accordingly. The unique AI functionality also enables the device to improve its evaluations, so it gets more accurate over time.

Now, Kevin says, the once skeptical Greek doctors use the device to check their diagnoses. “It's actually been found in some cases to be more accurate than a doctor, meaning it's found disease where a doctor missed it,” he adds.

The Pros and Cons of Public and Private Funding

There isn’t a straightforward answer to whether going public or raising privately is the best strategy for funding your medtech startup. Having done both, Kevin says there are pros and cons to each.

Going public is faster but comes with tough questions.

Kevin launched Sonosite on NASDAQ before the company even had a product, let alone FDA approval. The agency gave them the green light one-and-a-half years later, in September 1999.

Despite unfavorable odds, Sonosite raised $160 million -$100 million more than it needed. “When the money is out there and available, you tend to load up the bank,” Kevin says. Sonosite made $10 million over the final four months of ‘99, and $32 million in 2000.

Why Finding Investors Who Understand Your Product is Critical

Convincing people to invest their money proved to be the easy bit. The cash injection came with terms: Like any publicly traded company, Sonosite had to hold quarterly meetings where it announced whether it had met its revenue targets, and set new ones. This was particularly difficult for a startup, and put the company under pressure.

For example, Kevin says, the company had aimed to make $50 million in revenue in 2000, and fell $18 million short. Objectively, that was still an impressive take for a medtech startup, especially one in its first full year of having an FDA-approved product. But the team felt as though they had failed.

Sonosite operated on a model that put product development before profitability. At the time that was unusual, but today, many medtech startups run the same way. This made it less suitable for meeting the demands of shareholders than more profit-centric companies. And if your company functions the same way, Wall Street may not be for you.

Raising money in the private sector is a grind with long-term rewards.

Kevin admits he didn't realize how difficult it is to raise money privately until he started looking for funding for EchoNous. However, he says that if you can find the right partner, the freedom this type of investment gives you to dig deep into your product is worth it.

Since 2015, EchoNous has raised $120 million from investment company Kohlberg Kravis Roberts (KKR). In May 2021, EchoNous did a debt deal with credit manager Kennedy Lewis. And as of the recording of this interview, the business was closing out a Series C round.

One of the problems is that many investors don't fully understand the nuances of medtech devices. Kevin says that investors look at the buzz around a company like Butterfly, which went public through a SPAC in February 2021, and believe every vaguely related business should be operating in the same way.

> "Some of them have concluded, Look at all the money Butterfly is burning - and they're burning a lot, Kevin says. You're going have to do that too. To which I say, No we won't, because we did it before without having to borrow capital.

Why Finding Investors Who Understand Your Product is Critical

However, once EchoNous connected with KKR, Kevin understood the benefits of thoughtful private investment over the frantic pressures of the public markets.

The leaders at KKR and Kennedy Lewis believe in EchoNous' long-term potential, and don't interfere with the daily running of the company. This empowers EchoNous to spend as much time as it needs on getting the product where it needs to be, instead of rushing to market with something that still needs the kinks ironed out.

> "It's really important to have capital that's supportive, Kevin says. I learned that at Sonosite, but it's easier said than done in the public markets.

Lessons Learned From Leading and Selling 3 Medtech Companies

Summary

Robert Kline shares the lessons he learned from leading three medtech companies through successful acquisitions: never underestimate the importance and difficulty of fundraising, don't assume everyone has the problem you want to solve, and don't build your company around an exit.

Robert Kline

About Robert

Robert Kline left big pharma to start Medivance in 1998. He sold it for $260 million in 2011. His next venture, ViroCyt, a spin-off from the University of Colorado, sold in 2016 for $16 million. He joined startup Bolder Surgical in 2017, pivoted it, and sold it in 2021 for $160 million. He's now Chairman of ThermoTek.

Key Learnings

- If you're setting out to solve a problem, make sure other people are experiencing the same issue, and are looking for a similar solution. Talk to potential customers about what they really want, so you can be sure of product-market fit early on.
- Don't start a company with one eye on the exit. Buyers don't magically appear the moment your device is approved for the market. Build a self-sustaining business and the investors will come.
- Fundraising can't be viewed as a nuisance, it's part of your business model. Raise money early and raise it constantly. Remember that loving your product is not enough to convince investors: You have to sell them on its commercial viability and projected financial returns.

Lessons Learned From Leading and Selling 3 Medtech Companies

Leading one medtech company through a multi-million-dollar acquisition is a career high point. Robert Kline has done it three times.

Bob got his start in big pharma, including working for Pfizer. While in business development, he realized that he was most excited about the small companies creating innovative products.

In 1998, he traded in his comfortable job to strike out alone. He founded Medivance, developing non-invasive products that change core body temperature. The company was acquired for approximately $250 million in 2011.

Bob's next venture was ViroCyt, a spin-out from the University of Colorado. The technology reduces the time it takes to quantify small biologic particles (including viruses) from days to hours. ViroCyt was sold for $16 million in 2016.

Bob then took over a startup trying to produce surgical equipment for use in minimally invasive pediatric procedures. Now known as Bolder Surgical, the company pivoted, and was ultimately acquired for $160 million in 2021.

Bob now serves as Chairman of ThermoTek and actively mentors other healthcare entrepreneurs.

"I have had the great luck of being able to … found a company, grow it, and exit it: all the phases," Bob says. "I want to help others have that experience too."

In this episode, Bob explains why assuming your customers want the same thing you do is risky, his best advice for fundraising, and why building a company around an exit is short-sighted.

Don't Assume the Problem You've Identified is Universal

The desire to solve a problem is part of the creation story of many companies. Medtech is no exception.

Sometimes it comes from the clinical side: You've identified a disease that either has no treatment, or progress on treatments has stalled. And sometimes it comes from the engineering side: You're developing new technology that does something never seen before, or is more efficient or effective than existing solutions.

Lessons Learned From Leading and Selling 3 Medtech Companies

Founders often get so swept up with solving their particular problem, they convince themselves everyone else will share that enthusiasm. Just because something is obvious to you, doesn't mean it is for everyone. Before you start racing ahead with your idea, take the time to ask your potential customers what they actually want.

> I see a lot of companies [that] think they understand the market requirements and the customer requirements really well, so they rush out with their solution, Bob says. And in the early days, you really have to avoid listening to your own story.

For example, when he founded Medivance, there were other companies developing devices to change body temperature. While Bob was speaking to healthcare workers about what they needed from this kind of technology, his rivals were focused on making overly complicated devices.

Designed purely from an engineering standpoint, these devices were technically sophisticated. However, they were invasive and required specialist training, which limited demand. Emergency rooms (ERs) and trauma centers are two major clients for this type of equipment. If a hypothermic patient arrives in the middle of the night, they can't wait for the only person trained to use the equipment to show up at 9 a.m.

Meanwhile, thanks to his on-the-ground research, Bob focused on creating a non-invasive device that could also be operated by nurses. "And because of that, we ultimately were wildly successful, where the other companies really weren't: They ended up being acquired for pennies on the dollar," he says.

The same goes for clinical trial data. Don't assume that every potential customer or investor wants to see the same level of research before they're ready to support you. Although large randomized clinical trials remain the gold standard, Bob says that in his experience, clinicians can often be convinced with data from smaller trials.

He calls this "building a drumbeat."

"Clinical evidence in the hands of real clinicians over time builds enough information that others are willing to join," he says. You may need large randomized clinical trials to get regulatory approval: but don't assume you need it to build a market for your product. Ask your customers what they need to see.

Lessons Learned From Leading and Selling 3 Medtech Companies

Don’t Build Your Company Solely For the Purpose of an Exit

Medical device founders who are looking for the exit before they’ve even registered their corporation probably won’t make it, according to Bob.

Entrepreneurs with this attitude tend to see regulatory approval as the finish line. But approval doesn’t guarantee a multi-million dollar exit.

That’s a risky strategy, given how many factors have to line up perfectly for an exit to work out.

You could be stuck in a bad economy, when investors are less willing to take risks. Or, you could find yourself on the wrong side of a trend.

For example, during the dot-com bubble of the late 1990s, investors were so fixated on internet companies that medtech, along with other industries, was sidelined.

The exit you’re picturing on the horizon is likely a mirage. Instead of falling for it, put your effort into building a commercially viable product with a self-sustaining business model and measurable market impact.

“More and more in the medtech world, acquirers are waiting to see how the market is reacting to your product,” Bob says. “You’ve got to think bigger. You can't focus on the exit, because you can't plan that. Just build a great company: Do the things that you believe build long-term value in a great company.”

Don’t race so fast towards an exit that you neglect to build a company with mileage.

Fundraising: Don’t Underestimate It

Raising money is more than an inconvenience to be checked off your to-do list. It’s an essential part of your business plan.

Having been around the fundraising block many times, here’s Bob’s best advice on the aspect of entrepreneurship many medtech founders dread the most:

Lessons Learned From Leading and Selling 3 Medtech Companies

Prepare to be rejected.

The idea that someone could be anything less than wildly excited about your passion project is crushing. But it's not personal, and it will happen over and over again, so thicken up that skin.

Think commercially.

Despite what The Beatles told us, love is not all you need -not in the world of medtech investors, anyway. Investors don't care that you're passionate about your idea: You need to show them how it will make them money. "You're asking people for money who want to get more money back," Bob says. "You have to think commercially."

Raise money before you need it.

Fundraising is not something you can procrastinate on. Don't get yourself into a position where you're finally ready to set up your very expensive clinical trials, or build your very expensive prototype, only to realize the bank account is empty. "The best time to raise money is when you have money," Bob says.

Fundraising never stops.

You've just closed Series A, and raised enough money to fund the next couple of years. It's time to get started on Series B. As Bob says, "Even when you close a round, you have to be thinking about the next round."

Being a founder isn't glamorous.

Being a founder isn't all champagne toasts and dollar signs. Raising money is a grind, on top of all the other obstacles you have to overcome. Only the most resilient founders will make it. "Have passion, but be prepared for a long haul," Bob says.

Why Design Thinking is Crucial for Medical Device Innovation

Summary

Madorra co-founder and CEO Holly Rockweiler discusses the importance of listening to your patients when developing medtech solutions, and why having a cause can be a valuable motivator. She also shares her most valuable learnings from participating in Stanford University's Byers Center for Biodesign program.

Holly Rockweiler

About Holly

Holly Rockweiler spent the early part of her career working as a research scientist for Boston Scientific. In 2013, she took a fellowship at Stanford University's Byers Center for Biodesign, where she met her future business partner, Ryan Krone. Through the fellowship, Holly and Ryan developed Madorra, a non-hormonal medical device that treats vaginal dryness. As co-founder and CEO of Madorra, Holly's on a mission to improve women's health.

Key Learnings

- Don't skimp on the discovery stage. Understanding your patients and the unmet needs your device will solve is essential for innovative design.
- Working in medtech can be a slog. Having a greater purpose behind your pursuit will motivate you when things feel especially difficult. Getting to know your patients and seeing how your device improves people's lives can bring joy to a taxing industry.
- Finding the right regulatory and clinical trial consultants is an essential part of the process. Listen to them and don't neglect to listen to your patients.. Hear what they have to say and apply it to your development process.

Why Design Thinking is Crucial for Medical Device Innovation

Holly Rockweiler thinks of herself as an activist in a lab coat. It's an identity that she fell into, but one that she owns with pride.

Holly spent the first part of her career as a research scientist for Boston Scientific, focusing primarily on cardiovascular health. Craving a closer relationship with the patients she served, Holly enrolled in Stanford University's Biodesign program: an incubator for the medtech industry.

There, Holly fully immersed herself in the world of women's health. The program challenges participants to spend time identifying and understanding problems before looking for solutions.

Holly noticed one unmet need that continued to surface. Breast cancer survivors weren't able to take advantage of the hormone-based treatment options for vaginal atrophy.

The initial response to Holly's focus area shocked her. Many pointed out that she'd found a small niche. "I don't know how [helping] 43 million women is a niche, but [that's] interesting," she says.

This oversight highlighted a significant problem -one which has become Holly's career calling. Despite being half of the global population, there is a considerable lack of innovation in women's health.

Holly and her business partner Ryan Krone developed a non-hormonal medical device, Madorra, to treat vaginal atrophy in postmenopausal women and breast cancer survivors. The invention received breakthrough device designation from the FDA in 2021.

In this episode of Medsider, Holly discusses how to use design thinking to further medtech innovation, the pros and cons of seed funding versus grants, and why listening to patients is essential for anyone in the medtech space.

Design Thinking Fosters Creative Solutions

Stanford's Biodesign program teaches design thinking to stimulate innovation within the medical device industry. The approach trains fellows to think creatively about identifying unmet needs, and developing solutions.

Some of the program's methodologies can feel counterintuitive, especially to those with engineering backgrounds, who are used to having a solution-based mindset.

One of Holly's greatest takeaways from the program was the value of the discovery process. She learned to give herself time to understand the unmet needs before trying to solve the problem.

Why Design Thinking is Crucial for Medical Device Innovation

> They have this ethos that bright minds can solve anything together, but let's spend that effort in the right place, she says. It was helpful to really evaluate the different projects we were working on. With so much time spent on understanding that unmet need, it allowed us to frame the problem in a new way.

Through the extensive exploratory period, Holly developed a deep understanding of the patients whose needs weren't being met, and was better able to design solutions to address patient pain points.

She credits Biodesign for much of her success, and is especially proud that the university is committed to making information accessible to all aspiring innovators, by giving free access to course teaching materials and video lectures.

Find a Cause You Care About Because You'll Be in This For the Long Haul

The medtech industry isn't an easy one. Projects often take years of development before coming to fruition -or failing. As a result, you've got to care about your work, or you will run out of steam.

When Holly worked at Boston Scientific, her favorite day of the year was Quality Day: an annual event where the company invited patients to share their stories with its employees. The opportunity to hear directly from patients brought on tears, but also a sense of purpose.

Placing patients in the forefront has become an essential part of Holly's work. Her desire for a stronger connection with patients drew her out of the lab and into the incubator. Today, she interacts with patients regularly, and has a strong understanding of how her work directly helps underserved people in healthcare.

> When I talk about this activism, I don't see myself as someone who's going to be marching on Capitol Hill, talking to lawmakers about stuff, but I am a medical device scientist. I'm an engineer...I can do my activism by creating this technology, Holly says.

Why Design Thinking is Crucial for Medical Device Innovation

Hearing what the technology has meant for patients in the clinical trials has helped Holly endure the roller coaster ride of the industry. She keeps a note on her desk with quotes from women who've participated in Madorra trials, to serve as a reminder of her purpose on challenging days.

Holly and her team continue to discover ways that their device can support the medical needs of patients, especially those that are sometimes easily forgotten

Knowing that she can support people who have felt otherwise ignored by the healthcare system is one of Holly's greatest motivators.

Frankenstein Your Funding

In terms of funding, Holly's done it all. But unfortunately, she ran into a common pitfall in the early stages of development. To successfully solicit investors, she needed clinical data -but clinical data costs money.

Holly and Ryan were initially forced to take the grant route. Luckily, the connections they made during their fellowship opened doors for some small, but essential, preliminary university grants, which helped them get their foot in the door.

Those grants opened opportunities for additional non-dilutive funding, which came with name recognition and added credibility to their project. Having the support of well-respected organizations proved beneficial when Madorra pursued Series A funding.

Holly's gotten creative with funding over the years, and has managed to pull off a thrifty approach to financing clinical trials. For example, Madorra completed one clinical trial in Australia, to take advantage of the country's R&D tax write-off program. She also managed to partner with a well-connected clinical trial consultant in San Francisco, who had access to patients that fit the trial's profile. This sped up the process, and therefore, made it more affordable.

"Clinical trial recruitment can really stall things out. The overhead of the trial just starts to add up," warns Holly.

But Holly also believes the rapid response to clinical trial recruitment efforts is a testament to the reality that there's a high demand for devices like Madorra. The company experienced many women eager and willing to sign up for the trial.

Madorra just launched its Series B fundraising round, a step that keeps Holly up at night -partly through anxiety but also excitement.

Why Design Thinking is Crucial for Medical Device Innovation

Lessons Learned Along the Way

Holly's learned a lot since she first enrolled in Stanford's incubator program in 2013. She shares her top four pieces of advice for those new to the industry:

Prioritize your efforts.

Your top priority must be your company's most significant risk. At Madorra, they had a great concept, but investors needed to know if it would actually work before they were willing to finance the project.

Developing a fancy device may feel like the first step, but Holly and her team knew that before they could create a prototype worthy of hitting the market, they first needed to prove it would work. Critical viability was most important for Madorra, which meant that getting the clinical trial off the ground was the company's top priority.

Don't aim for perfection (at least not at first).

Most likely, companies will go through multiple prototypes. They won't all be perfect, but that's OK.

Holly recalls the early models of Madorra's device: "It was clunky. One lady told us her granddaughter thought it was a telephone, which was hilarious."

Instead of focusing on flashy design, aim to address the critical functions of your device, collect feedback, determine if the device works, and then move on to fine-tuning.

Listen to your patients.

Staying connected to your patients will not only bring you a lot of joy but will also lead to a better-designed device.

Staying in tune with patient needs empowers user-driven solutions.

Find the right consultants.

Holly found success at multiple stages of Madorra's journey by finding the right partners.

Her Bay Area clinical trial consultant helped keep costs low by having the right connections with the right patient group.

And Holly also struck gold when she partnered with a regulatory consultant with a strong reputation and experience in women's health. Holly credits the partnership for Madorra's breakthrough device designation.

At the core of Holly's success lies a common theme: a knack for listening to teachers, investors, consultants, and of course, patients.

Planning Your Regulatory Pathway Around Your Product Roadmap

Summary

John Murphy, CEO of Virtual Incision, on how to raise funds as an early-stage medical device company, planning a regulatory pathway that complements your product roadmap, and how to follow a dual-track approach to exiting (warning: it's a lot of work).

John Murphy

About John

With a background in life sciences, aerospace, private equity, and venture capital, John has been the CEO of Virtual Incision since 2012. The company makes miniature, portable robots that can be used to perform specific operations. The first iteration is designed for colon resections, with new variations planned for the future.

Key Learnings

- More funding is coming into the medical device space, but it's still tricky bringing investors on board in early rounds. Consider approaching regional funds, which might be more inclined than nationally known firms to support local companies.
- Design a regulatory pathway that complements your R&D strategy. If you're working on brand new technology and plan to create further iterations, consider applying for a De Novo classification. This can serve as a foundation for the 510(k) notifications you file for later variations.
- Consider a dual-track approach to exiting: preparing for an IPO and for a potential acquisition at the same time. You'll have to hit a lot of milestones, but it's worth the effort.

Planning Your Regulatory Pathway Around Your Product Roadmap

John Murphy is a hands-on kind of founder. One of his favorite things about his company Virtual Incision is that it makes a physical product. Specifically, a brand new type of surgical robotic that is uniquely portable .

It's named MIRA, an acronym for miniaturized in vivo robotic assistant. The first iteration is designed to perform colon resections, where part of the colon is removed and the two remaining ends reconnected. Virtual Incision already has plans to build more variations, which will be able to perform cholecystectomies (gallbladder removal), hysterectomies (uterus removal), and herniorrhaphies (hernia repairs).

These aren't the first robots that can perform surgery. But so far, all the others are so big and expensive that only hospitals in metropolitan areas or those attached to universities are able to access them. In contrast, Virtual Incision's robots are lightweight -approximately 2 lbs -and can be set up within 10 minutes. Target clients include community and rural hospitals, and ambulatory surgery centers.

John had an enviable resume even before he got involved with surgical robotics. With a degree in computer science, he worked in aerospace and life sciences, before getting an MBA and becoming CEO of a couple of private equity firms. He's also part of Tri-Valley Ventures, a venture capital firm supporting startups on the eastern side of the San Francisco Bay.

In this episode of Medsider, John outlines his best advice on fundraising, regulatory approvals, and the dual-track approach to exiting.

Critical Things to Remember When You're Fundraising

Fundraising is constant when you're a medical device startup. John recommends keeping your broad business goals in mind at each round, and raising the necessary capital to meet these initiatives. Specifically, think about:

- Series A: You need to fund preliminary investigations into your idea, including early prototypes and proof of concepts.
- Series B: You should be focusing on early clinical and regulatory hurdles, and the next evolution of prototypes.
- Series C: Prioritize finalizing clinical data and getting regulatory approval. Start to look into early commercialization opportunities.

Planning Your Regulatory Pathway Around Your Product Roadmap

The good news for medical device startups is that while it's still challenging to secure funding, it's getting easier due to an influx of investor interest in the space. John explains: "We're emerging from a nuclear winter in device funding... it's [now] considered part of the solution, with novel treatments and cost control -and there's data with everything too."

However, keep in mind that finding venture capital (VC) funding for your early rounds is incredibly challenging. "Most of the traditional VCs... are going [for companies at a] much later stage: at least a Series C," John says. He recommends looking to sources that might be more sympathetic to the risks that come with investing in early startups. For example:

- Family and friends.
- Regional funds: Virtual Incision raised part of its Series A round from private equity firm Bluestem Capital Co in Sioux Falls, South Dakota - three hours from Virtual Inclusion's headquarters in Nebraska.
- Funds that specialize in early-stage capital.

Once you have your early funds, John is very clear about where he thinks you shouldn't spend them. "The one startling mistake I've thought about is CEOs pouring on commercial team spending -probably the most expensive part of fielding a new device -way too early," he says.

From John's perspective, in the early stages, it's better to spend on the product than the marketing. One thing medical device leaders need to always remember is that they are making a physical product, and it needs to be rock-solid before you can sell it. "We're makers, we're problem solvers," John says. "You've got to have that orientation to solve these clinical solutions." In other words, put substance before sales.

Be Strategic with Planning Your Regulatory Pathway

Working on something as complicated as robotics made having a scalable strategy to manage the regulatory process essential. And it's something every medical device company could benefit from.

John explains that Virtual Incision took a two-part approach that complemented the company's highly-technical field.

First, Virtual Incision applied for a De Novo classification on behalf of its first robot, which is designed to assist in colon resections. As the name suggests, this is a Food and Drug Administration (FDA) classification given to devices that are first of its kind. In Virtual Incision's case, there are other surgical robots: but none designed like MIRA.

Planning Your Regulatory Pathway Around Your Product Roadmap

With the De Novo classification granted, Virtual Incision can point to the approved device when filing 510(k) notifications for future variations designed for different procedures. It's a stepping stone approach, rather than trying to get each robot through a distinct regulatory process each time.

You don't have to follow this exact path: Identify the one that works best for your product. "Having a strategic, pragmatic way to step through the process is really smart," John says.

Dual-Track Exits are Worth the Hard Work

If possible, John recommends a dual-track approach when thinking about a liquidity event: Planning for an initial public offering (IPO) while also being prepared for a merger and acquisition (M&A) exit. This keeps your options open once you know your company is in a strong enough position.

To be transparent, it's a lot of work, especially since John recommends going the old-fashioned route of having proven solid revenue before trying to exit.

In addition to that, before going public, you need to have the fundamentals in place:

- Regulatory clearance or approval
- High compound annual growth rate (CAGR)
- A clearly mapped research and development (R&D) pipeline

M&As can be trickier to predict, since they rely on finding another company to acquire yours.

Start this process early: Research potential buyers and develop a relationship. As John says, understand what each company wants from you in terms of communication. Some might prefer phone calls, whereas others may like demonstrations. Some like quarterly updates, some only want to hear when you hit specific milestones.

"Get to know the teams early and who you're dealing with, and what their interests are, and get on that rhythm," John says.

Meanwhile, to prove you are acquisition-worthy, you need to get the following components of your business in order:

- Clinical value proposition: What is your technology bringing to healthcare that no one else is?
- Intellectual property: Technology that isn't legally protected from those looking to knock off your concept is worth less to potential acquirers.

- Quality management system: Prove that your organization is structured to function effectively.
- Financials and financial audits: No one wants to inherit hidden debts and mismanaged accounts.
- Human resources: High employee turnover and internal personnel issues are red flags to potential acquirers.

Preparing for any exit is a lot of work, and keeping the door open to do two different options is even tougher. But having sat on both sides of the table as investor and a founder, John thinks it can pay off in the end and believes a dual-track approach will ensure your company has many options available when you're ready to exit.

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

Summary

Oculogica CEO Rosina Samadani on the importance of relationships in the regulatory and reimbursement processes, why first-time entrepreneurs shouldn't be intimidated by complex procedures, and lessons learned from her experiences raising capital.

Rosina Samadani

About Rosina

Rosina Samadani initially joined Oculogica in an advisory role, supporting her neurosurgeon sister's plan to develop EyeBOX, a diagnostic medtech device for concussions. In 2015, Rosina transitioned into her current role as President and CEO of the company. With a doctorate in biomedical engineering from MIT, Rosina has been involved with multiple startups. She also serves as a judge for Stanford's StartX Accelerator, and MIT's $100K Entrepreneurship Competition.

Key Learnings

- Put people first. It can be easy to lose sight of the fact that there's a human on the other side of every interaction. Forming authentic and meaningful relationships with your various partners -from investors to regulators -goes a long way.
- Prioritize function over flashy design, especially in the alpha and beta stages of your company. Prototypes should be easy to use and free of glitches if you want to move quickly through clinical trials.
- Don't be intimidated by complex initiatives. Breaking large objectives down into digestible action steps demystifies the process and makes challenging tasks manageable to achieve.

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

If you watch football or read the news, you already know that concussions have become an area of increasing concern for many sports associations, particularly the National Football League (NFL).

Rosina Samadani initially watched the emerging discourse around concussions play out from the sidelines of her sister's medtech company, Oculogica. Rosina's sister, Dr. Uzma Samadani, is a renowned neurosurgeon at the University of Minnesota At that point in time, she was in the preliminary stages of developing the EyeBOX: a cutting edge medical device designed to diagnose concussions by reading cranial nerve palsies.

Uzma periodically tapped Rosina for advice in the early days. As a serial entrepreneur with a PhD in biomedical engineering, Rosina wasn't just a trustworthy and supportive sister, she was also a valuable consultant. Rosina eventually moved over to work on the project full time, and is now the CEO of Oculogica.

In this episode of Medsider, Rosina shares her advice for managing various stages of the regulatory journey, the importance of nurturing relationships with key stakeholders, and why entrepreneurs shouldn't be intimidated by the complex reimbursement process.

Product-Market Fit: Know Where To Play (and Where Not To)

With an almost ubiquitous association between football and concussions, it's not surprising to Rosina that many are quick to ask if the EyeBOX will soon appear on the sidelines of NFL and collegiate games.

But for now, that's not Oculogica's focus. First, the medtech company is focused on placing its product in clinics and hospitals, where the device will be used under the supervision of physicians, and other qualified healthcare professionals.

Having a narrow focus is the result of careful planning and preparation, a strategy that Rosina credits to Steve Blank, her former teacher and the mastermind behind the Lean Launchpad, a popular methodology used by entrepreneurs.

The Lean Launchpad approach focuses on finding product-market fit, which requires extensive initial customer research. Only then should entrepreneurs move on to develop an actual product. It's a strategy endorsed by other Medsider guests, including Holly Rockweiler, who used similar research tactics while enrolled in Stanford's Biodesign program.

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

As a result of Oculogica's research, Rosina knows the NLF won't be its first client. "Everybody says, Oh my gosh, the NFL and the sidelines, this is where you guys are going to kill it," says Rosina. "But they've [already] got their concussion protocol." As a result of her research, she knows the NFL isn't going to be first-in-line to adopt brand new technology.

Similarly, Oculogica isn't targeting other athletics organizations, because current practice is to sit out any player with a suspected concussion for the remainder of the game, rather than try to diagnose it on the spot.

Instead, the company is targeting the medical professionals who are consulted after a game, who operate in medical settings.

By clearly defining product-market fit, Rosina and her team are able to develop an intentional and efficient go-to-market strategy.

The Alpha and Beta Stages: Make Sure It Actually Works

In addition to prioritizing product-market fit, Rosina thinks many entrepreneurs in the early stages of their company should change their focus when developing prototypes. Function should take precedence over form.

Oculogica's first prototype for EyeBOX was lovingly referred to as "the duct tape prototype," not because it was flimsy, but because it was held together and secured to the table with actual duct tape.

"It was really difficult to put together and set up at clinical trial sites, but it worked," Rosina recalls.

The prototype got the initial data they needed, but it had its flaws, mainly because the setup was too complex. Rosina advises that entrepreneurs focus on robust but basic devices that are stable and free from glitches. It's essential that those using your device can troubleshoot with ease. If not, they'll get frustrated and are less likely to enroll patients in the trial.

"They're not going to have the instinct that you do. So you need the software to be safe, stable, and you need the thing to be able to fall on the floor and still be OK -most likely that is going to happen," Rosina says.

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

Raising Capital: Know Your Audience and Customize Your Pitch

Rosina's best advice for raising funds: "Put yourself in the seat of the person you're talking to," she says.

Angel investors and venture capitalists (VCs) think differently about the return on their investments. Therefore, your presentation should reflect their specific needs and concerns.

Do your research upfront. Know a VC's portfolio and investment thesis. If a VC isn't a good fit for your company, don't waste your time (or theirs). Instead, only pitch to investors you believe are good fits for your company.

"Narrowing that down will really help you," says Rosina.

Earlier investors, particularly angel investors, are looking for something exciting. They're not afraid of risk and are willing to take a chance. But the further you move through the fundraising process, the more mitigating risk will become a vital part of your strategy.

Alternatively, consider building strategic partnerships. TitletownTech Ventures, a Wisconsin-based VC firm backed by the Green Bay Packers, is one of Oculogica's investors. The partnership makes sense from both a financial standpoint, and also because of the potential connections with the NFL.

The Wisconsin-native sisters didn't make their pitch by strolling down to Lambeau Field and knocking on doors. Instead, they asked one of their angel investors, Golden Seeds, to make the introduction. Which, when coupled with some cold calls, got their foot in the door.

The "surround sound" strategy is an approach that has worked for Oculogica, and shows the company's credibility and determination.

Relationships Matter: Authentic Connections Will Take You Far

Strong relationships have consistently been at the crux of Oculogica's success. Whether turning to a pre-existing connection or forging new ones, EyeBOX's evolution has benefitted from Rosina and Uzma's understanding that people are important.

Rosina shares three crucial moments in Oculogica's journey where relationships mattered:

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

Making friends at the FDA

Rosina believes in taking advantage of every moment of an interaction. At the conference table for their pre-submission meeting with the Food and Drug Administration (FDA), her team made sure they spread out instead of sitting next to one another. It allowed the team to make personal connections with as many of the regulators as possible. They were able to develop more personal connections, which continued to grow as they worked together throughout the regulatory process.

Advice from StartX's accelerator network

Rosina is a passionate advocate for StartX, an independent non-profit accelerator for Stanford graduates. When she needs feedback from a peer, or sample contracts, she turns to her network of fellow entrepreneurs. Members of the program are eager to support one another, and value community-wide success.

The clinician stamp of approval

When Oculogica went through the reimbursement process, it had 11 medical societies willing to support it. Uzma's connections in the medical field certainly helped at this juncture, but it was the team's commitment to cultivating long standing win-win relationships that drove the strategy home.

Rosina is quick to point out that relationship-building only matters if it's genuine. She recalls an interaction with the lead reviewer at the FDA, whom she'd gotten to know during the regulatory process. After reading news headlines about the government shutdown, she decided to check in on him. She sent an email to let him know she was thinking of him during such a stressful time. "It wasn't even about our submission. I actually cared about him as a human being," she explains.

Forming relationships, though, should never be forced. "You've got to read the room," Rosina says.

Building Relationships, Raising Capital, and Establishing Reimbursement Codes

Reimbursement: Remember, It's Not Brain Surgery

Many medtech entrepreneurs are quick to describe the reimbursement process as complex and time-consuming, but Rosina believes that shouldn't deter entrepreneurs from pursuing their medtech dreams.

Oculogica also needed to apply for a Current Procedural Terminology (CPT) code, which further complicated the process, but that didn't dissuade Rosina's team.

> Don't be intimidated when applying for a CPT code, says Rosina. A brain surgeon invented our technology, but what I tell people in my company is, we're not doing brain surgery.

It may seem overly simple, but Rosina says: "Google it."

Once a complex process is broken down into small, actionable steps, it becomes much easier to pursue.

> Maybe I'm foolish, but we did it. We'd never [applied for reimbursement] before, but honestly, it was fun. We went in front of the American Medical Association (AMA), we were really prepared, and we did a great job, Rosina says.
>
> One thing she wishes she knew in hindsight: You don't have to have FDA clearance before applying for a CPT code. We waited. You don't need to do that. Make sure you're applying as early as possible, she says.

4 Key Considerations to Win Over Investors

Summary

Glympse Bio CEO Caroline Loew discusses her "early-and-often" approach to dealing with regulatory issues and shares four things to consider ahead of conversations with potential investors.

Caroline Loew

About Caroline

Caroline Loew, Ph.D., has served as the President and CEO of Glympse Bio since 2018. Prior to that, she held executive roles at Merck and Bristol Myers Squibb, where she oversaw R&D. Caroline earned her bachelor's and doctoral degrees at Imperial College, London.

Key Learnings

- Instead of regarding regulatory agencies as a threat, Caroline has found that being proactive in her dealings with Food and Drug Administration (FDA) is the smart play.
- The COVID-19 pandemic and corresponding market collapse had a major impact on investor behavior. Empathizing with potential backers helped Caroline lead a successful fundraising round in a historically challenging environment.
- Authenticity and integrity are critical to successful investor relations - particularly with those who finance your startup. Backers aren't just funding a product, they're also investing in the people behind the product.

4 Key Considerations to Win Over Investors

The simplest ideas often lead to the most elegant solutions.

For example, the body changes when infected with a disease -and those changes are measurable.

This simple truth is the very foundation of Glympse Bio, a biopharmaceutical startup that is revolutionizing disease diagnostics and monitoring.

The company is developing biomarker panels to measure changes in protein activity for a variety of diseases. By analyzing proteins in a simple blood draw, Glympse can identify a disease state and determine whether it is advancing or regressing.

Caroline Loew's task as President and CEO of Glympse Bio is to ultimately get her company's technology in the hands of doctors, where it can then make a difference in the lives of patients. But to do so, she has to partner with the right investors to fund her company's initiatives and she has to work efficiently with regulators to get the technology approved.

An organic chemist by training, Caroline now works at the intersection of science, business, and clinic -a role that's anything but simple.

"The science can be incredible, absolutely astonishing, and amazing," Caroline says. "But if it never makes it to a patient, if it never makes it into a physician's hand so the physician can work with a patient to better their condition, it's all for nothing."

In this episode of Medsider, Caroline discusses the importance of being proactive when dealing with regulators. She also shares four key things to consider as you engage with investors.

See Regulators as Partners

Caroline describes the frequency of Glympse Bio's make-or-break interactions with the FDA as "early-and-often." It's an approach she encourages others in the life sciences arena to take.

> "A lot of people have this notion of trepidation when they think about engaging with the agency, particularly as a small company, Caroline says. But my experience has been mainly one of knocking on the door every day. They really want to collaborate. They want to help you, particularly with new technology, and they want to help you advance.

4 Key Considerations to Win Over Investors

Caroline found that through frequent dialogue and strong grasp of the regulatory framework, she was able to figure out how to keep things moving forward. She likens it to riding a wave -you want to ride at the crest to avoid falling off.

But even with a solid understanding of the regulatory pathway and great dialogue with regulators, there's no silver bullet to keep things progressing — that's why Caroline stresses the importance of flexibility.

> There are things you just can't control in the regulatory environment, Caroline says. Things that you plan might change because something happens with another company that causes the FDA to retrench. [It could be] the direction they were taking, or there's a bit of rulemaking that gets driven because of the political environment. You always have to be flexible.

Up Your Investor Relations Strategy: Four Best Practices

Is there a worse time to raise capital than during the outset of a global pandemic?

Probably not.

But that's exactly the position in which Caroline found herself and Glympse Bio in 2020. COVID-19 forced Caroline to stop and reassess how Glympse handled investor relations.

> We were fundraising as the markets bottomed out at the [beginning] of the pandemic, Caroline recalls. There was some real uniqueness to the experience, but I think there were a few things that I took away that are universal.

4 Key Considerations to Win Over Investors

Understand Your Value

If you can't quickly help a potential investor understand what your company does, how can you expect them to want to help you?

"You need to understand the science," Caroline says. "You need to understand your value proposition and your story. And you need to be able to clearly and succinctly articulate all of it."

Knowing your product inside-and-out so you're able to speak to the value your company contributes to the field with confidence and clarity is absolutely essential.

Understand What Your Investors Value

Prior to 2020, Glympse was taking what Caroline characterized as a "generic" approach to investor relations.

But when the markets crashed, Caroline knew that Glympse needed to stop and reconsider how the global economy affected the mindset of those looking to fund medtech startups.

"What investors were experiencing and how they were thinking about investments was wildly different," Caroline recalls. "We had to change how we thought about [ourselves], our engagement with them, and what they needed."

Glympse was able to meet its fundraising goals for the round by changing its approach and designing a strategy that reflected the unique needs of each potential backer.

"You really need to focus on the things that are important to them," she says. "I think that's critical. I mean, saying it now, it sounds almost stupid."

Step back and look at your pitch through the lens of each specific investor and adjust accordingly.

Understand How You Want to Present Yourself

Authenticity matters, especially when it comes to dealing with those you hope will fund your vision.

"We believe in being extremely transparent," Caroline says. "We're very authentic, we don't sugarcoat things, we say things as they are, and we don't hide anything. I think that transparency is very valuable."

4 Key Considerations to Win Over Investors

Investors are far more likely to trust those who are forthcoming with the challenges and hurdles their companies face. After all, if it's all sunshine and roses, what aren't they telling you?

Venture capitalists are often investing in the people behind an idea in addition to the product. So being your authentic self (even in a pitch) starts your relationship on the right foot.

Understand How to Engage

Similar to any other kind of relationship, communication is the key to success when dealing with your investors.

Be responsive. Share data. Answer questions right away.

It's easy to be responsive to them when they're sitting across the table from you. It's also easy to slip into an "out of sight, out of mind" mentality. Don't fall into that trap.

The old adage, "communication is key" is cliché for a reason.

How to Apply an Engineering Mindset to Your Medical Device Startup

Summary

Access Vascular CEO Jim Biggins shares his strategies for developing a clinical research roadmap and creative commercialization models with curiosity and flexibility, plus the reasons why clinician access is crucial for medtech entrepreneurs.

Jim Biggins

About Jim

Jim Biggins developed innovative products for companies like Boston Scientific, Ocular Therapeutix, and Medtronic before spending 18 months exploring venture opportunities by shadowing clinicians in real-life medical settings. His company, Access Vascular, has introduced a novel biomaterial for vascular access devices aimed at reducing common patient complications.

Key Learnings

- Don't underestimate the impact of getting into hospitals and talking directly with clinicians. Nothing beats observing procedures in real-life medical settings for understanding the actual need and how your product can address it.
- Randomized control trials may be the gold standard of clinical research, but smaller, well-timed studies can also tell potential investors and customers a compelling story about your technology and its applications.
- Don't assume that you know how to commercialize your device based only on past experience or observing others. Test your sales strategies in small pilot groups before scaling up based on your top-performing models.

How to Apply an Engineering Mindset to Your Medical Device Startup

It's easy to see that Jim Biggins, Founder and CEO of Access Vascular, is an entrepreneur at heart. He started business ventures as a teenager and has since strategically steered his career path to strengthen the skills needed to eventually launch his own medical device company in 2015.

But it's an engineering mind that Jim has employed to navigate the challenges of introducing a groundbreaking new biomaterial into the $4.5 billion global market for vascular access devices.

Access Vascular closed on a $20 million Series B fundraising round led by TVM Capital Life Science in 2021, and in early 2002, the company opened its new 40,000-square foot manufacturing facility outside Boston.

Jim founded Access Vascular based on a need he identified in the medical device market, and then proceeded to reverse-engineer the solution to a pervasive problem he encountered while observing clinicians through MassMEDIC's Ignite training and mentorship program.

As his company has evolved, Jim has leveraged a similar framework to complex clinical research, and commercialization processes -designing his own roadmap for developing, testing, and iterating various potential solutions.

In this episode of Medsider, Jim shares the importance of hearing directly from clinicians in the field, how to plan out a clinical research strategy, and the benefit of questioning assumptions when it comes to commercialization.

Clinical Access Offers Valuable Insights

Jim first fell in love with the medical device industry when he was an undergraduate student studying materials engineering at UMass Lowell and working second shift assembling devices at Medtronic. Over the next decade, he racked up experience in all aspects of the medical device space -R&D, clinical affairs, marketing, regulatory, marketing, and sales.

When he was ready to take the leap to start his own company, Jim joined the MassMEDIC Ignite program, and for 18 months, he shadowed clinicians in various capacities, listening to their experiences and complaints, and developing the concept that would eventually become Access Vascular.

It was a pivotal moment, he says, as this face-to-face access helped him uncover a huge market need he may have otherwise missed.

How to Apply an Engineering Mindset to Your Medical Device Startup

> It was really the amount of complaints and concerns that clinicians had regarding something as simple as vascular access that really got me to pay attention, he says. Looking at the complete lack of innovation in the space and the size of the market, I was very compelled to say, We should be doing better for patients.

Drawing on his materials background, Jim developed a proprietary new base material for vascular access devices that could reduce the main complications patients experience. In an industry with virtually zero differentiation among existing products, Jim felt that his new solution could move the needle in terms of improving patient outcomes and improving the economic impact of vascular access complications.

Jim credits his real-world clinical access with the idea for his company, and believes that getting into hospitals to observe and speak with clinicians is a missed opportunity among medtech entrepreneurs in the product design stage. It's a crucial part of the process that goes beyond ticking off the boxes mandated by design controls. And while Jim acknowledges that gaining this access has become increasingly difficult, the experience is well worth the effort.

Rolling up their sleeves allows entrepreneurs to really get in the weeds to figure out a device's use and impact. This experience can help you understand everything from how a device fits into a clinician's hand to how use of your device could extend procedure time, and whether that's an acceptable tradeoff for improved outcomes These are learnings you can't easily get from sending out a few electronic surveys.

> We live in a physical world, Jim says. At the end of the day, there's some sort of an interface with a real person in a real environment that needs to be the focal point.

How to Apply an Engineering Mindset to Your Medical Device Startup

Uncover Your Clinical Research Roadmap

Jim says that it wasn't always clear how Access Vascular should approach the issue of clinical research. Lots of people recommend a randomized control trial (RCT) right out of the gate, but that's an expensive avenue for a single study that may or may not have the desired impact on fundraising and sales efforts.

Thanks to great guidance from some advisors and his own due diligence, Jim was able to reverse-engineer his way to a solution.

He looked at five successful companies operating in arenas similar to Access Vascular and plotted each company's studies and publications on a five-year timeline. Then he looked to see what sort of clinical evidence they had in place at each pivotal point in the company's growth. What he found -rather than a single RCT -was a volume of studies put together to tell a compelling story.

This approach has worked well for the company. Jim found that value analysis committees are more than willing to evaluate the product based on these smaller studies that speak to specific aspects of the technology.

> "It's really about knowing what resonates, building that story up and making sure we have the right endpoints and the right sites, he says, and then we pull the trigger [to do an RCT] when it adds the correct amount of value.

Create An Iterative Process For Commercialization

When Access Vascular reached the commercialization stage, the company faced stiff competition from large, well-established sales forces. But instead of trying to hire dozens of representatives to match the size of their competition, Jim started with a handful of small, focused sales pilots.

> "There are a lot of different ways to sell devices, Jim says, and I think the big mistake can be making the assumption that you know how to sell it because of either past experiences or following someone else.

How to Apply an Engineering Mindset to Your Medical Device Startup

Jim approached the sales pilots like an engineering problem from the start, iterating each time he found a representative profile or distribution model that out-performed the others. The company's go-to-market strategy examined a number of variables including geography and likely early adopters. They also had to consider which hospitals would be willing to open their doors to a new medical device company in the midst of the COVID-19 pandemic.

Now that the company is ready to hire a sales team, they have a much clearer picture of the successful formula.

> "As we kept learning, we just kept track. Here's the pipeline with this sort of profile, with this geography, with this concentration of hospitals, Jim says. And then - who's letting us in the door? What's working? What's resonating? What's the messaging? All of those things certainly came into play.

Through navigating each of the processes involved in launching Access Vascular, Jim has kept the company's mission front and center.

> "Ultimately, if you're doing the right things by solving a real problem, and you're passionate about that, I feel like everything else will fall into place, he says.

How Medtech Companies Should Approach the Consumer Health Market

Summary

Movano CEO John Mastrototaro talks about how medtech companies can build a successful consumer-facing brand while developing products that meet the needs of payers and providers.

John Mastrototaro

About John

John Mastrototaro, Ph.D., has more than 30 years' worth of experience in the medical device industry bringing innovative therapies to market. He was part of the MiniMed team that helped develop the world's first ambulatory continuous glucose monitoring system and sensor-augmented insulin pump. After MiniMed was acquired by Medtronic, John went on to hold a number of positions in Medtronic's Diabetes Division. John is now CEO and Director of Movano, a health technology company that makes smart, personalized devices that can provide vital health information to users.

Key Learnings

- Don't discount the real world. Clinical trials are essential, but when a device's data also comes with applications beyond user intent, payers and investors will pay attention. Part of the appeal of Movano's model is that the device provides valuable health metrics for users while also providing doctors and researchers with usable health data, creating a win-win for multiple parties.
- Aesthetics matter. The Movano Ring design was a direct result of listening to customers. Yes, a wearable device needs to function, but it also needs to appeal to the user. If customers don't want to wear it, they won't. At the end of the day it's about form and function.
- Building an experientially diverse team leads to innovative solutions. Think outside of the box when hiring. Look to experts in other areas beyond the medical device space who can offer broad knowledge and insight.

How Medtech Companies Should Approach the Consumer Health Market

After three decades of working in the medical device space, with stints at leading healthcare companies like Lilly and Medtronic, John Mastrototaro is now setting his sights on digital health and bringing medical-grade technologies to consumers in the form of wearable devices.

There's a need to collect and leverage data from people remotely and in their homes - a need that is especially useful for patients with chronic conditions, like type 2 diabetes or hypertension.

Data collected from consumer health devices give insight into a patient's health and can identify when someone may need intervention.

That's where Movano comes in.

John joined Movano in April 2021, knowing he could use his decades of experience in the diabetes and cardiovascular medical device arena to help propel the company's technology forward.

Movano expects to launch its foundational product, the Movano Ring, in the third quarter of 2022, pending FDA clearance. The smart ring and accompanying app, which are targeted toward women, measures the wearer's heart rate, heart rate variability (HRV), sleep, respiration rate, temperature, blood oxygen saturation (SpO2), steps, and calories.

With its wearables portfolio, Movano distills health data and insights down for users.

> "We want to show people the cause and effect. We want to help them understand how their activities of daily living affect their health metrics, and maybe show how those are improving over time, John says.

In this episode of Medsider, John explains how digital health technologies can help consumers understand more about their health, give doctors and researchers insight into real-world health data, and how companies can convince payers that the technology is worth the expense.

How Medtech Companies Should Approach the Consumer Health Market

Demonstrate the Value of Your Technology

Medical-grade digital health technologies like the Movano Ring can be used across settings and by multiple stakeholders, including researchers, consumers, and payers.

Wearables could play a key role in helping pharmaceutical, biotech, and medical device companies gather data on their products in clinical trials and the post market setting. Data from digital health technologies could also help healthcare plans gain insight into their members' health and well-being which then can be used to help members make healthier lifestyle choices.

> "I think this has a number of applications where it could be phased in, and in a way that's so much more affordable than anything that's ever been accessible in the past, John says.

John advises medtech companies to focus on demonstrating value in two key areas when presenting their products to payers:

1. Show the value of your product in a controlled environment, such as in a clinical trial.
2. Show that the clinical work translates to real-world use of the technology. Make sure people continue to benefit from the therapy the same way they did in the clinical trial.

> "You have to show payers that the money saved by using the technology is more than the cost of the technology. The more expensive a core technology is, the more you need to show a big benefit to offset those costs, John says.
>
> Companies can access long-term data from users to see whether the data have evolved over time and translate that into benefit, John says.

How Medtech Companies Should Approach the Consumer Health Market

Focus on User-Friendly Cost and Design

Always do right by users and think about them when considering cost and design, John says. Listening to and understanding your audience is key to creating a successful product.

The technology's function should be commensurate with what a doctor would want to see, but at the end of the day, the consumer should want to actually wear and use the product. If users don't keep wearing your product, you won't be able to demonstrate value and benefit over time.

That user-first philosophy is what led Movano to design the Movano Ring, which is specifically targeted toward women.

When Movano looked at the wearables landscape, the company noticed women seemed to be an afterthought, especially when it came to design and user experience. At the end of 2021, the company announced the Movano Ring, which uses medical-grade technology, but is also aesthetically appealing and looks more like jewelry.

Movano also is considering offering its product through a subscription model where users get the device free of charge and pay for the service.

> Like Movano, a lot of big companies are trying to figure out how they can bring affordable healthcare to underserved, underrepresented groups across the United States, John says.

John suggests medtech companies weigh the costs and benefits of their technology against the cost of regular doctor's office or lab visits.

For example, a subscription service for a wearable might cost the user a couple of hundred dollars a year and provide a year's worth of health data and metrics. Patients would typically pay more than that for a single doctor's office visit to get blood work done, John explains.

The more accessible your technology is, the bigger your customer base will be. And you can make up for a lower-cost product with a higher volume of users.

How Medtech Companies Should Approach the Consumer Health Market

Think Outside the Box To Grow Your Company

Nothing is more important than the people on your team, John says. They're the ones that make the product work.

It's important to think big -go beyond the traditional avenues and recruit people from across industries who can bring different knowledge and expertise to your team.

> Other industries are often more evolved than the medical device industry in certain areas. Taking someone who's coming from that more evolved space and bringing them into your organization is important, John says.

John offered up four other key lessons for medtech entrepreneurs and companies just starting out:

Operate as a medical device company (from day one).

Movano set itself up as a medical device company right out of the gate. Movano has a quality management system and design control process in place, just like what would be used for a traditional medical device seeking FDA clearance. The product will even be made in a medical device manufacturing facility.

Every part of the Movano Ring development process, from the clinical trials to the accuracy of the metrics, will be looked at through the lens of a medical device company, which will better position the company to meet FDA standards.

Have a regulatory expert on hand.

John recommends medtech companies retain a regulatory expert to help guide them through FDA process.

The FDA has already published standards for how devices should collect certain metrics, like heart rate, SpO2, and respiration rate. A regulatory expert can help companies understand what they need to do to meet FDA standards and get clearance from the agency.

How Medtech Companies Should Approach the Consumer Health Market

Contract out certain tasks.

John's philosophy is that it's important to keep the "secret-sauce" internal, while contracting out other day-to-day tasks. For example, Movano outsources customer payments and credit card transactions to a third-party company.

Thinking strategically about what to outsource and what to keep in-house allows medical device founders to protect their intellectual property while still running a tight ship.

Don't be afraid to fail.

There are going to be a lot of speed bumps along the way, but John advises to stay true to your work and always keep the end goal in sight. All the hard work will pay off at the end of the day.

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> Always keep your chin up, keep the mission in mind, and keep marching forward toward the end goal, John says.

How To Make Health Technology Fun and Accessible

Summary

Osso VR Co-Founder and CEO Justin Barad explains why health technology companies should make their products not just accessible, but also fun for healthcare professionals. He also shares about managing through the chorus of voices trying to pull his technology in multiple directions, and staying focused on Osso's ultimate goal of modernizing the way surgeons are trained.

Justin Barad

About Justin

Justin Barad is Co-Founder and CEO of Osso VR. An orthopedic surgeon with a passion for technology and a history of working in the video game industry, he developed a virtual reality platform that can reform the way surgeons are trained and assessed.

Key Learnings

- Keep your eye on the prize. There are a lot of great ideas out there, and it can be tough to cut through the noise. Set clear goals for your product and your company, and follow through.
- Find new ways to spotlight your product and get it into people's hands. Go where your potential customers are and let them try the product for themselves. Medical conferences are a great place to interact with healthcare professionals.
- Make your product fun, accessible, and easy to use. Healthcare professionals can be hesitant to try new technology. Developers and engineers need to show their products are not only safe, but also that they provide benefits over legacy technology.

How To Make Health Technology Fun and Accessible

Justin Barad is an orthopedic surgeon who has found a way to combine his two passions: gaming and healthcare.

The self-proclaimed tech nerd has always loved video games -he even worked at the video game company Activision. His plan was to go into the gaming industry, but when a family member experienced health issues he began to wonder whether he could use his technology background to help people and solve challenges in the medical field.

In pursuit of his passion, Justin received a bioengineering degree from University of California Berkeley and a medical degree from UCLA.

During his residency at UCLA, Justin saw issues with the way institutions train and assess healthcare professionals, especially surgeons.

The problem is threefold:

1. There's too much to learn, especially considering the speed with which science and technology is expanding.

2. Modern surgery is complicated and newer procedures are harder to learn than more traditional ones.

3. There's no real way to assess technical proficiency in healthcare.

"I'd be in multiple surgeries where people would ask me to Google what to do, find a video or technique guide, and it felt off to me," Justin says.

Justin discovered virtual reality through the Oculus Rift DK1. He thought it was an "incredible solution" to the surgical training problem.

He and his business partner Matt Newport developed a prototype VR platform. They won an award and garnered interest from investors, and then in 2016 started Osso VR, which is now the leading virtual reality surgical training and assessment platform.

Osso VR's technology - a VR headset and controllers -creates clinically accurate simulations with a cinematic level of visual fidelity. The platform allows surgeons to measure their growth with analytics both inside and outside of the platform.

In this episode of Medsider, Justin shares how he avoids being pulled in multiple directions with his technology, why it's important to let potential customers get hands-on with your platform, and why tech can and should be fun -even in healthcare.

How To Make Health Technology Fun and Accessible

Set Clear Goals for Your Company and Your Product

In the early days of building a company and developing a product, you'll work primarily with customers who tend to be early adopters of new technology and have innovative ideas.

For Justin, one of the biggest challenges of working with VR is knowing that it could be used for practically anything. People have a lot of ideas about how it should work or what it can do, and there are endless opportunities. But Justin had a vision — he wanted to use VR to improve the way surgeons are trained — and he stuck to that vision.

As a surgeon, he had the insight and expertise to identify a problem in the healthcare space and come up with a solution.

Justin shares his advice for key steps you can take to ensure you don't get pulled in a hundred different directions.

Stay focused on the mission.

Focus is critical when you're developing a new technology and a new business, Justin says. Come into the project with a clear point of view — know what you want your technology to do, how it can be used, and who you want to target. And work with people who can help you along the way.

> Raising money is not the goal; the goal is to do something with the capital that you raise, Justin says.
>
> You really need to show what this could be. What is the size of the opportunity? What is the vision, and is that achievable? And you need to be able to get people to believe that and buy in on it, Justin says.

How To Make Health Technology Fun and Accessible

Partner up with an expert in the field.

> Coming into something without a lot of knowledge can be scary and overwhelming — you need to not only understand the clinical challenge, but also know how to build a successful product, how to scale the technology, and how to build a scalable business model. You're going to want to listen to everybody, but that could just lead to a 'spaghetti against the wall' approach, Justin says.
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> Find a partner who has domain expertise and can help navigate the waters, Justin says. Working with someone who has a core knowledge set and knows the space in which you're working is truly important, Justin says.

Care about the problem, not just the tech.

It's not enough to just understand the problem. You have to really care and be excited about it, Justin says. Starting a company is unbelievably challenging, but also can be truly exhilarating, he adds.

You should be able to wake up every day, thrilled to be tackling a problem that you are passionate about. Caring about the problem is just as important as caring about the technology, Justin says.

Let Potential Users Get Hands-On With Your Technology

Find new ways to get your product in front of healthcare professionals. Let them see and use the technology before they buy it.

Surgeons are overwhelmed with the myriad of choices that are available to them and it's difficult to comprehend the differences between products, Justin says. If you can get surgeons in front of your technology and let them try it themselves, then they can see why it's so important or useful.

How To Make Health Technology Fun and Accessible

> You can't just speak to it; you have to show it to someone, Justin says.

How do you do that? Healthcare conferences are a great place to start, but that's been difficult during the pandemic since so many conferences have been canceled and people just aren't coming in the same numbers as pre-pandemic.

Despite that, Osso VR is still investing a lot of time and money in conferences. But Justin is also contemplating alternative opportunities for getting the word out about his product.

Companies should be thinking about how they can create new avenues to show off their products and bring in new customers. Letting people try the product before they buy it, and perhaps even engaging them in training opportunities, could "supercharge" the sales process and make everything much more efficient, Justin says.

Make It Accessible and Make It Fun for People To Use

The healthcare industry follows a "one-and-done" approach. That is, doctors try new technologies once but then often never go back. Some are worried the newer technology feels less safe and will often revert back to using the tried-and-true modalities.

Engineers and developers need to show medical professionals that their product is not only safe but that it also provides a benefit over the older, legacy options.

In the world of surgery, for instance, there are simulation technologies that are used for training, but they typically are designed for a single type of procedure. They're also expensive and not portable. On top of that, the current simulation technology on the market doesn't decrease costs for hospitals, nor does it improve patient outcomes.

Surgeons also often have to take time to travel to simulation labs for training, which is distracting from their day-to-day practice.

Osso VR's technology solves these issues. The headset is low-cost, coming in at $300 each. The price and portability of the technology means you could theoretically get one for every single healthcare professional in the world, he says. It uses vibrations to train doctors and provide immediate feedback on their technique. It's even lighter (and cheaper) than a lot of medical textbooks.

How To Make Health Technology Fun and Accessible

> You can be fully immersed in the operating room and any procedure and simulate high-fidelity visuals and interactivity and basically train on any procedure you want, Justin says.

Accessibility, affordability, and portability are all part of what sets Osso VR apart from the rest of the technology in the medical care training arena.

A doctor could use the Osso VR platform to practice in between cases or even between surgeries, or they can do it in the comfort of their own home, Justin says.

Justin also suggests looking at what engineers and developers are doing in other spaces, like video games and entertainment, and try to create experiences that are just as fun and easy to use.

“Is anyone going to use this in the first place? Is it fun? Is it easy to use? Or do they have a reason to come back? These are often considerations I don’t see people talking about, and I think that’s something that we’ve really focused on that I think is going to pay off,” Justin says.

Technology is changing healthcare, and doctors and surgeons need cutting-edge tools to keep up. Understand what healthcare professionals need and want, and focus on finding a solution that hospitals and medical experts will want to use again and again.

Why You Should Weigh the Global and Economic Impact of Your Technology

Summary

David Neale, CEO and co-founder of Argá Medtech, explains how being a multinational company increased their chances of success, and why startups should incorporate economic outcomes into their clinical studies.

David Neale

About David

David Neale has three decades of experience bringing medical goods, services, and devices to bear across a range of sectors and in multiple countries. In 2020, he launched Argá Medtech, a multinational company focused on developing new, more efficient ways to treat atrial fibrillation.

Key Learnings

- Understand how clients will use your product across the globe, and get input from a diverse array of stakeholders and experts. It's important to consider the myriad of ways that healthcare is structured, reimbursed, and regulated worldwide.
- Think about the financial impact of your product, and measure healthcare economic outcomes in your clinical studies. Ask yourself how your product benefits all stakeholders, including patients, providers, hospitals, and payers.
- Don't just focus on meeting business and development deadlines — make sure that what you're producing is something that patients, providers and hospitals want and need. It's important to have a great technical solution to a problem, but also make sure you don't minimize other stakeholder's input or consider additional challenges that could arise.

Why You Should Weigh the Global and Economic Impact of Your Technology

David Neale, co-founder and CEO of Argá Medtech, has 30 years of experience bringing medical goods, services, and devices to bear across the healthcare space — from cardiology to neurology and nephrology to orthopedics. He's also helped lead product development teams around the world, including South America, Europe, and the United States.

David's international experience came into play when he decided to launch his startup, Argá Medtech, at the beginning of the COVID-19 pandemic.

He always had an interest in electroporation — the use of electrical currents to open up muscle cells, allowing them to absorb medication. And when he met up with an old friend, Randy Werneth, to go over ideas, they realized they had access to technology that could advance the use of electroporation to help patients with atrial fibrillation.

David and Randy pulled together a team and launched Argá Medtech, focusing on developing its Coherent Sine-burst Electroporation (CSE), the next generation of nonthermal cardiac ablation systems. The company hopes it can provide a safer, faster and more efficient technology to treat atrial fibrillation.

As a startup, Argá is more nimble and can move faster than a lot of larger companies, according to David. That flexibility was key to helping the company score initial investments and quickly develop the product for testing, all in the midst of a global pandemic.

"We've been able to deliver in 18 months what some of the big players, because of their structures, take so much longer to do," David says.

David believes his experience working with international teams across markets played a key role in helping get the business up and running.

In this episode of Medsider, David discusses how his experience working for multinational organizations helped him launch Argá, and why more medtech companies should focus on the healthcare economic impacts of their technologies.

Make Connections Around the Globe

David's international experience and outlook were critical to getting Argá up and running. Because of his connections and ability to work across borders, David and his team were able to successfully set up facilities in Switzerland and San Diego, establish business partners in Germany, and get input from international experts.

This global approach will also help ensure multiple countries can use Argá's CSE.

Why You Should Weigh the Global and Economic Impact of Your Technology

Healthcare is structured, reimbursed, and regulated differently across the globe, David says. To be successful, medtech companies need to understand how countries worldwide and in different markets manage through various dynamics.

The Argá team wanted the company's product to be used in any market, not just in the United States or Europe, David says.

> We really wanted to get the best and to understand and get the collection of experiences that others could deliver, and I think I could only do that because I had this global experience, David says.

Include Economic Outcomes in Your Clinical Trials

Anyone who's serious about introducing a new medical product should set out to discover how it will affect every single stakeholder, including the patient, surgeon, nursing staff, and technicians, as well as hospitals and payers.

David advises startup teams to start thinking about the healthcare economics now and incorporate those assessments into clinical trials.

Argá has planned a clinical trial strategy that assesses core outcomes — safety and efficacy — along with economic data and milestones that would affect buyer and healthcare system decisions. The goal is to prove that by using Argá's CSE, surgeons can more effectively treat patients while also saving time and money.

The company's first-in-human trial is already collecting economic outcomes data that a safety-only study typically would not evaluate.

"Is the hospital going to be able to make money off of it or not? Does the reimbursement system support this or not? Does it make more money [for] the hospital and allow it to treat more patients compared to existing technology? We have to aim for that," David says.

Why You Should Weigh the Global and Economic Impact of Your Technology

Stand Out From the Crowd: Answer the Tough Questions

In the early days of Argá, David and his team talked to customers and stakeholders in the field to find out what kind of technology people were looking for in atrial fibrillation. They asked about the shortfalls of devices and what Argá could bring to the table.

> We had to bring something different, David says.

After receiving input and putting the answers together, they had to challenge themselves to answer other key questions and focus on the bigger picture.

The team had to recognize what it didn't know. They also wanted to avoid getting tunnel vision — focusing too much on meeting product development deadlines and not enough on creating something that patients need and want.

> I think that's one of the biggest mistakes I see with some of the early-stage startups — you have a great technical solution and you trust the solution to be perfect, and you minimize a lot of the other input or other challenges that you could have, David says.

David says he and Randy always challenge themselves and their team to ask two key questions: So what? What if?

"It gets people out of their comfort zone … there's always something you didn't think about," David says.

It's not easy to stand out in the crowd, but David and his team were able to do it, all while in the middle of a global pandemic. David leveraged his experience working in markets around the world and received input from a diverse group of experts, proving to investors that Argá has what it takes to change the treatment landscape for atrial fibrillation.

The Importance of Going ‘All In’ On Your Medtech Business

Summary

SynerFuse Co-Founders Justin Zenanko and Greg Molnar share their experience launching an innovative therapy to address chronic back pain, how they are navigating challenging regulatory waters, and why they chose to invest heavily in their own venture.

Justin

Greg

About Justin and Greg

Justin Zenanko is a Certified Public Accountant who led fundraising efforts at Recombinetics. Greg Molnar is the former Director of Neuromodulation Research at Medtronic. In 2018, they joined forces to found SynerFuse, a clinical-stage startup developing an innovative therapy to relieve chronic back pain.

Key Learnings

- Be careful not to get stuck in the ideation phase. Imagining better solutions is laudable, but you won’t learn what you don’t know until your product becomes tangible.
- Trust your gut, and be willing to push back against conventional thinking. It’s never too early to be thinking creatively about how you’ll jump regulatory hurdles or approach the reimbursement landscape — especially if your idea is truly novel.
- Investing in your own business is a way to show that you believe deeply in its success and can help attract investors willing to make a bet on you and your management team.

The Importance of Going 'All In' On Your Medtech Business

Co-Founders Justin Zenanko and Greg Molnar are out to blaze a trail, one they believe will have an enormous impact on the lives of people living with chronic lower back pain.

Their company, SynerFuse, is in the clinical stage of developing an integrated therapy to address both the mechanical and neuropathic causes of back pain — at the same time. Typically, patients who experience residual pain following a conventional spinal fusion can wait up to 10 years before receiving neuromodulation therapy — battling additional surgeries and risky opioid medications along the way.

By creating a dorsal root ganglion (DRG) stimulator that doctors can implant at the time of spinal fusion surgery, Justin and Greg hope to short-circuit this long and painful cycle, provide faster relief to patients, and address chronic back pain without the extended use of opioid drugs. The first patient in the proof-of-concept study received a SynerFuse device in early 2022, and the team is well on their way to the fifth implantation.

As with any innovative therapy, SynerFuse faces a number of regulatory and clinical hurdles; Justin and Greg have encountered plenty of naysayers as they seek to challenge the status quo. But they remain invested, literally — most of the millions of dollars that SynerFuse has raised to date came from the founders' own pockets, as well as friends and family, a few angel investors, and one foundation.

In this episode of Medsider, Justin and Greg share how they balance innovation with action and what keeps them going in the face of regulatory obstacles.

Momentum Comes From Making Your Ideas Into Reality

SynerFuse's co-founders are no strangers to the medtech world. Trained as a CPA, Justin spent seven years leading fundraising and corporate development efforts at gene-editing technology developer Recombinetics. Greg is the former Director of Neuromodulation Research for Medtronic, where he spent nearly a decade before moving to the University of Minnesota.

Their combined experience in startups and medical device innovation helped them avoid what Justin says is a common mistake in the industry.

"You can develop too much," he says, explaining that it's easy to get stuck in the innovation stage and miss out on the work that will actually get your product to market.

The Importance of Going 'All In' On Your Medtech Business

Greg says, "I've seen it in big industry, and in academia especially, where people want to put everything and the kitchen sink into their first device. The thing is, you don't know what you don't know."

It's only by getting a product into the market that startups can begin to learn from customers, stakeholders, and real-world applications. Then they can integrate those lessons into subsequent generations of the product.

"So you really have to think about your generations of product and getting the input along the way," Greg says. "Or you could just burn up quickly trying to pack too much into your first offering."

This wisdom extends to building a great team for your startup, too.

"It's a safe exercise, depending on your team, to just keep inventing, keep growing," Greg says. "And then you never have to deal with reality, because you're never gonna get out of the early concept phase. So you also need people that know how to take it from concept to commercial on your team."

One of the moves pushing SynerFuse into the action stage is forging a strategic partnership with Cirtec Medical Corporation, announced in early 2021. Not only is Cirtec an established medical device manufacturer, they are also the developers of a neuromodulation platform that SynerFuse used to bring their initial solution to market.

"What the 'gen one' device contract and the partnership with Cirtec did was to set the groundwork to put everything else in motion," Justin says.

Bring Both Grit and Creativity to the Regulatory Table

Navigating the regulatory process, especially with an innovative product, is as much art as it is science, says Greg. Beyond the required paperwork, there's also room for strategy and intuition.

"You need partners that not only know that you've got to fill out these forms, but also understand the strategic thinking in this, [what is a] largely process flow — those that can propose great arguments to the reviewers and write up the documents in a convincing way, " he says.

He recommends shopping around, talking to colleagues and collecting testimonials when looking for these partners. Founders should continue checking in to ensure the partners they found are the right fit — and not be afraid to go a different direction if the partnership is not working.

The Importance of Going 'All In' On Your Medtech Business

Justin says innovators should expect to encounter negativity and pressure to conform to the usual ways of doing things. Founders should listen to their instincts and never give up, even when it means questioning the status quo.

"A lot of times I think the bigger company mentality is, Well, you can't be wrong, you have to have it all figured out," Justin says. "But if you're committed to your team, and you're committed to your vision and your passion, and you have faith to persevere, it's amazing how you will find ways to overcome."

It's Never Too Early to Talk About Reimbursement Strategy

Justin and Greg bring a similar level of confidence to the question of reimbursement — how will doctors and hospitals get paid for a brand-new therapy that doesn't even have a medical code?

"It's not a hurdle that can't be overcome," Justin says, adding that if SynerFuse's therapy can keep patients out of the pain-surgery-opioid continuum, it could save the industry $20 billion per year.

The reimbursement conversation — which for SynerFuse includes a big-picture look at the economics of their technology — is one that has to take place up front. Ultimately, it's the payments that make the world go round, says Greg.

Opioid treatment for chronic back pain can run up to $80,000 per year and can continue for several years, he says. Compare that to the $25,000 cost of a device like the one SynerFuse is developing, and the math is pretty obvious.

The co-founders have also had conversations about how much patients would be willing to pay out-of-pocket for access to effective pain relief. And they've discussed alternative reimbursement approaches — including large, self-insured employers that might see the benefit of paying to treat injured workers.

Planning for all of the possibilities aside, Greg and Justin seem certain that the process will work out in their favor.

"As long as you have a therapy that works and helps patients, and the data is good, and it's effective and safe, it will get paid for," Greg says.

The Importance of Going 'All In' On Your Medtech Business

Find Investors Who Align with Your Vision — Even if That Investor is You

SynerFuse's strategic advisors and board of directors include doctors, regulatory officers, and former leaders of large insurance companies — partners that will help their innovative therapy find a home in the medical ecosystem.

What you won't find there are any VC (venture capital) investors. Justin and Greg have raised SynerFuse's funding from friends, family, and angel investors — and from their own pockets. They have led every fundraising round so far.

"It changes everything," Justin says. "When you're having a conversation — regardless of the concept or the vision — the final due diligence is, Well, what are you in for? If you're not in for it, then you're telling me to my core, to my gut level, that you don't believe in it."

He says taking venture capital funding can put companies in a difficult situation, especially if the management team and VC investor(s) disagree on the vision or timeline. SynerFuse understands the importance of finding angel investors who are aligned with the startup's trajectory.

"All of our angels have made a bet on myself and Greg, that we are the two to make the thing happen and to get to the promised land," Justin says, adding that he and Greg and their families are also heavily invested for the long term.

"We can't walk away. If things don't go right, I can't just leave," he says. "I have no choice but to push through, and for us to push through together."

How to Convince Investors, Payers, and Patients Your Device is Worth the Cost

Summary

Bone Health Technologies CEO Laura Yecies shares why you should look for investors who are passionate about your mission, how FDA clearance can boost consumer confidence in your technology, and why patients should be at the center of everything you do.

Laura Yecies

About Laura

Laura Yecies is a Silicon Valley veteran with more than three decades of experience at major tech companies and startups. She's always had an interest in improving people's health and wellness and was drawn to medtech startup Bone Health Technologies, which is developing a vibration belt intended to prevent osteoporosis.

Key Learnings

- Identify the right investors. Find people who connect with your company's message and mission, and are passionate about your product.
- Consider getting the FDA stamp of approval, even with a consumer-centric device. Taking your products through the regulatory process is expensive and time-consuming, but can boost patient and provider confidence in your technology.
- Think about how patients will pay for your product and price it accordingly. Bone Health Technologies is pursuing and making a commitment to an affordable self-pay path (for now).

How to Convince Investors, Payers, and Patients Your Device is Worth the Cost

About 54 million Americans have osteoporosis and low bone mass, which can lead to serious and painful bone fractures. Studies estimate that about one in two women and up to one in four men ages 50 and up who have the condition will break a bone, according to the Bone Health Policy Institute.

Though osteoporosis is a common condition, there are gaps in treatment — some can put patients at risk for further fractures while others have relatively low patient adherence rates.

Laura Yecies understood that need, which is why she became CEO of medtech startup Bone Health Technologies in 2020.

Laura is a Silicon Valley veteran with 30 years of experience leading major companies, including Netscape, Yahoo, SugarSync, and CheckPoint, as well as startups such as SyncThink and Catch.

She's always had a deep-rooted interest in people's health and wellness and was looking for her next big project — something she could connect with on a personal level.

That's when she came across Bone Health Technologies and its OsteoBoost belt, which is intended to prevent osteoporosis. Wrapped around the user's waist, the belt produces gentle vibrations that mechanically stimulate the bones to improve bone density.

The National Institutes of Health's National Institute on Aging awarded Bone Health Technologies a $2.7 million grant to help fund the company's late-stage research and development.

Bone Health Technologies also is currently enrolling participants in a one-year study assessing whether OsteoBoost can successfully treat osteopenia in postmenopausal women. They are conducting the trial in partnership with the San Francisco Veterans Affairs Health Care System; the University of California, San Francisco; and the Northern California Institute for Research and Education.

In this episode of Medsider, Laura talks about the importance of finding investors who are passionate about your mission, why Bone Health Technologies decided to pursue FDA clearance for its technology, and how the company's commercial plans through a cash-pay approach.

How to Convince Investors, Payers, and Patients Your Device is Worth the Cost

Identify the Right Investors for Your Product

“Find groups that connect with your mission and message,” Laura says.

Bone Health Technologies’ investors fall into a couple of different categories: clinical experts who understand the unmet medical need in osteoporosis, and groups that are focused on women’s health and want to invest in women-led companies.

Laura found many of the company’s investors also have personal experience with osteoporosis or know someone who does, and as a result, they are all very passionate about what Bone Health Technologies is doing in the space.

> “I think that’s important. You see this generally with angel investors. They’re making a considerable financial decision, but oftentimes, they’re investing in fields that they care about. And I think that passion and care is important for all of the roles, Laura says.

Once you identify investors, you need to perfect your pitch. Be clear about the need for your product, Laura advises.

If the need is small, be prepared to explain where you see demand for your product and how investors will benefit financially. You shouldn’t have to work too hard to prove there’s demand, Laura says.

“If you're working too hard on that, something’s wrong and the investors will see it,” she says.

Pick Your Regulatory Path Wisely

Going through the FDA premarket clearance path is a lengthy endeavor and can be expensive, but Bone Health Technologies thinks the time spent will be worth the effort.

Doctors and patients generally trust the FDA stamp of approval — all the more reason to pursue a clinical development strategy through the agency, Laura says.

Bone Health Technologies initially tested its product as a device marketed OTC (over the counter). While people were interested in the product, they were hesitant to spend money up front without the rigorous clinical data to back it up.

How to Convince Investors, Payers, and Patients Your Device is Worth the Cost

> The science is good, but from a market perspective, we recognize that there's potential for skepticism. That's all the more reason to hold ourselves to the most rigorous data standards, Laura says.

The company decided to forego the OTC route (for now) and instead pursue a Class II FDA authorization pathway for OsteoBoost, which Laura says will also allow insurance to cover the device.

In 2020 FDA granted breakthrough device designation to the OsteoBoost belt, meaning Bone Health Technologies will have more frequent interactions with FDA reviewers throughout the product development stages. The company's more rigorous clinical strategy should also yield fruit in the future should it want to pursue the OTC market.

There are a lot of products that started out as prescription and transitioned to OTC, and the OTC version benefits from the prescription version's "seal of approval," Laura says.

Consider How Patients Will Pay for Your Product

Bone Health Technologies focuses on making its product affordable so that patients can pay out of pocket.

> We haven't set pricing yet but we are aiming for something that is reasonable. It seems like a no-brainer decision, Laura says.

Laura expects the device will prove useful in curbing more serious, expensive bone injuries, which could eventually spark interest among payers, including Medicare.

Most bone fractures due to osteoporosis occur in senior citizens, who are often Medicare patients. Fractures are on the rise, are costly to treat, and get expensive for payers. But those costs can be headed off with a relatively inexpensive device, Laura says.

How to Convince Investors, Payers, and Patients Your Device is Worth the Cost

OsteoBoost has not been assigned a current procedural terminology (CPT) code — a five-digit number that providers use to identify medical services and procedures for insurance claims. The device also is not covered by insurance, but the ultimate goal is to have a CPT code and coverage, Laura says.

In the absence of insurance coverage, Bone Health Technologies will let patients pay out of pocket for the device. As there are 50 to 60 million osteoporosis patients, Laura expects there will be enough demand for OsteoBoost that the company will be able to make a lot of headway with a cash-pay approach out of the gate.

Laura also acknowledges that many people who would benefit from OsteoBoost are on a fixed income and might not be able to pay out of pocket, which is why the company plans on working overtime to obtain insurance coverage.

“It's important from a health equity point of view, and of course, as a business opportunity for us. But we can start and we can make progress at the beginning with self-pay,” she says.

At the end of the day it’s about the patients — understanding their health journey, their needs, and what they want out of a product — and then communicating that with investors so you have the resources to bring that product to fruition. The more you know about the patient, the better and more successful your product will be.

Demonstrating Value with Robust Clinical Trial Data

Summary

Miracor Medical CEO Olivier Delporte explains why he advocates for randomized clinical trials, how remote monitoring tools can make clinical trial programs more efficient, and why startups should increase their fundraising goals.

Olivier Delporte

About Oliver

Olivier Delporte has more than 20 years of sales, marketing, and general management experience, mostly in the medical device industry. In 2016, he became the CEO of Miracor Medical, a medical device company based in Belgium. Under Olivier's guidance, the company is advancing its flagship PiCSO treatment for severe myocardial infarction.

Key Learnings

- Keep collecting data even after you get regulatory approval. Generating strong clinical evidence through randomized trials substantiates the value of your technology to patients, doctors, and payers, even after you've hit the market.
- Miracor Medical takes advantage of remote monitoring tools to make its clinical trials more efficient and cost-effective. Consider going virtual using high-end surgical monitoring platforms, like Avail and ExplORer Surgical. You can also use more common video conferencing platforms for less complicated procedures.
- Focus on long-term fundraising goals and aim to raise more money than you think you need. You want to be prepared should you encounter development delays or challenges.

Demonstrating Value with Robust Clinical Trial Data

When Miracor Medical CEO Olivier Delporte joined the company in 2016, he had one stipulation: The company needed to conduct randomized clinical trials to demonstrate the value of its flagship product, the PiCSO (Pressure-controlled Intermittent Coronary Sinus Occlusion) Impulse System, a novel treatment for acute myocardial infarction, more commonly known as a heart attack.

PiCSO is intended for use during percutaneous coronary intervention (PCI), a first-in-line procedure to treat heart attacks as a way to reduce infarct size, which Olivier says should lower mortality rates and lead to fewer hospitalizations due to heart failure.

Under Olivier's guidance, Miracor is focused on building a strong evidence base for PiCSO and is pursuing an expansive randomized clinical trial program to demonstrate value for doctors, patients, and payers — by showing that PiCSO can reduce heart failure that can often occur after a heart attack.

> "The standard of care [for heart attacks] today is still stenting. Stenting has helped these patients, but at the cost of heart failure hospitalization, Olivier says.

The company is conducting clinical studies in Europe and plans to initiate a randomized controlled trial for FDA clearance in 2023.

In this episode of Medsider, Olivier talks about the importance of gathering robust clinical evidence in randomized clinical trials, how the company uses remote video monitoring to guide procedures, and why startups should raise the bar on their financial goals.

Generate Strong Evidence in Randomized Trials

Randomized trials have always been the gold standard, and the need for strong clinical evidence has only increased over the years

Without this type of data, you won't have adequate evidence for health care providers and you likely won't get reimbursement, Olivier asserts.

> "As a company, you want to know the true efficacy and the true value of your product. In the end, randomized trials will help you understand, Olivier says.

Demonstrating Value with Robust Clinical Trial Data

Miracor is conducting randomized trials with a focus on patients who experience ST-elevation myocardial infarction (STEMI), a more serious heart attack.

The company launched its first randomized study in Europe in July 2019, and the trial demonstrated positive results. The European Union has already granted marketing authorization to PiCSO, but Miracor isn't resting on its laurels. The company continues to focus on generating strong clinical evidence in its other European clinical studies, too.

Miracor is currently enrolling patients in its second randomized trial in Europe. The company also is conducting an observational study to gather data from the real world and bolster its evidence base.

Miracor is also pursuing regulatory approval with FDA and plans to launch additional clinical trials in the United States and Canada to support its submission.

Take Advantage of Remote Monitoring Technologies

Clinical trials are expensive and time-consuming, especially when, like Miracor, you're collecting data across multiple sites.

To boost efficiency, Miracor is using remote proctoring — where clinical specialists use a laptop to virtually monitor and guide cardiologists through the PiCSO procedure.

Miracor's clinical specialists have proctored procedures from their cars and even the airport, Olivier says.

Virtual surgical consultation platforms like Avail and ExplORer Surgical provide higher-quality video and communication options than platforms available to the general public. But Miracor also uses FaceTime- and WhatsApp-based video. PiCSO is a fairly simple technology, Olivier says, so the learning curve is smaller.

"I think this is only one of the areas where technology is revolutionizing healthcare and will continue to," Olivier says.

Demonstrating Value with Robust Clinical Trial Data

Up the Ante on Your Fundraising Goals

Olivier says more traditional investors — what he calls the “old-money” shareholders — often will direct companies to be more conservative when raising money. But Olivier believes companies should raise more money than they think they will need.

Building a startup is going to require twice the money and twice more time than you think it will, he says. Companies need to make sure they have a financial cushion, especially in case of major disasters or other unforeseen events, like a global pandemic.

Startups should avoid “managing toward a wall” — that is, when leaders focus on raising money to reach a single milestone in the hopes that hitting it will open up opportunities to raise more money.

Think about the long-term goals when setting fundraising targets, Olivier says. Your plan should be to create value for your company and translate that into financial returns for investors.

“I've become very pragmatic. We need to create value for the company. And in the end, a company needs to be able to be independent in some way,” Olivier says.

Miracor is currently focused on raising money for its clinical trial program. Olivier believes PiCSO is a transformational therapy, and he wants to make sure Miracor demonstrates that to investors and payers through robust clinical evidence.

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> The focus is really on clinical studies and getting access to the U.S. market with the right data and with the right reimbursements, Olivier says.

In the medical device world, data is king. Strong clinical results can help medical device companies better understand the efficacy, safety, and true economic value of their products and ultimately boost their chances of success.

Why Your Product Should Generate Revenue Versus Reduce Costs

Summary

Cognetivity Neurosciences Co-founder and CEO Sina Habibi discusses the importance of collaborating with regulators and end users, why he primarily focuses on the value of revenue generation versus cost savings, and the benefits of teaming up with an expert fundraiser.

Sina Habibi

About Sina

Sina Habibi has a Ph.D. in engineering from the University of Cambridge, where he met his business partner Seyed-Mahdi Khaligh-Razavi. The two co-founded Cognetivity Neurosciences, which develops cognitive assessment tests for clinicians and patients to detect cognitive impairment, including dementia. Sina is an active member of Cambridge University Entrepreneurs.

Key Learnings

- Get input from experts at every step of the development process, starting with regulators and working back to your end users. Regulators let you know what's needed to get your device or technology to the finish line, while end users will help you drive toward a compelling product offering.
- Think about the value and benefits of your products first; cost-savings should come second. Focus on showing clinicians that you can generate revenue for their practice. Making sure users get a return on their investment is key to seeing early adoption of your technology.
- Team up with fundraisers who have experience raising money in your field. Worry less about dilution and focus more on raising smart capital. A small piece of a large cake is worth more than a big piece of a smaller pie.

Why Your Product Should Generate Revenue Versus Reduce Costs

Cognetivity Neurosciences Co-founder and CEO Sina Habibi met his business partner Seyed-Mahdi Khaligh-Razavi while obtaining his Ph.D. at the University of Cambridge. Sina and Seyed-Mahdi bonded when realizing both had loved ones diagnosed with dementia in the later stages of the disease, when it was too late to reduce its effects. Sina, an engineer, and Seyed-Mahdi, a neuroscientist, set out to fix the process for diagnosing dementia, resulting in the launch of Cognetivity in 2013.

Cognetivity is on the cutting edge of neuroscience and uses artificial intelligence (AI) for early detection of cognitive impairment, dementia, and Alzheimer's disease.

When it first launched, the company was on the front-lines of the digital health space, which required blazing new trails with regulators. The Cognetivity team had to learn the ins and outs of digital health product development and regulation on their own.

"There was not much that we could look at in terms of peers or examples that had gone down the pathway, both from a regulatory point of view [and in] product development. So we had to do a lot of the work ourselves," Sina says.

Since then, the company has launched two products: Cognetivity's Integrated Cognitive Assessment (CognICA) and OptiMind.

CognICA is a five-minute, computerized test that measures cognitive function. Considered a medical product, it has marketing authorization in the European Union and the United States. OptiMind is a wellness app that measures users' everyday cognitive performance.

In this episode of Medsider, Sina discusses the importance of getting input from both end users and regulators throughout the development process, why companies should focus on how their product can generate revenue versus reducing costs, and the importance of teaming up with an expert fundraiser.

Reverse Engineer Your Development Process

When Cognetivity was just starting out, Sina and his team made sure to regularly interact with regulators to help them understand the nuances of the technology. Regulators at that point were used to reviewing and approving medical products shown to be safe and effective for a specific function and with clear parameters around how to use the device.

Why Your Product Should Generate Revenue Versus Reduce Costs

CognICA is not a traditional medical device; it's a computer program developed for an iPad, featuring AI that changes and gets better the more the program is used.

The Cognetivity team had to educate regulators about the product and the nuance behind the technology. Regulators are now using Cognetivity's platform as an example for other companies developing similar technology, according to Sina.

Sina encourages other medtech developers to speak with regulators throughout the product development process.

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> [Regulators] never tell you 'do this or do that,' but they will make you aware of the risks and things that you might have overlooked, Sina says.

Once you have input from regulators, focus on getting feedback from your intended end users, whether clinicians or patients. Those conversations can help ensure your product vision aligns with what users truly need and want. In Cognetivity's case, the company talked to clinicians who would eventually be administering the CognICA test to patients.

"It's easy to sit down and imagine a product that is ideal for your customers. You can do all the hard work, and then face a brutal reality that that's not the case. One of the good things that we've done ...from the very early days is [being] in direct communication with end users, which are clinicians, and have taken a lot of input," Sina says.

Make it a priority to obtain input from multiple experts along the way, including the planning for your clinical trials. Product area experts can help identify overlooked issues that might affect the design, length, and cost of your clinical trial.

"[Spending] tens of thousands of dollars at the very beginning can save you literally millions of dollars down the line," Sina says.

Why Your Product Should Generate Revenue Versus Reduce Costs

Focus on Revenue Generation, Rather Than Cost Savings

Show how your technology or device can generate revenue to end users (clinicians), Sina says. That's how you get early adoption of your product.

End users need to see that your technology can provide a return on investment. The healthcare economic value of your product should be your primary focus.

"In any commercial discussion, the other side of the table will ask you, 'What's in it for me?' You need to have a strong argument that this [healthcare benefit] is what you're going to make out of this [investment]. Cost savings come second," Sina says, when you're focused on getting payers on board.

Because the digital health space is a relatively new sector, regulators and payers are playing catch-up, and payers are often behind regulators.

There are reimbursement codes for computerized cognitive assessments, but they focus on the amount of time that doctors spend with their patients. That's counterintuitive to Cognetivity's technology, which is intended to quickly and accurately assess patients.

It's about the outcome, rather than the process, which falls more in line with Cognetivity's approach in its clinical development program: the model of value-based healthcare. The company wants to generate strong health economics evidence for CognICA for use in value-based pricing and reimbursement.

"That's going to be presented to the payers for specific reimbursement codes. So that's our strategy. But again, digital health in its infancy, [so] there's a lot of work to be done on the reimbursement front as well," Sina says.

Team Up With Fundraising Superstars

Team up with a "fundraising superstar" in your sector — someone who knows how the system works, has a good track record of raising capital, and is hands-on with companies, Sina says.

"I'm not talking about placement agencies and brokers. Even investment bankers have that 'throw the spaghetti at the wall and see what sticks' approach … [look for] someone who gets involved, has strategic value-add, and has done this with other companies before."

There are plenty of people with those qualifications, especially at universities.

Why Your Product Should Generate Revenue Versus Reduce Costs

Sina recalls that as he was building Cognetivity, he had the opportunity to raise seed capital with a superstar fundraiser. He decided, however, to take another offer with a different group that had more favorable dilution — that is, when the company offers new shares by decreasing equity ownership for existing shareholders.

If he could go back in time, Sina says he would be less concerned with dilution and work with the investor that was more familiar with the space and had a better track record of raising capital.

> The more you raise, the more you're known in the space, the more you are connected, Sina says.

He also reminds developers that fundraising is a complicated science in and of itself. That's why you need to work with people who have experience, starting at the earliest stages of development.

"Bring in someone who has done it before. That will help you a lot down the line. Don't worry about the dilution. A small piece of a huge cake is a lot more valuable than a big piece of a smaller one," he says.

Final Thoughts: Listen and Learn

Sina and his team have made a point of listening to experts at every step of the development process, from the regulators to the end users. Being humble and ready to learn are key to success, he says.

"Always be open to different ideas," he says. "Encourage questions from your team, encourage pushback from your team, and give everyone a voice because it's important that collectively you get to the right answer as a team, before it goes out."

How to Build a Strong Network of Investors and Partners for Your Medtech Startup

Summary

DermaSensor CEO Cody Simmons shares why he thinks companies need to focus on regulatory and reimbursement alignment from the very beginning, the importance of finding ally investors, and how to build trust with potential partners in your network.

Cody Simmons

About Cody

Cody Simmons spent four years learning about business strategy and analytics at biotechnology giant Genentech before becoming CEO of DermaSensor in 2016, where he leads development and commercialization efforts for the company's novel skin cancer detection tool. In 2018, Cody was included on the Forbes 30 Under 30 list in healthcare.

Key Learnings

- One study is not enough. DermaSensor learned early on that it would need multiple to get regulatory approval and qualify for reimbursement. Pinpoint the criteria needed to satisfy regulators and insurers and focus on satisfying them.
- Show investors that you have the capability and competency to establish a manufacturing process and that you're prepared to ramp up supply when getting to market. Having commercial product ready to go shows the ability to execute your plans.
- Spend some time each month proactively reaching out to potential investors. Focus on building strong relationships with people in your network who can become trusted allies and provide help during challenging times.

How to Build a Strong Network of Investors and Partners for Your Medtech Startup

DermaSensor CEO Cody Simmons knew he wanted to work in the medtech space as an undergraduate at Brown University. While completing the master's program at Stanford, he realized his passion for developing and commercializing health technologies.

But at the age of 22, he wasn't quite ready for a full-time startup role and decided to join the corporate world and spent four years at Genentech — two years in the company's leadership development program and two years in the U.S. pricing contracting strategy group for oncology drugs. While at Genentech, Cody learned about business analytics; strategy and commercialization; and how high-functioning, high-performing organizations operate.

In 2016, he met entrepreneur and DermaSensor Co-Founder and Chair Maurice Ferré, who asked Cody to join the company and help bring its namesake product — a handheld skin cancer detection tool — to bear.

With Cody at the helm, DermaSensor has raised $27 million to launch the world's first point-and-click skin cancer detection tool for primary care providers.

DermaSensor carries the European Union CE mark, and is also registered and available for sale in Australia and New Zealand.

Pursuing FDA marketing approval, the company received breakthrough device designation for the DermaSensor product and in 2021 completed the first-ever FDA pivotal study for a primary care-focused skin cancer detection tool.

In this episode of Medsider, Cody talks about the importance of discovering whether there's alignment between regulatory requirements and payer needs, as well as finding opportunities to streamline your clinical testing plan to meet both sets of criteria; why you should seek out ally investors; and how you can de-risk your technology for potential investment partners.

Understand Where Regulation and Reimbursement Align

Early on in the DermaSensor development process, the company set out to better understand both the regulatory criteria to get marketing approval and what payers were looking for so the product could qualify for reimbursement. Through that process, the company learned it could not rely on just one study to satisfy both FDA and payers.

"That was a helpful North Star in a sense [for us]," Cody says.

How to Build a Strong Network of Investors and Partners for Your Medtech Startup

DermaSensor decided to take a two-step approach to development that involved a large clinical validation study for the FDA regulatory pathway and several clinical utility studies to show payers how the device would benefit patients in the real world.

> [Get] a sense of your regulatory path and [whether there] is some way to align that with reimbursement so you can maybe do one or two studies in parallel versus sequentially. For us, unfortunately, that wasn't the case, but knowing that in advance was really important, Cody says.

Cody also suggests bringing in an expert or multiple experts who truly understand and can guide you through the regulatory process, which is filled with nuance. It's worth investing the time and money to hire someone with domain expertise, he says.

"If somebody only does pharma, and you're a medtech or diagnostic startup, keep looking. There's plenty of folks that you can speak to," Cody says.

De-risk Your Product to Build Investor Confidence

Getting to market is great and can provide key insights, but investors also want to know that you can successfully set up a manufacturing process that complies with regulations and allows for scalability, Cody says.

"Having that commercial product, even if it's not the cleared medical device you ultimately want, shows that you just have the … capability and competency as an executive and as a company to execute on that," Cody says.

Getting all your manufacturing and supply ducks in a row can help de-risk the company for investors. That's one less thing investors will have to worry about, and it shows you're prepared for commercialization.

And don't be afraid to pivot when things don't go as planned.

DermaSensor had two year-long setbacks. The first was due to a technical issue that led the company to completely change the design and strategy. The second setback was due to production work that led the company to switch manufacturing groups.

Don't stay wedded to your original plans. Work the setbacks to your advantage, tear up your playbooks, and work within the new timeline, Cody says.

How to Build a Strong Network of Investors and Partners for Your Medtech Startup

Build Strong Relationships and Find Allies

Cody admits that he underestimated the importance of fundraising and networking when he first got started with DermaSensor. He learned that you need to build strong relationships with potential investors to be successful.

“[You think] if you do a good job building the business and the product, then you don't really need to worry about money … that’s just not true. You’ve got to have people that know you and trust you and who you've been keeping updated on your work, especially in the earlier days,” Cody says.

Cody suggests finding an ally investor — someone who believes in you, your company and technology, and who will go to bat for and open up their networks to you. Don’t be afraid to take an equity cut or give the backer a discount in the first investing round to get them on board, so they can help you raise more money.

In the end, it’s worth the effort because those allies will be able to help during hard times.

“It's people like that, that aren't just strictly financial investors, but who really believe in you and the product and company [so much] that when there are dark days — which there most undoubtedly will be — [they] will still be there by your side and can help,” Cody says.

Spend some time each month going to lunch or getting drinks with people in your network, Cody advises. Allow potential partners and investors to get comfortable with you as a person and as an entrepreneur.

Successful entrepreneurs do a good job of building and nurturing relationships, and they make better salespeople, Cody says.

“A lot of success in this [startup] world comes down to finding people that believe in the company and that will put money behind it,” he says.

Turning Your End Users Into Key Investors

Summary

Lazurite CEO and co-founder Eugene Malinskiy shares how planning out every step of ArthroFree's regulatory and development process helped streamline the FDA clearance process, the importance of preparing for failure and being ready to solve problems, and why entrepreneurs should seek out input from investors at every step of the process.

Eugene Malinskiy

About Eugene

Eugene Malinskiy is a self-proclaimed serial entrepreneur with expertise in the IT and medical fields. He also has hands-on experience as a medic and has worked in operating rooms. He founded Lazurite, a healthcare and innovations company focused on cutting-edge surgical and lighting technologies, in 2015. That same year, Eugene was selected as one of Forbes 30 Under 30 recipients in the manufacturing sector.

Key Learnings

- Put together a regulatory and development roadmap from the start. Hire a consultant to help you refine the plan. When it's time to submit your application to the FDA, you'll be glad you formulated a regulatory strategy early on.
- Eugene sought input from surgeons throughout every step of the ArthroFree development process. Those surgeons then turned into investors who drew in more investors. Maintain a strong line of communication with your financial partners, and gather feedback from them through every stage of development. Let them be a part of the process.
- Be prepared for things to go south. Technologies fail and start ups face many problems. Facing issues early and head on dramatically increases your chances for success.

Turning Your End Users Into Key Investors

Lazurite CEO and Co-founder Eugene Malinskiy is a self-described serial entrepreneur. He had a successful run working in the IT sector, but has always had a passion for medicine. He even has experience working as a medic and has spent considerable time in hospitals throughout the country.

Eugene's IT and medical skills came together when he received a Master of Science in biomedical engineering from Cleveland State University (CSU).

"I was actually able to combine both the things I was good at with my passion, into one path," he says.

After graduating from CSU, Eugene launched DragonID, a healthcare innovation and engineering company specializing in medical devices for the fields of cardiology and orthopedics.

The idea for Lazurite and its bellwether ArthroFree product came to Eugene when he witnessed a physician's assistant, minutes before surgery was supposed to start, trip over a bunch of surgical camera wires in an operating room. The cords were connected to the surgeon's handheld camera and light, both of which are needed to perform minimally invasive surgery.

"There's literally multiple cables running out of the surgeon's hand, [which is] holding this camera that takes the video from inside the body. There's a light to that camera that provides light into the body. Multiple cables that are heavy, that are bulky [and] dirty, go into the surgical tower that's across [the room] on the opposite side of the patient — and that's been the same way for the last 50 years," Eugene explains.

Eugene recalls wondering why there were so many wires.

"The year is 2014 [or] 2015. Why are there all of these cables and wires to the surgical tower that shouldn't be there? Wireless surgery should be possible," he says.

That incident led him to launch Lazurite and begin developing what would eventually become the company's flagship product, ArthroFree, a wireless camera system for minimally invasive surgery.

Eugene leveraged his experience with previous startups to make Lazurite a success.

FDA granted market clearance to ArthroFree in March 2022 after only a three-month review — a quick turnaround for any medical device. It's the first wireless camera for minimally invasive surgery to ever receive FDA clearance.

Turning Your End Users Into Key Investors

As of the third quarter of 2022, Lazurite has raised about $25 million across multiple fundraising rounds. After ramping up hiring, the company is working through the manufacturing and supply chain logistics to prepare for a full market launch for ArthroFree.

In this episode of Medsider, Eugene shares how planning out every step of ArthroFree's regulatory and development process helped streamline the FDA clearance process, the importance of preparing for failure and being ready to solve problems, and why entrepreneurs should seek out investor input at every stage of development.

Create a Development and Regulatory Roadmap Early On

Eugene recommends startups flesh out their regulatory and development plan upfront.

One of the first things Eugene did when he launched Lazurite was call in help from regulatory consulting firm Musculoskeletal Clinical Regulatory Advisers (MCRA). "[Days after] after I formed the company, I called [MCRA]," Eugene says.

He then mapped out the company's development and regulatory pathway and modified it based on feedback from MCRA.

Once the plan was finalized, Eugene made sure to follow it for the entirety of ArthroFree's development lifecycle. When it was time to go to FDA, the company already had a full submission package put together and ready to submit to the agency.

Eugene also quickly hired a Director of Regulatory Compliance, Patrick Polito, who is with the company to this day. It was an expensive but critical hire, Eugene says.

"Without Patrick being in the mix the entire time, there's no guarantee that we would have stayed on course, on track to go through all the paperwork and all the processes that we would need to in order to be successful," Eugene says.

Eugene believes taking those two key actions at the outset — mapping out a development path and hiring a regulatory compliance lead — helped the company's product get through FDA review in three months.

"We had a plan. We followed the plan. We had a person who was in charge of leading the plan, and then when we did put a package together for the FDA, it was very comprehensive," Eugene says.

Turning Your End Users Into Key Investors

Seek Out Input From Investors and End Users Every Step of the Way

Much of Lazurite's initial seed money came from physician-investors who wanted to use ArthroFree.

Eugene made sure to connect with surgeons early on in the ideation process when ArthroFree was just a prototype. He began gathering input and connecting with surgeons across the country to talk about what they needed and how they wanted the device to work.

He received positive feedback from surgeons who said they've needed a wireless camera option for a long time. After a month or so, and after developing a couple more prototypes, Eugene went back to that same group of surgeons, laid out his plans, and asked if they would invest in his startup. The answer was a resounding "yes."

Eugene made sure to stay in touch with those same surgeons throughout the development process and get advice on the design of ArthroFree, which allowed those surgeon-investors to be a part of the development and planning process.

"As I developed the product over the years, I kept going back to that well, talking to those surgeons: What's your market? How much would you pay for it? Who's on your team? How are the decisions being made? For you as a surgeon, if I got rid of these cables, do these matter? And they provided me with a lot of input, which I then incorporated. I was able to use those surgeon-investors to help build … and create a very nice product," Eugene says.

Those surgeons also came back to invest in Lazurite when the company entered its Series B financing stage. And because Lazurite had backing from physician users, the company was able to attract "more sophisticated" investors, Eugene says.

Eugene's advice to medtech entrepreneurs: Keep in touch with investors. Enlist someone on your team — preferably the CEO or founder — who can be the conduit of information and let the investors know how valuable their input is.

"When it's time to have them come back for an additional round, they will happily do so," Eugene says.

Eugene offers up some additional quick-hit fundraising advice for medtech entrepreneurs:

Double down on your fundraising goals.

Expect everything to take twice as much time and twice as much money, and then double that again. That's how much money you'll likely need.

Build out your IP portfolio.

The sooner you can get your intellectual property filings in, the sooner you can get them granted and the stronger your portfolio will be, Eugene says.

"Good money management [is] always important," he adds.

Prepare for Failure

Eugene combined several different kinds of technology to create ArthroFree, but getting those components to "play nicely together" and not in isolation proved to be difficult, he recalls.

It's a common mistake among medtech startups to think that separate platforms or modules — once put together — will work flawlessly in a single device, but that's not usually how it goes, Eugene says. For example, Eugene knew he needed to ensure a strong wireless connection for ArthroFree so he decided to use ultra-wideband technology: a fast, encrypted transmission technology that's often used for military applications. A few years later, he entered into the alpha and beta testing stages for ArthroFree and started putting all the components together with the ultra-wideband technology.

Things didn't go as planned. Eugene found that even though ultra-wideband worked great on its own and in other capacities, it actually caused an "incredible amount of lag" between the camera and the screen. That obviously wasn't going to work for surgeons.

"If you're a surgeon doing surgery, you really cannot have any lag between what you perceive as your hand movement and what you see on the screen," Eugene says.

The Lazurite team knew it had a module that worked well (the ultra-wideband technology), but had limitations when it was combined with other system modules. They had to clear out those limitations, Eugene says.

Those kinds of situations happened repeatedly during the ArthroFree development process, Eugene says.

The team had to work quickly and efficiently to identify and solve those problems. The trick is to be aware of the problems and don't brush them off, Eugene says.

Turning Your End Users Into Key Investors

“Don’t put your blinders on and ignore that this is a problem because if you try to pretend it’s not [there], it’s just going to come back and bite you,” he says.

And if something isn’t working — whether it’s a technology, communication, or a different company issue — don’t be afraid to move on and try something new. That’s one key piece of advice Eugene would give to his younger self.

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> Knowing what I know now, I definitely beat a dead horse longer than I should have more than once, whether it was a people issue, a company issue, a communication issue, Eugene says. We’re all prone to just trying to keep something going, even though it’s obvious to everybody that you need to move on, you need to change. I fall into that trap, just like everybody else. Don’t forget to rely on the people around you for help. A good, reliable team will help you solve any problems that arise, Eugene says. It’s all about having the right people in place to bring the technology to bear.

How to Find Product-Market Fit by Going Deep Versus Wide

Summary

New View Surgical CEO Bryce Klontz shares insights from his decades of experience in the surgical devices space, from building relationships of trust with regulators and investors to working closely with practitioners to perfect product-market fit.

Bryce Klontz

About Bryce

With over 20 years of experience working in the surgical device space from Canada to Singapore, Bryce Klontz brings a tactical advantage to his role as the CEO of New View Surgical. Under his leadership, New View Surgical has closed a successful Series B with a cumulative total of $14.5 million in investments and secured 510(k) clearance along the way. He previously worked as the VP of Commercial Strategy for Emerging Markets at Covidien in addition to several other start-ups.

Key Learnings

- Be laser focused on product-market fit. Building great teams and creating innovative technology are crucial, but ultimately, meeting the needs of both the patient and practitioner must be the priority.
- Go deep when gathering data. You'll learn a lot more by forming long-term relationships with a select number of practitioners than by collecting data from far and wide.
- Investing in relationships and effective communication are essential to both fundraising and regulatory approval. It's crucial to understand the incentives of those sitting across the table so you can help them help you.
- Investors know that the path to profitability is rocky. Being transparent with them about the challenges you face builds your credibility and furthers your goals.

How to Find Product-Market Fit by Going Deep Versus Wide

When Bryce Klontz started his role as CEO and President of New View Surgical six years ago, he already had two decades of medtech experience under his belt. Experience he's since leveraged to close out a successful Series B round of financing and secure 510(k) FDA clearance.

Before joining New View, Bryce was the Vice President of Commercial Strategy and Emerging Markets for Covidien. There, he expanded the medical devices conglomerate across Asia, Africa, Latin America, and the Middle East.

Under Bryce's leadership, New View is pioneering laparoscopic technology. Their VisionPort combines the laparoscope, camera, light, and access port into a single instrument that promises to slash the cost and preoperative time of a laparoscopy.

The device also shows the potential to reduce the number of incisions needed for some surgeries and widen access to the surgery by making laparoscopic technology easier to transport to the patient's location.

These innovations garnered New View Surgical widespread recognition. At the Keiretsu Forum Investor Capital Expo in 2020, angel investors selected New View as the "Most Valued Company." Funding and regulatory successes followed, with the business attracting over $14 million in total capital and securing 510(k) clearance.

In this interview, Bryce Klontz shares insights from his decades of experience in the surgical devices space, from building relationships of trust with regulators and investors to working closely with practitioners to perfect product-market fit.

Leverage Your Experience at Large Strategics to Accelerate Start-up Success

Bryce likes to say that start-ups "bookended" his career. Straight out of college, he joined a cardiovascular startup in his native Boston, PLC Medical Systems, as a marketing manager.

The appeal of guiding early-stage companies is the opportunity to build something new. He agreed to join New View six years ago to "see if I could build something, bring a product to market that excites me, and just learn from that experience."

In between his time at start-ups, Bryce spent a decade honing his skills at Covidien, one of the world's largest producers of surgical devices.

He spent time there heading up marketing efforts in emerging economies as the VP of Marketing for Asia and VP of Commercial Strategy for Emerging Markets.

When he returned to the start-up world, first at Woven Orthopedic Technologies and then as CEO of New View, he brought his hard-earned expertise with him.

In his words, “I think some of that vulnerability and that willingness to open communications with the confidence of a 25-year career and also just the understanding that the journey is not going to be smooth and trusting that people know that already.”

Product-Market Fit Must Come First

For Bryce, building a successful medtech start-up is all about a disciplined focus on product-market fit. “You might have an interesting idea, cool technology, and an alpha prototype. But does it meet the expectations of the end user, the customer, and not only the clinical user but the economic buyer as well?”

That’s not to say that technology needs to have a viable market to be a great innovation. Rather, not every great technology makes a great business.

“You can build a great product with a great team, but if you can’t ultimately sell that product, drive profitable revenue, and scale a business out of it, it’s probably not a good idea to have started that company.”

It’s also not enough to have great product-market fit if that market isn’t large enough to support a scaled business. If only “50 people will buy it. And that’s your market size, Bryce commented, that does not make for a sustainable, scalable business.”

Finding product-market fit is great in theory, but can be very challenging to achieve. The key is to develop as nuanced an understanding of your customer’s needs as possible. At New Vision, they formed long-term relationships with a small number of surgeons to understand how their products were used in practice.

For Bryce, “The real proof of adoption comes if you’re doing 20, 30, 40 cases in a single center with two, three, four surgeons…The deeper you go with single users in hospital, the more you learn.”

How to Find Product-Market Fit by Going Deep Versus Wide

The Power of Relationships

Building relationships is crucial to success in any industry. That's as true in the medical device space as it is anywhere else.

Bryce credits relationship-building and effective communication for New View's success with regulators. The company was able to secure 510(k) clearance from the FDA within 2 months of applying.

According to Bryce, working with regulators is all about understanding their goals and incentives. The FDA wants to protect patients, but is also motivated to shepherd new technology to the market where it meets requirements.

Moving innovations through the FDA is about communicating your value and limitations effectively. "The more you can help the FDA in this instance and the regulars understand your technology, the better."

"A lot of founders that I speak to that are struggling with the FDA, and it's taking a lot of time. Fundamentally it's come down to a misunderstanding with the FDA, a misunderstanding about what the technology is meant to do and how that translates into the indication."

Building relationships with the FDA as early as possible is also a secret of New View's success. Bryce recommends taking advantage of Q-sub meetings if you can.

This same concept applies to investors as well. Bryce suggests medtech business leaders should trust that investors appreciate the ups and downs of taking a start-up to market.

"They know you're going to make some poor decisions that you need to navigate through and get back on track. And the more you have a dialogue and an openness with investors. I think the more credibility you can build."

How Flexibility and Curiosity can Influence a Successful Medtech Startup

Summary

EvoEndo CEO Heather Underwood shares how her unique background influences her approach to every aspect of a startup from fundraising to 510(k) clearance to commercial adoption.

Heather Underwood

About Heather

Dr. Heather Underwood is a medical device and health technology entrepreneur with a highly interdisciplinary background at the intersection of computer science, global health, human-centered design, education, and international development. Heather is passionate about the healthcare space and innovative ideas that lower costs, empower patients and physicians, improve health outcomes, and make a meaningful impact on people's lives.

Key Learnings

- You don't need to come up with something completely new to solve a difficult clinical problem. Starting with a deep understanding of the challenge you're trying to solve and staying solution-agnostic allowed EvoEndo to use key learnings from other fields of medicine to create something unique that ultimately meets patients' needs.
- Stay open and be creative when it comes to fundraising. It doesn't have to all come from venture capital. Angel investors can provide more than money: their care and emotional investment means they're in it for more than financial returns.
- The FDA is definitely a hurdle, and 510(k) clearance is something worth celebrating. But it is not the end of the race. Figuring out reimbursement can make or break a company. The earlier you start to think about it, the better.

How Flexibility and Curiosity can Influence a Successful Medtech Startup

EvoEndo CEO Dr. Heather Underwood thinks about things a little differently than your average CEO. Her flexible and curious approach to running a medtech start up has certainly proved successful: recently EvoEndo was able to fundraise millions and get 510(k) clearance for their single-use endoscopy system they call the "EvoEndo System."

So where did Heather's unique approach to running a company come from? Her interdisciplinary past can shed some light on the subject.

Starting with her Bachelor of Science, cum laude, in computer science and engineering from the University of Washington, Heather's analytical mind was at work: her undergraduate research focused on developing multiplayer educational game platforms for primary schools in India.

Continuing onward, Heather completed her Ph.D. at the University of Colorado Boulder's ATLAS program where she developed and implemented clinical decision support systems for midwives and nurses in Kenya, receiving the NSF Graduate Research Fellowship Grant and a Gates Grand Challenges Grant to support her research.

Heather then cofounded Inworks—an interdisciplinary initiative offering courses and certificate programs in innovation, prototyping, and design as a professor at the University of Colorado Denver. Her last stint in academia occurred when she was selected for the 2018-2019 Stanford Biodesign Fellowship Class. Upon completion, she entered the medtech space and has been leading EvoEndo ever since.

As Heather's roles have changed, she's never left behind her distinct skill sets, but instead honed them to positively influence her role leading EvoEndo.

In this episode of Medsider, Heather elaborates on her unique approach to innovation in the medtech arena, how fundraising isn't one-size-fits-all, and why regulatory clearance isn't the end of the road.

Don't Bother Reinventing the Wheel

It's easy to get caught up and overwhelmed by the urge to create something brand new that solves all the problems in your given field, but it's rarely doable. This was the case for EvoEndo early on, when they were first trying to nail down prototypes around solving endoscopic challenges.

How Flexibility and Curiosity can Influence a Successful Medtech Startup

As Heather puts it, they overshot the initial design and created something that was too different from what physicians were used to. This wasn't a complete failure though, thanks to early user feedback and consistent input from our co-founders. Heather explains that, "[after] getting people to evaluate the prototypes and just kind of have them in their hand and play with them, [we learned] it was not intuitive to them at all."

This setback, while difficult, didn't stop EvoEndo. It simply forced them to reevaluate their approach. One bit of insight Heather shares is simple: "The departure from what they're used to, to what they're going to use now can't be so vast if you want them to adopt it quickly and incorporate it into their day-to-day practice."

It seems obvious when she says it, but it's easy to fall into the trap of creating something so new and impressive that you forget that the actual people using your product have to want to use it, and that the jump from one technology to the next can't be monumental.

Looking at the big picture, Heather explains, "new ideas are not new....oftentimes they're just mashups of other ideas." This concept was central to what eventually became the "EvoEndo System."

By using and combining ideas from other fields, and taking to heart valuable feedback from their clinical partners, Heather and the team at EvoEndo were able to come up with a physician-friendly system that allows endoscopic procedures to be performed without the need for general anesthesia or conscious sedation.

While the initial innovation was sparked by a need identified in the pediatric field, the application also has value for adults: a smaller, less intrusive scope is a win for people of any age.

"Stay curious and stay flexible. Things are going to change," Heather says.

Keep Your Investment Options Open

Fundraising is a crucial part of every company's path, which is hardly arguable. The journeys raising capital vary wildly from one company to the next, though. Rolling with the punches and adapting your strategy to different investment opportunities is crucial, especially when it comes to innovative medical technology.

Heather and EvoEndo ran into a series of particular situations. Early on, they approached traditional venture capitalists and were met with a surprising response: the investors wanted to put more into EvoEndo; they wanted to write bigger checks for ultimately bigger returns.

However, VCs were skeptical of the possibility for larger returns based on what they viewed as the small market opportunity in pediatrics, and wanted the company to demonstrate commercial traction before considering an investment.

So EvoEndo shifted their approach to something that felt more applicable to their journey: angels. From the beginning, there had been a core group of angel investors, but after getting feedback from traditional venture capitalists, EvoEndo decided to double down.

Heather explains, “[Angels] are some of the most passionate, committed, involved people. They care on multiple levels. They're not in it for just a return. I'll say if you're looking for other angels and you've already got angels interested, just leverage their enthusiasm to put the word out to their networks. And that was kind of how we saw our angel group, our investor group, grow.”

Aside from angel investors and traditional venture capitalists, Heather says there are other routes to funding as well. “I would recommend that [you] don't limit yourself. There's a lot of opportunities for non-dilutive funding through grants or Department of Defense or whatever it is, where your solution or your device really resonates with the population. There might be some funding there.”

Regulation, Commercial Adoption, and Reimbursement: All Things to Consider

No two aspects of an innovative medical technology journey are the same.

One company’s successful path does not guarantee future wins. Just because you raised millions doesn’t mean your device will pass regulatory standards, and just because you pass regulatory standards doesn’t mean that commercial adoption will be easy. On top of those layers, and often overlooked, is reimbursement.

EvoEndo was fortunate to receive 510(k) clearance relatively quickly. The news came on Valentine’s day, like a nice gift from the FDA. But it wasn’t good luck that carried them through clearance: diligent planning and knowing what to include in their submission is what propelled them over the FDA regulatory hurdle.

This sort of future planning is integral to EvoEndo’s success. By considering the common challenges that face medtech companies, and anticipating future hurdles, Heather and her team have been able to cross the chasm to commercialization.

How Flexibility and Curiosity can Influence a Successful Medtech Startup

One of the largest obstacles Heather thinks is deserving of time and effort is reimbursement. She says EvoEndo spent a lot of time on this topic, and that she's glad they did.

"We did a reimbursement landscape [analysis], and I would highly recommend it. It may not seem worthwhile early on and it may seem like a very expensive endeavor for an early stage startup, but that was absolutely crucial to our success and why we're commercializing now."

Staying ahead of the game is always important, and it can't be stressed enough in the startup world. "Maybe the biggest takeaway is if you're developing a device and you've got a working prototype and hopefully a little bit of funding: it's never too early to address the reimbursement topic."

Lessons in Leadership — Building a Successful Team and Checking Your Ego at the Door

Summary

Check-Cap Founder and CTO Yoav Kimchy shares how feedback from regulators can help streamline your development process, why you should shift and expand your team as your company grows, and the importance of knowing when to lead and when to follow.

Yoav Kimchy

About Yoav

Yoav Kimchy, Ph.D., has more than 20 years of experience in the development and management of innovative medical device companies. In 2005, he founded Check-Cap, a clinical stage medical diagnostics company that aims to change the colorectal cancer (CRC) screening landscape with its C-Scan ingestible capsule, tracing, and imaging system.

Key Learnings

- Take every opportunity to get feedback from regulators. Getting regulatory input, especially early on in your development process, can help pinpoint what is and isn't working. Regulators can help you figure out how to streamline your processes.
- Know when to lead and when to follow. Yoav realized soon after launching Check-Cap that he didn't want to run the company, so he hired someone to take on the CEO role. It was a good decision, he says, as it allows him to focus on what he's good at — R&D — while letting other more experienced people lead the company.
- Expand and diversify your team as your company grows. Over time, as you get further into the development process, you'll need to focus more on logistics and regulation, rather than solely focusing on R&D. Hire people accordingly.

Lessons in Leadership — Building a Successful Team and Checking Your Ego at the Door

It's estimated that about 40 percent of people who are at risk for colon cancer have never been screened. People avoid screenings for a number of reasons, including fear of and discomfort with the screening and an uncomfortable preparation process leading up to the screening.

That's why Yoav Kimchy, Founder and CTO of Check-Cap, launched the company in 2005 with the goal of creating a technology that could make colorectal screenings easier and less invasive for patients.

The company developed a first-of-its-kind technology — the C-Scan ingestible capsule, or C-Scan Cap. In lieu of a traditional colonoscopy procedure, patients can swallow C-Scan Cap, just like a normal pill. The capsule then travels naturally along the gastrointestinal tract while scanning the inner lining of the colon.

C-Scan Cap actively communicates with C-Scan Track, which records and stores the scanning data. When the screening procedure is over, C-Scan Cap is excreted naturally. The patient is notified, and the scanning data is analyzed using Check-Cap's C-Scan View software.

"The person is free to do whatever he wants while the capsule is traveling naturally, and then it goes out. All the data is recorded and then reconstructed for the physician to look for potential polyps, which are the precursors of colon cancer," Yoav says.

The goal is to find polyps before they become cancerous, he adds.

Check-Cap received a CE mark from the European Medical Device Regulation in 2018. The marketing approval was reauthorized in 2021 for another five years.

The company now focuses primarily on getting clearance from FDA for the U.S. market. In May 2022, Check-Cap launched a pivotal trial that soon will (/was)l be conducted across 15 clinical sites across the United States, with a goal of enrolling about 1,000 trial participants between the ages of 50 and 75.

Check-Cap is also working with the Centers for Medicare & Medicaid Services to obtain reimbursement for C-Scan.

Yoav says the company is exploring additional products that can use the C-Scan system.

"It looks like we have quite a few potential components or potential products that can come out of what we have, which is very exciting as well," he says.

Lessons in Leadership — Building a Successful Team and Checking Your Ego at the Door

In this episode of Medsider, Yoav shares how getting feedback from regulators can help streamline your processes, why you should shift your team's focus as your company grows, and the importance of knowing when to lead and when to follow.

Use Feedback From Regulators To 'Clean Up Your Act'

Looking back on the early days of Check-Cap, Yoav says he would have interacted with regulators earlier on in the process to better understand the regulatory process and expectations.

Getting input from regulators like FDA can help you pinpoint what is and isn't working in your development plan, which is especially crucial as you start testing your product in humans.

Regulators essentially can help you tidy up your process and even point out things you may have missed, Yoav says.

As an example, he adds, Check-Cap just recently learned about FDA's breakthrough device designation process, which allows device makers to interact with FDA experts throughout the premarket review phase and prioritizes review of medical devices that qualify for the pathway.

That's one thing Yoav says he wishes Check-Cap would have known about sooner.

Yoav suggests working with regulators as soon as possible so you can better understand the regulatory landscape, get feedback, and refine your processes before heading into human clinical trials.

Know When To Lead and When To Follow

About three years after launching Check-Cap, Yoav began to realize that he did not want to be CEO. Running the company, he says, would not allow him to continue his R&D work.

He hired Guy Neev for the CEO position, and Yoav took on the CTO role in 2009. Guy helped take the company public, with backup support from Yoav.

Alex Ovadia is the company's current CEO, and has been with Check-Cap since 2013. He served as the Israeli site manager, vice president of R&D, and chief operating officer before being named CEO.

Lessons in Leadership — Building a Successful Team and Checking Your Ego at the Door

> [It works best] for me to have an experienced person. [Alex is] running the company as the public company that it is, and I can do my work in the R&D, Yoav says.

He's certain that the company is better with him as CTO, rather than CEO.

Yoav advises medtech startup leaders to check their egos at the door.

"We really have an incredible team of people that are working very hard to get the technology to where it needs to go, to where it can go. So, ego is not something that you can leave on the table there. You need to put it aside and do the actual work," Yoav says.

Make Sure Your Team Grows and Evolves with the Company

Over time, your company's focus will start to shift and your hiring needs will change. At the beginning, you'll want people who are technical experts, but as your work expands, you'll need people who are more process- and regulation-oriented.

At that point, it's time to hire more people and focus less on trying to be innovative and more on trying to streamline your processes, Yoav says.

Check-Cap still has a relatively large R&D team that comprises of 30 people, but that only accounts for a third of the company's nearly 90-person staff. The remaining staff are focused on logistics, including manufacturing and quality assurance processes, Yoav says.

> [There's] a lot of functions that you don't think of and that you don't need earlier on, but afterwards, they're very crucial to the process, Yoav says.

Lessons in Leadership — Building a Successful Team and Checking Your Ego at the Door

As your programs evolve, think about your ideal team structure and hire accordingly.

The world of medtech is a complex and interesting space, and there's room for multiple voices at the table, according to Yoav. The key to success, he adds, is making sure you have the right people in place, and that those people believe in what you do.

Be patient and listen.

How to Pull the Right Regulatory Levers

Summary

Linear Health Sciences Founder and President Dan Clark explains how his company raised capital, tips for navigating complex regulatory pathways, and why you need to be your own worst enemy as a medtech entrepreneur.

Dan Clark

About Dan

Dan Clark started his career in the private sector at Parker Hannifin, a Fortune 200 organization which he calls “the largest company you’ve never heard of.” After going through the medtech innovation cycle many times over, he was eager to step out on his own. He teamed up with Dr. Ryan Dennis to found Linear Health Sciences in 2015. The company created Orchid, a device designed to minimize unwanted or accidental IV dislodgement.

Key Learnings

- Don’t skimp on research early on. Soliciting feedback from a broad range of stakeholders before commercialization will make scaling smoother.
- Know your skill sets, find the right partner, and divide and conquer. Dan focused on product development, marketing, and regulatory, which freed his co-founder to tackle fundraising full-time.
- Bring the FDA into the conversation early. This will smooth the regulatory pathway from the start. Be your own worst enemy, asking the difficult questions to ensure you’ve done all you can to be compliant

How to Pull the Right Regulatory Levers

Dan Clark is no stranger to setbacks. His medtech startup, Linear Health Sciences, spent years navigating the regulatory waters, but that didn't stop him or his team.

Like many medtech company founders, Dan was technical by training. He started out his career in the private sector at Parker Hannifin, which he describes as “the biggest company nobody’s ever heard of.”

Although the company had a small medical device segment, the industry wasn’t on his radar.

But after diving deeper into the medtech space, he learned about the innovation cycle and eventually managed strategic relationships toward the end of his tenure.

But he was itching to innovate on his own.

“I can't stand the idea of not having a new innovative way to do things or a different perspective,” he explains. As he considered his next steps, he knew that eventually, he wanted to start something himself.

The right opportunity came in 2015 when a friend introduced him to Dr. Ryan Dennis, who pitched him the product that would evolve into the Orchid Safety Release Valve.

Linear, the company they built together, is shifting the standard of care of medical tubing dislodgement.

In this episode, we explore how Linear raised capital, navigated regulatory pathways, and innovated by being its own worst enemy

Building the Foundation of Commercialization

Today, Linear is full-scale commercial with the Orchid safety release valve. The device is designed to mitigate unwanted or accidental IV dislodgement by creating a sterile barrier between an IV extension set and administration set.

If the IV is dislodged, an occlusion alarm sounds, and the separated valve halves can be replaced. This allows for a simple return to treatment, bypassing the need for a full replacement of medical equipment.

Even with a product that good, success didn’t come by accident. Linear took strategic steps before and during the early commercialization stage to build the foundations of later growth

How to Pull the Right Regulatory Levers

1. Start Market Research Early

Before commercialization, Linear gathered feedback from a wide variety of stakeholders to aid product iteration and development.

Drawing on experience from other projects, Dan knew that medtech companies need to gather data not just from physicians but also the nurses and technicians who use the product every day.

For example, Linear changed The Orchid's color from white to purple following feedback from nurses who were having trouble finding the device on patient's bed sheets.

The price point is also essential. Know where you fit into the market and understand the limits of your customer's budgets.

Prior to commercializing, make sure your manufacturing can be scaled exponentially. For Linear, this includes ensuring that the geometry of the valve was universal to all forms of medical tubing. A unique product may have been better for a particular use-case, but producing multiple product lines would have been a logistical nightmare at scale.

2. Educate Providers on the 'Why' of Your Product

Education was a central part of Linear's process. Don't assume that users will intuitively understand why your product is worth adoption.

That's why Linear invested a lot of resources into explaining why the device would improve the standard of care.

Without The Orchid, the process for replacing a dislodged IV produces a lot of waste. The IV itself, the tubing, whatever is being infused, and the IV bag all need to be disposed.

For complex treatments like chemotherapy or total parenteral nutrition (TPN), these waste materials are expensive. Additionally, introducing more needles means more trauma for the patient and redundant clinician activities.

Orchid aims to resolve those issues through replacing a simple valve set. Although the advantage of The Orchid appears intuitive, it was still important to educate practitioners.

This is because there are few metrics on tubing dislodging, so even improving the extent of the problem with data is a challenge. For basic IVs, reported dislodgements range from 9.5 to 24%. But in reality, it is actually a much larger problem.

How to Pull the Right Regulatory Levers

For devices like the Orchid — that solve largely unreported issues — founders must educate audiences not just on how the product solves the problem, but on why there is a need in the first place.

“[Medical tubing dislodgement] has been fundamentally accepted as status quo when it doesn't have to be and, quite honestly, it shouldn't be,” Dan says. “Right now, we’re in the early stages: commercialization and education, the most difficult and most exciting component of this.”

From Bootstrapping to Full-Time Fundraising

Linear arrived at the commercialization stage seven years after its genesis. Like many medtech projects, it evolved from a bootstrapped, part-time project to eventually needing capital.

Although Dan and his team didn’t have to raise money for the first two years, he certainly learned valuable lessons at major inflection points of the company’s evolution. At first, the team thought that they could bootstrap Linear. Now Dan believes that was naive .

Looking back with the benefit of experience, he knows that to reach a point of “liftoff,” financing is necessary. But it’s important to start fundraising at the right time, particularly because most investors want to see a proof of concept and to know that you understand the market before they’re willing to invest.

One of Dan’s keys to success for others who are fundraising is to find people in your network that believe in what you’re doing. Linear has raised three rounds of funding for a total of $10 million. Much of the first rounds of capital came from family, friends, and physicians connected to his co-founder.

While Linear’s story of success is encouraging, Dan cautions, “It's no easy path to go raise money because you have to be the biggest proponent of what you're doing.”

He goes on to explain that while you’re focused on developing the product, you might not be as focused on the needed conversations with various investors. For that reason, many people with experience say that fundraising is a full-time job.

Dan’s focus on product development, marketing and regulatory work opened up his partner to concentrate on fundraising, a reminder of the importance of building a team with balanced skills and interests.

Lucky for Linear, the duo found dedicated investors who believed in the work and came back for multiple rounds. But to anyone raising capital, Dan advises that fundraising can feel deeply personal, so it’s critical to get comfortable with being told “no”

How to Pull the Right Regulatory Levers

Shifting Regulatory Narratives

While raising capital comes with its own challenges, Linear has faced a particularly uphill battle in moving through the regulatory process.

Over the course of seven years, product development at Linear was relatively straightforward. But the team has spent years locked in a difficult battle with FDA — during which time it received several Not Substantially Equivalent (NSE) Determinations — and often felt like it was going nowhere.

Finally, after a formal appeal and a three-year journey, Linear found success.

On paper, the device's function exists in other spaces already. Many would assume this means a smooth regulatory process. But the FDA review group considered The Orchid to have a higher risk profile than the market and end users would suggest.

The Orchid went through multiple rounds of enhanced testing that similar medtech companies didn't face. Dan recalled that at the height of this ordeal, his stress hit a peak. "My exact words were, 'This type of regulatory environment is what is killing innovation in this space,'" he says.

They also called in outside resources, including well-known attorney Mark Duvall to guide the regulatory legal process.

The key to Linear's eventual success was reframing the narrative on treatment. Regulators thought of The Orchid as being a risk for removing treatment from patients. Dan and his team convinced them that IV dislodgement was the real risk, which The Orchid mitigated.

Dan's learned a lot the hard way and encourages others to involve the agency as early as possible. Despite the challenges Linear faced, he still acknowledges that FDA's goal is to approve safe products that don't adversely impact the public.

The sooner they are involved, the more thoroughly they can understand your device — and the smoother your approval is likely to be.

How to Pull the Right Regulatory Levers

Dan also advises innovators to be their own worst enemy. In other words, you need to ask yourself the hard questions:

- What have I done wrong?
- What have I not done?
- What should I redo?

The exercise allows you to enter difficult conversations with more confidence in your product and your overall compliance efforts.

Admittedly, Dan says, the Linear team was afraid of the FDA at times, particularly because they didn't want to be on its bad side. But they had to remind themselves that, as much as was within their power, they had executed the right way and were not at fault. From there, they had to trust their team, their resources, and their product.

"Pulling the right levers at the right time is absolutely critical, and you cannot be afraid to do it," he says.

Building a Consumer-Focused Medtech Business

Summary

Tivic Health Co-founder and CEO Jennifer Ernst talks about why direct-to-consumer business models will be the next big focus in medtech, and how patients can play a key role in boosting support and evidence for over-the-counter medical devices.

Jennifer Ernst

About Jennifer

Jennifer Ernst came to the medtech space after more than 20 years in the computing and electronics industries, serving in high-profile roles at Xerox PARC and Thin Film Electronics. She participated in the launch of the Global Women's Leadership Network, which aims to provide women with the opportunity and resources to make a difference in their communities. In 2016, Jennifer founded direct-to-consumer medtech company Tivic Health and helped lead development and commercialization of the company's flagship device ClearUP.

Key Learnings

- Think about how your product's form and function aligns with consumer expectations. This is especially true if you are selling for consumers. Your advertising and instructions for use should be as clear as possible from the outset.
- Build support for your device through user reviews and word-of-mouth. If consumers back your product and use it every day, they're more likely to share that with physicians who will then recommend it to other patients. This effect will compound and create further opportunities for growth and collaboration.
- Don't shy away from challenges, but do prepare for them. Getting financial backing in the direct-to-consumer space isn't easy. The more you demonstrate the value of your device in the real world, the more comfortable investors will be in funding your vision.

Building a Consumer-Focused Medtech Business

Jennifer Ernst, Co-founder and CEO of bioelectronic medicine company Tivic Health, didn't follow a traditional path to the medtech industry.

Her career began in computing, as a communications manager and business development director at Xerox PARC, before becoming Chief Strategy Officer for Norwegian electronics manufacturing company Thin Film Electronics.

But then the field of bioelectronic medicine caught her eye. She knew this was an area where her experience in translational science — taking groundbreaking research and turning it into a commercial product — would make a difference.

"It's really an exploding area in science. I was incredibly drawn to it in part because of how little is actually known about how the electrical system of the body works," Jennifer says.

In 2016, she and biomedical engineer and inventor John Claude founded Tivic Health with the goal of developing advanced bioelectronic solutions that treat disease, increase wellness, and improve lives.

Their flagship product is ClearUP, an over-the-counter handheld device that uses gentle pulsed electron waves to relieve symptoms of sinus and nasal inflammation, nasal allergies, sinus infections, chronic sinusitis, cold, and flu.

The device received FDA clearance in early 2019 and entered the market later that same year. Tivic has since sold more than 30,000 units of ClearUP.

"It's been a pretty fast, rapid and exciting journey from concept through commercialization now to actually providing our investors liquidity and having the opportunity to grow the company in the space of bioelectronic medicine to a multi-product company," Jennifer says.

In this episode of Medsider, Jennifer shares how consumers can play a key role in boosting support and evidence for over-the-counter medical devices, and why she thinks direct-to-consumer business models will transform the medtech space.

Focus on User-Friendly Design

People tend to come in with preconceived notions of how something works or should work. For example, when they see something that's supposed to help with sinus pain, they might automatically think it should be inserted inside their nose and operate like a nasal spray.

But that's not how Tivic Health's ClearUP works. Users should hold the device against their cheeks, nose, and below their eyebrows.

Building a Consumer-Focused Medtech Business

The Tivic team had to figure out how to communicate that information to people buying the product on Amazon or at their local drug store.

“We had to really think about: How’s this form factor going to communicate that you don’t want to [put this in your nose]? That’s not how you use it,” Jennifer says. “How are we going to communicate with all the video, with the advertising to make sure that the first time somebody picks up the product that we aren’t feeding into a mental model that’s going to lead them into misuse?”

How much time will it take to train the user on how to use the device? That’s something any company that is making an over-the-counter (OTC) or home-use device should think about, Jennifer says.

Jennifer and her team concluded they had about 2.3 seconds to show consumers how to use ClearUP, and they figured out how to communicate that information succinctly through advertisements, videos, and the user manual.

This user-centric philosophy is something all medtech companies should consider when developing direct-to-consumer devices

> “
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> This is not ‘open up the book and let them really study and read the user manual in detail.’ As medical companies, we have to be aspiring to the level of design that the best of consumer product companies have achieved, Jennifer says.

Jennifer emphasizes that entrepreneurs need to design products that people want to use every day. Developing devices with consumers in mind will have a major impact on the future of OTC devices, she says

Let Consumers Lead the Way

About 40% of the potential ClearUP user population — those that experience pain and congestion from sinus inflammation — never see a doctor, Jennifer says. That statistic was the driving force behind Tivic’s decision to make the device available over the counter

Building a Consumer-Focused Medtech Business

Jennifer hasn't ruled out the possibility of making it available via prescription and eligible for reimbursement later down the road, but the team needs to figure out what reimbursement codes would apply to the device.

In the meantime, Tivic is focused on building up a consumer base and a body of evidence for ClearUP.

"[That evidence] includes your Amazon reviews, it's your product reviews, it's people talking about your product, it's your news coverage. So [it's] really building up the base of the consumer first, and making sure that we're creating benefit for the person that has to pay for the product," Jennifer says.

Jennifer believes this consumer-first strategy is the future of healthcare.

"There are a couple big trends that suggest this is going to become a more dominant part of the health tech world," she says.

She points to Roman, a digital health clinic for men, and Nurx, a female-focused telemedicine company, both of which offer prescriptions after allowing patients to consult with a physician online.

There's also a movement in which treatment for certain conditions is moving from specialty clinics to the primary care setting. For example, patients might go to a specialist for a migraine diagnosis, but most of their care might be managed at their primary care office.

"More and more of the consumer [experience is] realizing that they're stewarding their own healthcare, and beginning to use doctors more and more as the consultant in the process, but not always as the single-source provider," Jennifer says.

There was a similar situation in the market with AliveCor, a medical device company that developed AI-enabled electrocardiogram sensors that deliver heart data digitally. AliveCor started with patients as its end users, and those patients introduced the product to their doctors. Doctors then created more demand for the product and asked for the device to be integrated with their health systems.

In that same vein, Tivic Health believes patients are the key to success. Being able to excite end users and making sure your product is well-positioned for them is the critical first step for consumer medical devices. Users will then help bring the medical community on board as part of their care journey, Jennifer says.

"I honestly believe that we're going to see that as a pattern that starts to emerge the same way we have seen direct-to-consumer emerge in other industries," Jennifer says.

Building a Consumer-Focused Medtech Business

Take Risks and Try Something New, but Keep in Mind the Challenges Ahead

If you're working with a business model that hasn't been used before, be prepared for more of an uphill battle when it comes to fundraising. It's an even steeper climb if you're looking to enter the direct-to-consumer space. It can be difficult to find medtech investors who want to invest in direct-to-consumer healthcare models, according to Jennifer.

"When we think about the medtech funds, people haven't been out raising capital to tell people, 'I'm going to invest in a direct-to-consumer new model in healthcare innovation.' Those investors are on the rare side. They may have raised it to say, 'We're going to invest in early-stage medical device companies,'" Jennifer says.

Jennifer likens it to the early days of Warby Parker — a first-of-its-kind direct-to-consumer prescription eyewear company.

"In the early days of Warby Parker, they did not have backing … until the breakthrough moment where they demonstrated that people really would buy glasses online," Jennifer says. "It was a really strange concept … that's [now] an iconic case study."

Now, entrepreneurs will often say they want to be the Warby Parker of whatever industry they're in.

Jennifer predicts similar things will happen in the medtech sector as companies show they can be successful.

"As we build success cases, and as we see companies that successfully build and acquire and exit, then firms will become more comfortable investing in that model," she says.

Jennifer envisions Tivic as being the "acquirer of choice" for emerging bioelectronic medicine technologies.

The way to do that is to continue listening to consumers and doctors, building trust within the science and investor communities, and always being prepared for the challenges ahead.

About the Author

A self-described medtech and healthtech enthusiast, Scott is a Founding Partner and Managing Director of Big Sky Biomedical, a medical technology incubator focused on designing and developing novel interventional therapies. He currently serves as President and CEO of FastWave Medical, a spin-out company founded by Big Sky Biomedical partners, which successfully closed on an investment plus milestone-based acquisition agreement within 6 months of the company's inception.

Scott is also a Co-Founder and Advisor to Crossfire Medical, a Big Sky Biomedical portfolio company, which has garnered its own share of attention and is focused on the chronic venous insufficiency arena.

He founded Medsider in 2010 with one simple goal: help ambitious doers learn from experienced medtech and healthtech thought leaders. Scott's work with Medsider has been featured in publications like Forbes, Mass Device, MedCity News, and MD +DI.

Scott is also a Co-Founder of Joovv, and since launching their first device in February of 2016, Joovv systems are now used in salons & spas around the world and are trusted by pro sports teams, Olympians, and world-class trainers.

He has participated in highly-popular podcasts with Dave Asprey, Skinny Confidential, Ben Greenfield, Aubrey Marcus, and many others. He's also been featured in media outlets like the New York Times, ESPN, and Men's Journal. In addition, Scott serves as an advisor to the several other health & wellness brands and is a contributor to Forbes and Mass Device. Learn more at **scottnelsonlive.com**.

About Medsider

The chief aim of Medsider is to help ambitious doers learn from proven medical device and health technology experts. These experienced thought leaders will show you how to:

- Improve your commercialization plans.
- Enhance your regulatory submissions.
- Strengthen your reimbursement strategies.
- Streamline your R&D efforts.
- Raise capital for your startup.
- Advance your network and career.
- And much, more more!

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