MEDSIDER








VOLUME VII

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF CANARY MEDICAL, PRISTINE SURGICAL, ADONA MEDICAL, CORVISTA, INSTYLLA, AND MORE.







SCOTT NELSON

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INTRODUCTION

Medtech is a space where bold ideas meet hard realities. But for those who persevere, you can truly change lives. It's a field full of challenges, from securing funding and navigating regulatory hurdles to scaling new technologies and gaining market traction. It's also one of the most rewarding areas to innovate in, because the work we do impacts real people.

That's why we're excited to bring you Medsider Mentors: Volume VII. These collections are all about learning from medtech entrepreneurs who've been in the trenches. Their experiences offer invaluable lessons, not just in strategy and execution, but in the mindset it takes to thrive in this industry.

Whether you're here to find inspiration, practical advice, or just a bit of solidarity in knowing you're not alone in facing the complexities of medtech, this volume has something for you. In these interviews, you'll hear candid stories about tackling fundraising challenges, building world-class teams, refining product-market fit, and navigating the intricate web of clinical and regulatory processes.

Ready to dive in? Here's a glimpse at the wisdom packed into this edition:

Joe DeVivo, CEO of Butterfly Network
on Creating a Buyable Business

Joe DeVivo's journey in leadership spans medtech startups and multibillion-dollar companies, with a proven track record of turnarounds, exits, and acquisitions. Now at the helm of Butterfly Network, he's driving the adoption of handheld ultrasound devices that are making medical imaging more affordable and accessible. Joe explains why starting lean beats scaling too fast, how direct-to-consumer strategies can outmaneuver industry giants, and why befriending competitors could be your ticket to a successful acquisition.

Jason Hannon, CEO of Mainstay Medical
Proving Value Before Scaling Big

Jason Hannon's journey spans law, leadership, and medtech milestones. As COO of NuVasive, he drove the company to remarkable revenue growth, and now, as President and CEO of Mainstay Medical, he's tackling chronic low back pain with ReActiv8, an implantable neurostimulation system designed to restore spinal stability. Jason shares how early prototype testing can validate groundbreaking concepts without breaking the bank, why clinical trials must prove both patient and economic impact, and the keys to winning over skeptical investors.

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Beth Rogozinski, CEO of Oncoustics
on Bringing Silicon Valley to Medtech

Beth Rogozinski, CEO of Oncoustics, has experience in digital health and FDA-cleared therapeutics, which she now applies to tackle liver disease diagnostics with AI-driven, cost-effective ultrasound analysis. Beth shares why early alignment with clinicians, payers, and regulators is critical, how to decide whether FDA clearance adds value to your product, and offers practical strategies for understanding payer ecosystems.

Bill Hunter, CEO of Canary Medical
on Reducing the Provider Burden in Healthcare

Dr. Bill Hunter, CEO of Canary Medical, is pioneering smart implant technology that turns medical devices into tools for real-time patient monitoring. Known for his role in innovations like the TAXUS drug-eluting stent, Bill now focuses on devices like Persona IQ, which tracks recovery progress after knee replacement surgery. He shares strategies for creating devices that fit seamlessly into healthcare workflows, why empowering patients can alleviate system-wide pressures, and how to focus on practical solutions that improve outcomes without adding complexity.

Dan Nardi, CEO of Reimagine Care
on Bringing Treatments Into the Home

Dan Nardi, CEO of Reimagine Care, is bringing high-quality cancer care to patients where they are—at home. Dan has over 20 years of experience in healthcare IT and digital health, including helping scale Livongo to its IPO. Dan shares how to design win-win strategic partnerships, why early adopters are critical to proving ROI in healthcare, and how understanding the shift toward fee-for-value models can help startups position themselves for long-term success. He also offers insights on building the right team, choosing investors wisely, and crafting a business model that works for patients, providers, and payers alike.

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Sumit Nagpal, CEO of Cherish Health
on Stage-Appropriate Thinking

From working with Steve Jobs at NeXT to leading Accenture's global digital health initiative, Sumit Nagpal, founder and CEO of Cherish Health, has honed a talent for solving big problems with simple, scalable solutions. His latest venture, Cherish Health, uses radar-based sensors to monitor health and safety risks at home, especially for the elderly. Sumit shares why a "stage-appropriate" framework—whether in funding, strategy, or leadership—is crucial for scaling a startup, how he draws inspiration across industries, why listening and pattern recognition are key to solving healthcare's toughest problems, and how calculated partnerships can open doors to growth.

Reinhard Krickl, CEO of Phagenesis
on Stripping Complexity for Better Outcomes

Phagenesis' former CEO Reinhard Krickl has been pivotal in the company's fight against dysphagia, a condition that impairs swallowing for half of stroke survivors. Under his leadership, Phagenesis developed a neurostimulation system that helps patients regain swallowing function. The device, already adopted across Europe, is now preparing for entry into the U.S. market, bolstered by a $40 million Series D funding round. Reinhard reflects on why simplicity in device design is key to adoption, shares his "market access checklist" for navigating commercialization, and opens up about the tough decision to step down as CEO to position the company for its U.S. launch.

Amarpreet Sawhney, CEO Instylla
on Creating 'Wow' Moments in Medtech

Amar Sawhney is a serial entrepreneur and prolific inventor of FDA-cleared products, including surgical sealants and spacers that have reached over 8 million patients worldwide. Currently, as CEO of Instylla, he's leading the development of liquid embolics that shut down blood supply to tumors. With over 120 patents and a career built on bold solutions, Amar shares how he evaluates risks in medtech, designs clinical trials for success, and chooses the right initial indications for platform technologies. He also explains why startups should focus on creating immediate, undeniable value to pull market demand.

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Bryan Lord, CEO of Pristine Surgical
on Building Momentum Despite Challenges

Bryan Lord calls himself "an entrepreneur trapped in a lawyer's body." After starting his career in law, Bryan navigated his way into tech and medtech, ultimately becoming CEO of Pristine Surgical. Today, he's leading the charge with Summit, a single-use 4K digital arthroscope that simplifies endoscopy. Bryan shares lessons from his journey—how to protect competitive advantages with trade secrets, not just patents; why validating market demand always comes before technology development; and how he focuses on momentum, even in tough market conditions.

Brian Fahey, CEO of Adona Medical
on De-Risking Medtech Startups

When Brian Fahey found himself at the Stanford Biodesign Innovation Program, he discovered a passion for solving real-world healthcare problems. Today, as CEO of Adona Medical, Brian is leading the development of an interatrial shunt for heart failure that combines therapeutic and diagnostic capabilities. Brian shares insights on managing medtech's three biggest risks: product-market fit, technical feasibility, and clinical validation. He explains how to assess ideas strategically, design smarter clinical trials, and how to approach fundraising with a time-efficient mindset.

Aakash Shah, CEO of Wyndly
on Learning by Doing

Aakash Shah, co-founder and CEO of Wyndly, has reimagined how allergy sufferers find relief. Leveraging his engineering background and teaming up with his cousin, Dr. Manan Shah, they created a telehealth platform offering personalized, at-home allergy immunotherapy. Aakash talks about the power of simplifying healthcare for patients and why learning by doing is the fastest way to grow. He also shares how video-based social media became a surprisingly effective tool for engaging patients and even attracting B2B partnerships.

Eric Goslau, CEO of Transverse Medical
on Moving Forward With 'Good Enough'

Eric Goslau is the co-founder and CEO of Transverse Medical, where he leads the development of the Point Guard Cerebral Embolic Protection Device—a tool designed to reduce stroke risks during cardiovascular procedures by protecting the brain from harmful debris. With 29 years of experience in medtech sales, marketing, and product development, Eric brings a commercial-driven perspective to his leadership, emphasizing practical execution, effective fundraising, and getting products to market quickly. He shares why perfection can be the enemy of progress, and his strategy for navigating the ups and downs of medtech fundraising.

Time Rosa, CEO of Somnee
on Building Customer-First Brands

Tim Rosa's career spans launching the videogame NBA 2K to scaling Fitbit into a global phenomenon. Today, as the CEO of Somnee, he's commercializing a sleep headband that combines EEG monitoring and neurostimulation to help users fall asleep faster and better. Tim brings a deep understanding of brand strategy and customer experience, shares how he applied lessons from Fitbit and gaming to rebuild Somnee's brand, why clear messaging and precise data are critical, and his strategy for turning a consumer wellness product into a category-defining healthcare solution.

INTRODUCTION

Don Crawford, CEO of CorVista
on the Power of Focus in Startups

Don Crawford, CEO of CorVista and a medtech veteran, knows how to lead startups to success. After guiding Sapheon to a $238 million exit, he's now spearheading the development of CorVista's non-invasive, advanced machine-learned algorithms to detect heart conditions. Don talks about the power of staying focused, the importance of collecting pristine data, and how fostering transparency and collaboration can build an adaptable and efficient team.

Steffen Hovard, CEO of Neuspera
on Assessing Market Opportunity

After two decades at Coloplast and a pivotal role in an acquisition, Steffen Hovard is now leading Neuspera—a company set to change how overactive bladder (OAB) is treated. Neuspera's minimally invasive sacral neuromodulation system stands out by being wireless, compact, and patient-friendly, offering a game-changing alternative to bulky, invasive implants. Steffen shares his insights on assessing market opportunity, aligning development speed with critical milestones, and building meaningful relationships with both regulators and investors.

Thank you for your continued support as a reader. I'm always open to your ideas and suggestions for future Medsider Mentors features, so don't hesitate to share who you'd like to learn from next.

Best wishes,

Scott Nelson

Founder of Medsider
Co-Founder and CEO of FastWave Medical

How to Compete with Industry Goliaths

Interview with Butterfly Network CEO Joe DeVivo

Joe DeVivo

Preview

Joe DeVivo, President and CEO of Butterfly Network, is a medtech veteran with extensive leadership experience at both startups and industry giants. Butterfly is developing hand-held ultrasound devices that make medical imaging easier, cheaper, and more widely accessible. Joe shares insights on why a lean start in commercialization is better than a high-burn, high-risk approach, the difference between your company being sold and being purchased, and best practices for managing M&A transactions.

About Joe

Joe DeVivo is the President and CEO of Butterfly Network. He's a proven executive with 35 years of business leadership experience, including 22 years in the medical device industry spanning small start-up companies to multi-billion-dollar organizations. He has acquired and fully integrated eight companies, engineered four business turnarounds, and delivered five company exits.

Key Takeaways From Joe's Experience

- Don't be afraid to explore unconventional ideas if your product and the market conditions warrant it. For example, you may want to really lean into sales and distribution strategies tailored to your product's strengths—like building a broader ecosystem around your device. This may attract other parties not directly in your stakeholder loop, generating value outside of your direct product sales.
- To outmaneuver incumbents, adopt a lean, adaptable commercialization strategy based on the advantages of your product. As a startup, don't make the mistake of scaling your salesforce prematurely. With a focused, low-cost initial launch, you can gather vital market feedback and refine your approach. And if your technology is novel, invest in education.
- When it comes to M&A, you want your company to be purchased, not sold. Focus on building a strong, desirable business to attract buyers organically. Befriend potential acquirers, including competitors, and foster trust over time.

How to Compete with Industry Goliaths: Interview with Butterfly CEO Joe DeVivo

Think Outside the Traditional Sales Cycle

When it comes to commercialization, Joe has followed two different but equally successful strategies with Butterfly.

First, Butterfly found success early on by commercializing directly to end-users without a field-based sales team. While this approach is somewhat atypical in medtech, Butterfly's position was aided by the fact that its ultrasound probes are very user-friendly. Today, a high percentage of Butterfly's sales are made by doctors who purchase the device online.

By establishing direct relationships with doctors worldwide, Butterfly built a strong value proposition and rapidly scaled its operations across a diverse customer base. Today, the product is available via eCommerce in 18 different countries and languages.

Secondly, on top of engaging directly with physicians online, Butterfly's direct sales force sells to hospital systems, medical schools, clinics and other out-of-hospital settings in the United States and in key international markets. With distributors and global health partners extending reach further across the globe, Butterfly devices can currently be found in over 100 countries.

How to Compete with Industry Goliaths: Interview with Butterfly CEO Joe DeVivo

Commercialize with Precision

Joe's approach to commercialization is all about measured steps instead of the high-burn, high-risk trap that most startups fall into.

“Sometimes only one salesperson is enough. Start small, test, and learn,” Joe suggests. A lean initial model allows you to be adaptable and saves money as you learn and grow. “The biggest mistake I see people make is: They just go boom, and they deploy all kinds of resources. Next thing you know, they're burning a million dollars a month,” warns Joe.

Direct market interaction is also key. You often get more pertinent information on pricing, what customers might love or hate, and educational needs.

For example, Butterfly competes against giants like GE, Phillips, Siemens, and Fuji. But their direct-to-physician e-commerce sales model creates a competitive advantage. “When you sell directly to a doctor and into their practice, you start building a brand, you start building awareness,” Joe points out.

“If you read Malcolm Gladwell's book, David and Goliath, the ‘Goliaths’ have their ways of fighting battles. But when you're small and you're new, you have to find a way to be a little disruptive,” Joe explains. It’s not just about building a website or having a reputation. For Joe, what you have to do is to come up with a model that accentuates your unique benefits.

“Once you've proven a concept, it's very easy to want to scale quickly,” says Joe. But trying to hire tons of people and optimize everything all at once is a big challenge. For example, by having a single salesperson test a particular territory, Joe suggests you can learn, “What are the objections that doctors have? Have you priced it right? Is there a training issue? And so, whether it's dipping your toe in the water and making your product available online and then doing some basic marketing, or whether you put one or two salespeople into a good market, you can take a bit of a slower path in terms of cash deployment for your launch.”

In addition, stakeholder education might also be essential, especially if you’re changing the game like Butterfly is changing the ultrasound space. That’s why the company offers extensive educational initiatives like training videos, its AI-guided ScanLab™ app, and courses on Butterfly Academy. Although it requires significant resources, these educational programs are an absolute necessity. As Joe points out, “You can’t sell a car if people don't know how to drive it.”

How to Compete with Industry Goliaths: Interview with Butterfly CEO Joe DeVivo

It’s Better to Be Purchased Than Sold

Joe, having seen five companies through their exits, is an expert when it comes to medtech M&A. “A successful M&A deal is one where you're purchased, not sold," he reiterates, "If you create a posture of trying to sell your business, you won’t get the full value.”

According to Joe, the best strategy is to keep a reasonably low profile while building value. But that's not always feasible. You occasionally need to engage with potential buyers directly. For that, Joe suggests that you identify the potential acquirers – especially competitors – and simply befriend them. For example, build relationships at industry events over time.

Not every strategic is looking to make a purchase, but they might be open to partnerships. Starting with conversations around distribution, for example, is a great way to demonstrate your company’s strengths and prove your reliability at the same time.

“When you're doing something, you think the whole world revolves around it, but the potential acquirer might not fully understand how you'd fit in their company,” explains Joe. You need to show them what you’re doing, and how successful you are at it. Here, openness and transparency are key, yet this doesn’t mean you should divulge the secret sauce. Use your communication channels to educate the key players – those who might be potential acquirers in the future. Joe shares, “You can even steer them towards synergies between your business and theirs.”

All these efforts in communication are essential in creating trust, which is a significant part of acquisitions, according to Joe. “They can do a lot of due diligence, but if there's something they miss, it’ll hurt them badly after the deal is done.” Maintaining a strong posture and confidence in your mission will attract those already in acquisition mode. It could even spark interest from other likely strategics. That’s how you make sure your company is purchased, not sold.

A Roadmap for Proving Clinical Efficacy and Economic Value

Interview with Mainstay Medical CEO Jason Hannon

Jason Hannon

Preview

Mainstay Medical has developed the first restorative neurostimulation treatment that alleviates chronic mechanical back pain. Jason Hannon, the CEO and President of the company, shares his experiences on iterative product development, considerations for clinical trial design, the importance of patient education, and why reimbursement is paramount.

About Jason

Jason Hannon holds a J.D. from Stanford University Law School and a B.A. from the University of California, Berkeley. After 12 years at NuVasive, where as COO he led the company to incredible revenue milestones, he transitioned to his current role as the President and CEO of Mainstay Medical, where he and his team are commercializing ReActiv8, an implantable neurostimulation system for intractable mechanical chronic low back pain.

Key Takeaways From Jason's Experience

- Validate your therapy's core concept before investing heavily in device design, especially when introducing a disruptive treatment. You can create a prototype using off-the-shelf products for early testing. This allows you to focus on understanding the therapy's mechanism of action and potential benefits.
- Design clinical trials to demonstrate both the clinical efficacy and the economic benefit to healthcare providers – it is crucial for securing reimbursement. This involves considering the cost impacts of patient care, like hospital readmissions and the need for further interventions.
- Gain your investor's trust with a detailed financial plan and by consistently achieving your goals. Build credibility and prove that you can deliver on your promises in order to best position your company for a future financing event.

A Roadmap for Proving Clinical Efficacy and Economic Value: Interview with Mainstay Medical CEO Jason Hannon

Put the Patient Experience and Clinical Need Front and Center

In medtech, the well-trodden route is often optimizing for regulatory requirements and commercializing as soon as you can. However, if you're developing a disruptive technology that challenges the treatment status-quo, you must first become an expert on your solution's mechanism of action. "We want to prove objectively exactly what changes in the body when we apply this therapy," says Jason.

Mainstay's focus lies squarely on the patient experience and finding solutions for their needs. "We are therapy first, not technology, not size or features. Therapy first." Jason explains. "We focus on what the patient is experiencing and how we can address it. Then, we develop the technology to serve those needs."

Mainstay focuses on the multifidus muscle that stabilizes the spine. This muscle is inhibited by pain, and once the brain shuts it off, it doesn't naturally reactivate until the pain goes away. Therefore, the main question is, "If it has turned largely to fat, can the muscle be restored with the stimulation over a period of time?" To answer this, the team needed a muscle stimulator.

Instead of developing a new device from scratch, they repurposed an off-the-shelf spinal cord stimulator and programmed it to target the specific nerve associated with the multifidus muscle. This was helpful for Mainstay's team to understand the therapy's potential without spending years developing the perfect device.

It was apparent that patients were feeling better, but Jason wanted to fully understand what was actually happening. They went straight to the world leader in studying multifidus muscle in Australia and ran randomized studies on animals. Eventually, their team was able to see the effect of the therapy. "If we hadn't done that, it would be just a theory forever," says Jason.

Once the team knew what the therapy was specifically doing, it was easier to further refine what is now ReActiv8. For example, there were limitations with the stimulator in real-world scenarios like patient movement causing leads to shift position. But understanding the therapy's underlying mechanism allowed Mainstay's engineering team to move through technical challenges more efficiently.

It's also important to keep in mind that not all patients will respond to the treatment the same way. So selecting the right crowd for your trials is also important. ReActiv8 is a therapy that aims to address the underlying cause of back pain, which is very different from temporary symptom relief. Jason explains, "In order to realize the full clinical benefit of this therapy, you need to be compliant with it for months."

A Roadmap for Proving Clinical Efficacy and Economic Value: Interview with Mainstay Medical CEO Jason Hannon

Design Clinical Trials to Prove Efficacy and Economic Benefit

ReActiv8 is a promising therapy with compelling clinical results from early testing. However, changing the status quo means answering some tough questions. "The more disruptive your therapy, the more you need to demonstrate how it works and frankly, why it works," Jason shares. That’s why he prioritized two goals in clinical trial design at the outset: proving the concept delivers clinical results and demonstrating its cost-effectiveness to healthcare providers.

Proving efficacy is seldom enough. You must also prove economic benefits and secure reimbursement for widespread adoption. This means getting into the weeds. Instead of just counting how many people feel better, you need to analyze factors like whether the therapy lowers hospital readmission rates, decreases the need for further surgeries, or impacts other costly aspects of patient care. "Our first senior-level hire as we approached FDA approval was our head of reimbursement," Jason shares. He further adds, “Writing the study in a way that foresees ultimate reimbursement as the issue is critical because you can't go back and rerun that study.”

When it comes to building out a financial case, while you’re likely the most passionate party to prove your device’s utility, you’re also probably the most biased. That’s why an independent economic report can build tremendous trust. Jason advises partnering up with third-party experts and having them run an analysis that shows your therapy is either a break-even or a net gain to the system. This bolsters your case and increases the likelihood that insurers will see the value in covering your device.

On that note, it's never too early to start building relationships with the decision-makers at insurance companies. Engaging with medical directors helps tailor studies and evidence to match the criteria these payers use, ultimately improving a therapy's chance of widespread reimbursement.

Jason also emphasizes, “If you introduce a new therapy that copycats an existing therapy, you have instant access to reimbursement in the US. But if you do something new and novel, it's a long process.” Achieving broad insurance coverage is rarely an overnight success. You need to consistently demonstrate cost savings over time, address the questions from different insurers, and have the perseverance for what can often be a long process.

A Roadmap for Proving Clinical Efficacy and Economic Value: Interview with Mainstay Medical CEO Jason Hannon

Educating Patients and Winning Over Investors

Disruptive therapies often require you to focus on the long game. You need a shift in patient expectations and to gain the trust of potential investors.

ReActiv8 is a long-term therapy, so it takes a while before patients start seeing results. For it to be successful, patients need to understand that benefits unfold over time and that everyone's recovery journey is different.

That’s why, above all, the ReActiv8 website serves as a channel for patient education. “I don't care if no one can find my name on the website. That's not the point,” Jason shares candidly. Instead, they highlight patient stories on their way to recovery. “The patient who's six months out who can talk about their journey, that's an incredible education pickup for someone,” Jason explains. Similarly, with physicians, he notes that testimonials focusing on patient progress over time are far more impactful than simply sharing that they’ve used the device. Their patient ambassadors are also key players in dispelling misconceptions and setting the right expectations about the therapy.

It’s easy to think that the vast number of chronic low-back pain sufferers and the underserved treatment landscape suggest a slam dunk for investors. However, it’s never the case, especially with disruptive technologies. On top of proving efficacy and educating patients, you also have to convince investors to write sizable checks.

According to Jason, “Can this team do what they say they're going to do?” is the major question in every investor’s mind. If a company needs to raise more funds before achieving broad coverage, it introduces a significant risk factor. Even if they believe you’re going to get broad reimbursement, the question is, “How quickly?” This influences their decision whether to invest now or wait two or three years and see if you come back with milestones in hand. In Mainstay’s case, it took almost a year to earn the credibility they needed. And it was by developing a detailed financial plan and relentlessly executing – hitting their goals consistently, month after month.

Furthermore, Jason notes that investor interest can wax and wane due to their own funding cycles and priorities. That’s another reason for maintaining open communication, because, as Jason explains, "A ‘no’ now may eventually turn into a ‘maybe’, and then a ‘maybe’ can turn into a ‘yes’ over time." His own experience with Mainstay’s recent lead-investor coming through two years after the initial introduction, demonstrates this. “There was an initial meeting and nothing happened for a year. We just kept them up to speed on what we're doing. And then we reengaged toward the middle of last year and they did a ton of work. But it doesn't happen if you write the group off, because timing is everything, not just for the company. Timing is everything for investors, too.” The end result was a $125 million equity financing, an exceptional deal size that validates the company’s work to date and prospects for future growth.

Interview with Oncoustics CEO
Beth Rogozinski

Beth Rogozinski

Preview

Leveraging her extensive experience in digital medicine, Beth Rogozinski leads Oncoustics, a company that uses advanced AI to analyze ultrasound data to offer a cost-effective alternative to traditional diagnostic methods. Beth shares her insights on the importance of persistence and resilience in fundraising, the value of engaging with a diverse range of investors, and the need for a strong narrative about your technology, particularly when it involves AI capabilities.

About Beth

Beth Rogozinski is the CEO of Oncoustics, a company developing low-cost, non-invasive AI solutions for disease monitoring. Previously, she held a variety of leadership roles in the field of digital health, including the development of the first FDA-cleared prescription digital therapeutic. Beth advises numerous startups and accelerators and has consulted with organizations like Stanford, UnitedHealth, and the National Mental Health Innovation Center. She is a guest lecturer at UCSF Health Hub and Columbia's HIT Lab and serves on BIO's Digital Health committee.

Key Learnings From Beth's Experience

- Clinicians, regulatory bodies, and commercial stakeholders may have different requirements. Address each of them early in the development process. Engage with key decision-makers as soon as feasible to ensure your product is commercially viable.
- FDA can be your best friend if you engage the right way. Consider them a part of your team. However, before approaching the agency, evaluate whether it's a real necessity for your product. Your solution might be eligible for a simpler and more straightforward pathway.
- Fundraising for startups requires persistence, building relationships with a wide range of investors early on, and having a clear narrative about your technology. Engage with prospective capital partners even if they typically invest in later stages. And don't limit yourself to investors strictly within your niche.

Silicon Valley Approach to Medtech: Interview with Oncoustics CEO Beth Rogozinski

Who is Going to Pay for Your Product?

To develop their AI model, the Oncoustics team directly engaged with clinics and healthcare professionals to understand their needs and expectations – specifically what they needed to know about patients' liver conditions. However, balancing these clinical needs with FDA requirements and commercial objectives presented challenges. While clinicians had specific demands, the regulatory groups had different requirements for approval.

Many medtech startups fall into the trap of focusing predominantly on regulatory approval while deprioritizing the commercial implications, which often leads to slow adoption. Beth understood the importance of involving key commercial stakeholders, including payers, early in the development process to ensure the product not only met regulatory standards but was also commercially viable. She says, “You have to have the payers, their mindset, and their thought process in the room. It's a wonderful thing to innovate in healthcare, but somebody's got to pay for it. It's critical for us to figure that out early.”

For entrepreneurs, understanding how payer ecosystems work is essential. Many payer groups have innovation and venture arms. For example, United’s venture arm is Optum Ventures and their innovation lab is Optum Labs. Getting involved with Optum Ventures and Labs can be a great way to progress if you want to engage with United, for example. But you need to align your solutions with their different needs. “We want to address their pain points rather than sell something. It's really got to be mimetic to what their needs are.” she says.

This is why Beth talked to an entrepreneur in Anthem Blue Cross Blue Shield and learned that diabetes was a major pain point for them at the time. Knowing this, Beth could position Oncoustics to address the bi-directional relationship between diabetes and liver disease.

You Don’t Always Need Clearance

When approaching FDA, Beth shares, “Fundamentally and strategically, I see the FDA as collaborators, and I really balk against the idea that they're antagonistic.” This type of framework is important when trying to foster a productive dialogue. You should get their feedback and advice early on, engage in pre-submission meetings, and think about FDA as a part of your extended team.

This attitude helps in more than one way, as you should also carefully consider whether getting FDA clearance is truly necessary and beneficial for your specific product. Beth suggests that a regulatory stamp of approval shouldn’t always be the default goal. For example, at ModalityAI, a company where Beth is an independent board officer, they are developing a speech recognition diagnostic, which is considered safe and may not require a traditional FDA review process. Instead, they could be exempt or qualify for a simpler “generally regarded as safe” (GRAS) clearance, avoiding the lengthy and costly process of a 510(k) submission.

Beth suggests that instead of asking "how" to get clearance, you ask “should” you get clearance. You need to decide if it will make your product more valuable or give you an advantage over competitors. Getting FDA clearance often involves making specific claims about how the product works and what it can do, and sometimes, it might be better to make fewer claims about your product’s medical benefits and get it to market faster.

Silicon Valley Approach to Medtech: Interview with Oncoustics CEO Beth Rogozinski

Your Audience Might be Wider Than You Think

Despite the challenging environment, Oncoustics successfully raised over $5 million through a Seed Round in 2022.

“Fundraising is always hard because the easiest thing for an investor to say is ‘no’,” Beth says. It’s a numbers game that requires you to be persistent and resilient. “People invest in people” explains Beth, “I've been talking to people that only invest in B rounds even though we're still in round A. They get to know me, they follow our process and the traction that Oncoustics is having. When I'm ready to start raising that B, they won't be strangers on a Zoom call.”

Beth also suggests securing a strong lead investor to attract others, even if it means accepting a lower valuation. According to her, fixating on dilution and valuation at the expense of closing a deal is not a good idea, as momentum is a vital asset for startups. In her words, “Nobody ever died from dilution. Getting the highest valuation is often not the most important thing. You should think about it strategically and have a long view.”

When it comes to active fundraising efforts, her strategy is to go wide: reach out to a diverse array of investors and don’t be afraid to pitch to audiences that seem outside of your niche at first glance – they might not be. For example, Oncoustics is a hybrid of deep tech and health innovation, so it makes sense to target both deep tech and traditional health tech investors. Beth highlights, “Google, Meta, Microsoft, Apple, NVIDIA, Tesla. Besides Tesla, every single one of them is going after healthcare, and they're all really, very interested. Amazon and CVS are investing in health innovation today.”

However, there is a challenge when approaching some of these non-traditional investors: they may be wary of FDA regulations while traditional healthcare investors might not fully grasp software valuation. That’s why bridging the gap with a clear and persuasive narrative is so important. Beth says, “We basically had to create a story and find those people that would meet us in the middle in a way that’s going to move this industry forward.”

However, Beth cautions against using buzzwords like “AI” in your narrative. For example, building an AI-centered technology is a hot topic these days. If companies claim to have AI, they should genuinely have AI and not just an algorithm. Beth explains, “People can see through those kinds of false claims really fast. Using AI as a buzzword doesn't mean that you're going to get funded or garner interest.” According to her, it’s also unrealistic and poor judgment to aim to replace doctors with AI. Instead, the goal of entrepreneurs should be to create systems that support and enhance clinicians' work, not replace them. Afterall, there are global shortages of doctors and ever-increasing needs of patients in a fast growing and aging world.

Interview with Canary Medical CEO
Dr. Bill Hunter

Dr. Bill Hunter

Preview

For over a decade, Dr. Bill Hunter, CEO of Canary, and his team have developed smart, implantable medical devices that report on function, patient activity, and more. Bill talks about his perspective on innovation in medtech, discusses what it takes for a device to be commercially viable, how Canary is alleviating the workload of healthcare professionals, and offers advice to physicians contemplating the transition to industry.

About Bill

Dr. Bill Hunter is a former practicing physician with 30+ years of healthcare entrepreneurial experience and over 200 patents and patent applications to his name. He's been intimately involved in the development of renowned devices like the TAXUS DES and paclitaxel-eluting balloons and spearheaded the success of companies like Angiotech and Correvio. As the CEO of Canary Medical, he's leading the development of a smart, digital approach to patient monitoring and post-surgical care.

Key Takeaways From Bill's Experience

- To find an unmet need in the market, you don't always have to look at niche problems with a magnifying glass. Examining overall trends and assessing structural gaps can uncover opportunities. For example, Bill realized the growing tension between increasing patient demands for personalized care – and the strain it puts on healthcare providers – and decided to develop digital solutions that aim to solve this issue.
- Innovation in medtech takes a superior, not just an alternative, product approach framework. Moreover, you must consider its real-world impact on the healthcare system and the workflow of providers. Think about streamlining processes, reducing hospital stays, and empowering both patients and physicians.
- If you're a physician contemplating a full-time move to a startup, embrace your entrepreneurial spirit by leveraging the stability of your medical career. Start small, experiment, and be honest with yourself about your priorities.

Distributing the Workload Through Digital Healthcare

As a former medical practitioner, Bill observed a significant shift in patient expectations over the years. He looks back, "When I was in medical school, it was very paternalistic. It was, 'Yes, doctor, thank you, doctor.'" However, perhaps with the rise of informed patients and the convenience of instant access to medical information, consumer and patient patterns have changed. Today, people demand answers right away, and want to take a more active role in their healthcare decisions.

"When you get a hip replacement, for example, you'll have some questions. Is this normal? When can I stop walking with a cane? How long do I have to take my narcotics?" Bill explains. Most patients don't know what to expect after major procedures, and traditional follow-up appointments don't provide real-time insights. On the other hand, there aren't enough healthcare providers – physicians, nurses, and physical therapists – to address all these concerns. This is where Bill saw an opportunity. "Who wants to do more work?" he asked. And the answer was, actually, the patient.

The gap between patient needs and limited resources demands a new approach to patient care, and Bill believes it's going to be through digital technology. He says, "It's not necessarily doing less per se, but having different people doing the right things, and not having the most overworked or overburdened members of the care team having even more things to do. It's about spreading that across and making it more of a collaborative effort, because that's what patients want as well."

That's the idea behind Canary's devices: empower patients to monitor their own progress, compare it to established benchmarks, receive personalized guidance, and make informed decisions about their recovery by providing real-time feedback and insights as well as invaluable data to physicians when required. Bill explains, "That's what we need in all kinds of rehab. We need an organized and coherent way to go through the recovery process to give you the best possibility of a high-quality outcome."

Build for the Real World

This may seem obvious, but the first thing about innovation is that you should always improve upon existing treatments. In other words, don't just offer an alternative, aim to deliver superior outcomes. That's a given.

Then, there come more nuanced aspects that are often overlooked: the impact your product makes in the healthcare system and how it eases the workflow of practitioners. Bill says, "You need to think more about how your device is going to be used and how it's going to be incorporated into the practice of medicine."

Making a positive impact in the healthcare system means streamlining a difficult procedure. That is to say, if you can convert an in-hospital procedure to an outpatient one or allow for earlier discharge, it holds great value. On the other hand, adding a step to the workflow, even if you improve the outcomes, is a tough sell. Bill's words of wisdom are, "We need to think about less invasive options and getting the patient out of the hospital as quickly as possible."

Then, you need to think about how your device is going to be integrated into the physicians' day-to-day practices. Focus on streamlining processes, reducing the number of in-person visits, the time spent on examinations, and the resources spent on procedures.

"You have to reduce the workflow. Period," says Bill.

The recent AI trend, for example, revealed the importance of data management in healthcare. It's easy to believe collecting data can improve results. However, it's also important to manage data efficiently. Simply overwhelming healthcare professionals with data worsens their workload.

Adding too many features is another common pitfall in the world of startups. Don't focus on adding more. Let the "less is more" principle guide you, especially during product development.

Bill's advice boils down to this: when designing a medical device, think beyond the technology itself. Consider how it will be used in the real world, how it will impact the healthcare system, and how it can empower both patients and providers. By taking this holistic approach, you'll be well on your way to developing impactful innovations.

Making the Leap to a Full-time Entrepreneur

If you're a physician with a burning entrepreneurial spirit, Bill's advice is simple: “Just get started. Don't think about the end game.” If the idea doesn't work out, you'll realize it soon enough; and if it does, you'll progress naturally. Your medical career is a great safety net; it’s a stable profession that you can always go back to.

When deciding to transition full-time to entrepreneurial work, Bill suggests taking a long hard look at your priorities. If you cherish clinical practice, consider keeping it separate and partnering up with others to bring your idea to life. However, if you're driven to see your vision through to the end, embrace the journey, and be aware that it may fully consume your medical career. “Doing both is just not possible,” says Bill.

According to Bill, there are two entrepreneurial paths in medtech. You can improve upon an existing technology or venture into a green field, where there aren't any real foundational parameters. The first requires understanding your market and differentiating your product, and the latter requires solving a technical problem first – which Bill, a natural inventor, likes to do. On that matter, his recipe is unconventional. While the well-trodden path is to find a gap in the market and develop a solution that fills it, Bill believes that the biggest risk in healthcare is technological viability. In his words, “Does the technology work: yes or no.” This is the primary question he likes to tackle before anything else.

He continues, “I take the field of dreams philosophy. If you build it, they will come. George Merck always said that if you practice good medicine, the profits will follow. And so, I think if you can solve a specific clinical problem, you can figure out the business model.”

Forging Win-Win Collaborations in Healthcare

Interview with Reimagine Care CEO Dan Nardi

Dan Nardi

Preview

Dan Nardi is known for his operational expertise, understanding of value-based care, and success in building high-performing teams. Today, as the CEO of Reimagine Care, he's working to extend cancer care beyond the clinic, giving patients a break from the arduous treatment journey, and alleviating the strain on caregivers, clinical teams, and the broader healthcare system. Dan shares how he forms strategic partnerships that prioritize long-term value over short-term gains, how to leverage early adopters, and how he's positioned his company in the emerging fee-for-value healthcare model.

About Dan

Dan Nardi, CEO of Reimagine Care, has over two decades of experience in healthcare IT and digital health. Before Reimagine, he served as COO of Carrum Health, where Dan focused on value-based care and oversaw operations, including care delivery and growth. He also played a key role in scaling Livongo from 13 employees to its IPO as Vice President of Operations.

Key Learnings From Dan's Experiences

- Partnerships are essential for growth in the healthcare industry. Focus on building strategic alliances that leverage both your core competencies and those of your partners. Prioritize long-term, win-win collaborations over short-term gains. Be selective when choosing partners, and don't hesitate to walk away from deals that don't align with your long-term goals.
- If you're disrupting a market, early adopters are your life vest, but they are not enough. Work closely with them to demonstrate the value and ROI of your offering while further proving its outcomes through clinical studies. Gather robust data to convince larger stakeholders and secure wider coverage.
- Healthcare has been slowly shifting from a fee-for-service model to a fee-for-value model. When introducing novel solutions, it's important to understand the incumbents, key stakeholders, and the flow of funds. To build a venture that generates long-term value, be selective with your investors, support risk-based agreements where payment is tied to patient outcomes instead of a one-time service, and make sure you clearly demonstrate the ROI of your solution.

Forging Win-Win Collaborations in Healthcare: Interview with Reimagine Care CEO Dan Nardi

How to Find the Right Partners for Your Startup

If you check out Reimagine Care’s recent press release, you’ll see a cohort of big partners, whether it's VCs, customers, or partnerships within the broader ecosystem. Dan is quick to acknowledge the need for cooperation when it comes to the business of healthcare. “Whether you're a founder just getting off the ground or joining an A, B, C round company, you're never going to be able to do it all on your own.” In Reimagine Care's case, to bring cancer care treatment to homes, he knows that he has to work with a network of partners.

Dan also makes a note on developing core competencies vs. outsourcing or delegating. According to him, as the company grows, you may want to be intentional about bringing more capabilities in-house. But in the early stages of a company, it’s not the best idea to build out every function internally. For that, he champions partnerships over outsourcing.

To find a partnership that’ll truly bring value, you first need to identify your company's unique identity and strengths. What do you want to own? What do you want to be known for? What sets you apart? What are your core competencies? Dissect everything and evaluate your position in the market. Dan says, “That's where my engineering background comes in. We take all the pieces apart and start thinking about whether there's someone already doing it really well. If so, let’s go partner with them.” Answering these questions will show you where to deploy resources and efforts. By leaning on your strengths and leveraging your areas of expertise, you can create core competencies that stand out, allowing you to truly differentiate your startup, and ultimately, get to market faster and stronger.

However, successful partnerships require careful planning. It's tempting to focus on short-term gains when forming relationships, but you need to approach partnerships as true collaborations rather than client-vendor transactions. “If you end up with a great deal but your partner can’t succeed, then your whole thing is going to fall apart. You have to make sure that it's a win-win for everyone involved,” Dan says.

It might be tempting to focus on big, high-profile customers, especially when you need the revenue. But as you get to know them better, you may not necessarily want to renew the contract at the end of the term. “It’s always great to have 100% client retention, but it's okay if you lose a couple of clients for the right reasons.” Dan suggests. His advice is to partner up with those who are willing to collaborate, provide feedback, and who genuinely believe in your mission.

He also adds, “I've learned to appreciate saying, ‘Yes, we could make money on that deal, but it won't be good for us in the next 12 months.’” Sometimes it's better to say no to something, even if it means sacrificing some short-term gains.

Forging Win-Win Collaborations in Healthcare: Interview with Reimagine Care CEO Dan Nardi

Convincing Stakeholders on Your Novel Approach

Dan believes Reimagine Care has achieved product-market fit. However, despite the digitalization trend, the service they are providing – at-home virtual cancer care – is still unorthodox to most people in healthcare. While some are enthusiastic about it, others are skeptical.

When you're disrupting the workflow in any way, finding early adopters – people who are innovative and are willing to work with you on your mission – is paramount. But how do you convince them?

For example, Reimagine Care has partnered up with the University of Colorado Anschutz Medical Campus to provide home-centered care to bone marrow transplant (BMT) patients. The institute is also an investor of Reimagine Care. Their first findings were published at the ASH conference in November 2023 and the team continues to build upon that early work.

"Your future client base is going to need a lot of data before they say yes, sign on, and start paying you for what you're delivering," Dan reflects. There are early adopters in every industry. What you need to do is to find those who are open to innovation, collectively establish a win-win relationship, prove clinical outcomes, and learn along the way. He adds, "You've got to find the right client partners to work with as you establish traction."

If your product makes sense, you might convince some innovative spirits to become early adopters who might even be willing to pay for it, and this grants you some initial credibility. But as you reach more traction, product-market fit, and scale, you'll start getting pushback from larger systems and stakeholders.

As you see commercial uptake, it's important to keep in mind that you'll have to eventually present outcomes around both efficacy and cost savings. Dan shares, "If we're asking health systems to take a chunk of their already-tight budget and put it towards our program, we have to provide data."

Even if you shake hands with some early adopters, you need to work on establishing traction through clinical trials and studies. That's how you secure partnerships with big players in the industry and secure reimbursement, which is a critical asset in disrupting the healthcare system.

Forging Win-Win Collaborations in Healthcare: Interview with Reimagine Care CEO Dan Nardi

Follow the Flow of Funds

When introducing new solutions, you're going to disrupt incumbents. For that reason, understanding the flow of funds and whose cheese you're biting into is essential. There are so many stakeholders in healthcare, like physicians, hospitals, employers, and payers. "We can't just have a great idea; we need proof and a strong understanding of unit economics," says Dan.

“Healthcare is slowly shifting from fee-for-service to fee-for-value. It’s a slow shift, but we’re getting there,” Dan observes. In this model, risk-based agreements, where payment is tied to patient outcomes, get the most attention.

Reimagine Care’s business model is to work directly with providers who pay for their virtual cancer care services. "We work with them very closely so they understand the ROI they're getting back," says Dan. So, he makes sure providers see tangible benefits from day one. How? By demonstrating workforce optimization and increased patient volumes. This strategy has proven to be successful for Reimagine Care so far, and their near-term plan is to keep building on it. As Reimagine Care gains more traction in certain geographies, Dan aims to bring the company together with providers and payers to create new risk-based arrangements and handle funds collectively.

Regarding fundraising, Dan has a clear strategy: "Really know your business.” Being picky and choosing investors strategically hold immense importance. "Be targeted and focused. If you're adding someone to the cap table, be thoughtful about the value they'll bring to you and the business moving forward." This means you also need to have the confidence to decline funding opportunities when they don't fit your long-term vision – even if it means financial strains in the short term. "Being mindful of your investors and finding a good strategic fit adds much more value than just the capital," he concludes.

Interview with Cherish Health CEO Sumit Nagpal

Sumit Nagpal

Preview

Sumit Nagpal is a digital health veteran who was inspired by Steve Jobs himself to become an entrepreneur. He's now founder and CEO of Cherish Health, a company that develops intelligent radar-based sensor platforms to support proactive self-care for the elderly, frail, and those with chronic conditions. Sumit shares his take on the importance of being stage-appropriate—both mentally and business-wise—and how to recognize patterns in the market by simply listening. Oh - and constantly learn from others because, as Steve Jobs paraphrasing Picasso put it, "great artists steal."

About Sumit

Over the past three decades, serial entrepreneur Sumit Nagpal has co-founded and grown five companies that have tackled some of the boldest challenges faced by the healthcare economy. Today, Sumit is the founder and CEO of Cherish Health, a company developing radar-based health and safety monitoring devices, and serves on the board of HIMSS where he also chairs the Nominating Committee.

Key Learnings From Sumit's Experience

- Steal like an artist. Draw inspiration from the successes and failures of other adjacent industries. Try to see the recurring patterns and simplify them to see if they translate to your domain, too. To nurture this framework, foster a collaborative environment where ideas are openly shared and feedback is actively sought.
- Each phase of your business, from invention to scaling, requires different resources and priorities. Be clear about what the moment needs and adapt your strategy and mindset accordingly. Set clear and stage-appropriate goals, raise the necessary amount of capital—without excess—and meet those milestones. When complete, adapt your mindset and strategy for the next stage.
- Cultivate an inquisitive mindset and make listening an integral part of your company culture. Gather input from diverse sources to see patterns and make an informed roadmap. Choose partners authentically and invest time in those relationships to build trust, understand their goals, and support each other.

A Stage-Appropriate Framework for Startups: Interview with Cherish CEO Sumit Nagpal

How to Steal Like an Artist

The concept of stealing like an artist is not about stealing but about being open to new possibilities. “When you look elsewhere, in out-of-the-box places, breakthroughs happen,” says Sumit. He likes to identify the root cause of complex problems by looking at the problems that other companies, both within and outside his field, fail to overcome.

Sumit learned how to distill very complex ideas down to their essence from none other than Steve Jobs. It also helps that he’s a great observer and a strong proponent of learning from others' lessons.

Sumit knew that a solution to lowering expenses in healthcare, while massively reducing hardship, would be a solid business. The main culprit of cost in healthcare is when people wind up in ambulances, emergency rooms, and hospitalizations– and a significant portion of these incidents are either avoidable or can be more treatable with quick intervention. So that’s why he started looking for a way to predict and point to emergencies at home.

The development of Serenity took four years. During this time, Sumit again drew inspiration from other industries. For example, he knew that wearables are often discarded due to user fatigue, ending up in drawers. Then he looked at adjacent industries, like home security, which uses passive ambient sensing to detect unwelcome intruders. He took this idea and turned it into protecting people, rather than just their property.

Having an open mindset goes a long way, and it’s an attitude that applies to company culture as much as it does to your business strategy. For example, at Cherish, they crowdsource ideas: "We constantly reach out to our investors, advisors, board members, and our extended network asking questions, looking for ideas, and opinions," Sumit shares. By doing so, their team can break out of the echo chamber that often exists within most organizations and teams.

A Stage-Appropriate Framework for Startups: Interview with Cherish CEO Sumit Nagpal

Be Stage Appropriate in Funding and Beyond

Raising money for completely novel technology is especially hard. “Creating something new requires leaps of faith because it doesn’t achieve any scale or economies of scale until it actually works,” says Sumit. Still, Cherish Health has impressively secured over $30 million in funding. But they didn’t do it the traditional way. They started by raising capital on a SAFE (Simple Agreement for Future Equity) with wealthy individuals and corporate sponsors instead of venture capital—and continually increased their valuation through milestones and strategic investments. The team is now targeting a $30 million Series B round to reach a $200 million valuation.

“The biggest lesson we've learned is the power of doing more with less. That allows you to focus on what matters,” says Sumit. This helps the team stay focused on their competitive advantage rather than spreading their effort on features and services that may be commodities.

Being super disciplined about the capital you raise keeps you focused, but it requires thoughtful iteration and adaptation. “Our plan continued to evolve,” says Sumit, and it’s okay. During the development phase, Cherish Health persistently refined Serenity and its market strategy, discarding what was unnecessary and constantly looking for alternatives.

“Sometimes having too much money means you wind up doing things that you just don't need to at that moment,” says Sumit. With excess funds, you might start unnecessary departments, burn resources, and create a cycle of fundraising that doesn’t lead anywhere. That’s why he advises stage-appropriate fundraising: set your goals, raise just that amount, accomplish the goals, and repeat.

Cont...

A Stage-Appropriate Framework for Startups: Interview with Cherish CEO Sumit Nagpal

Be Stage Appropriate in Funding and Beyond

For Sumit, being stage-appropriate applies to most other aspects of the business, even to his mindset as the CEO. At the beginning of his career, Sumit didn't necessarily enjoy the process of raising capital, but that was something he had to overcome. He shares his thought process around fundraising now: "If this strategy is going to work out, I'm going to have to become the guy who loves this. And that's what I do now. You either become the person the moment calls for, or you bring in the person the moment calls for. It all boils down to what the moment needs and then going and figuring out how to do that."

Once you've actually achieved a certain target or milestone, you ought to celebrate, but look to rinse and repeat. Sumit explains the stages Cherish has been through: "First, it's been about the invention, actually making it work. Then, it's been about building it. Then it's been about scaling that and taking the cost out." All these stages require their own way of capitalization and have their own set of skills and priorities.

Sumit puts it this way: "There's got to be stage-appropriate funding, stage-appropriate strategy, stage-appropriate work, stage-appropriate boards, stage-appropriate everything. And it changes as you evolve. Once you've actually achieved a certain target and met a goal, you need to pivot to what's next, and that will require its own way of capitalization and it will have its own set of priorities." This is why for Cherish's next round of capital, Sumit envisions more traditional funding sources. This is because the company has now de-risked and developed its technology. Investors "can now touch and feel it, they can see our distribution agreements, they can see our readiness for scale and our manufacturing operations. And we've, one step at a time, peeled away at the layers of risk to a point where what's left is more about scaling a business than inventing nuclear fusion."

A Stage-Appropriate Framework for Startups: Interview with Cherish CEO Sumit Nagpal

How to Get Lucky: Listen and Be Open-Minded

“Listening is a constant activity,” says Sumit. “It becomes the culture and the lifeblood of the company.” And that’s what he’s building at Cherish. As Sumit puts it, they are “constantly inhaling input.” The feedback eventually makes its way into formal roadmaps, but ultimately, you want to have a lot of signal to see the patterns.

“Alarm.com has been one of the most incredible partners anyone could be lucky enough to have,” Sumit says. This collaboration with the leading smart home security provider has been instrumental in Cherish’s growth, bringing clarity, rationality, and data-driven insights. Cherish partnered with several other global corporations along the way, all well-aligned with its mission.

Effective partnerships are rooted in the reality of an opportunity, a shared technology, and a common vision. Currently building his fifth company and having made deals with many partners along the way, Sumit emphasizes the importance of authenticity in choosing partners. Investing time, building trust, and, most importantly, listening is absolutely crucial. You need to understand each partner’s journey, recognize where you can contribute to their success and yours, and be able to work together to achieve it.

After aligning around your goals and how to achieve them, maintain an open mind about your target market. For example, Serenity is currently a consumer-facing product—the insights the team gained from direct user interactions have been invaluable for perfecting Serenity. But for Sumit, just because you can succeed in the consumer market doesn't mean you shouldn't also consider the enterprise opportunity—even though it’s a very demanding market to sell in. Sumit says, “One of our investors is the largest health system in New York state. I have the largest private payer in the U.S. on my board, we've done an 18-month pilot with them that has gone tremendous and has proven some incredible value.”

One might say cultivating luck is a form of art in entrepreneurship. Some keys to Cherish’s succcess proved to be proactive listening, well-calculated partnerships, and maintaining an open mindset toward different opportunities. These three allowed Sumit to transform luck from a fleeting happenstance into a renewable resource that made it possible for the company to cultivate new avenues for growth.

Build for the User, Not the Spec Sheet

Interview with Phagenesis CEO
Reinhard Krickl

Reinhard Krickl

Preview

Under the leadership of Reinhard Krickl, Phagenesis is commercializing a neurostimulation system designed to treat dysphagia, a condition that impairs a patient's ability to swallow and can lead to complications like malnutrition and aspiration pneumonia. Reinhard shares insights on the importance of simplicity in design, what thorough market understanding truly means, and how he engages with stakeholders effectively. He also reveals the "market access checklist" he uses before entering the commercialization stage.

About Reinhard

Reinhard Krickl, CEO of Phagenesis, is an Austrian engineer with over 25 years of experience in medtech, specializing in neurology-based medical devices. After beginning his career in academia, Reinhard got his industry start with Medtronic in 2000, where he would eventually lead the company's efforts with deep brain stimulation (DBS) therapy across Europe. He is also an INSEAD-certified director and serves on several boards, chairing two of them.

Key Learnings From Reinhard's Experience

- It's easy to get caught up in adding features that don't necessarily translate to better usability or functionality. In medtech, the primary need is often the simplest device with an intuitive design. To achieve that, you need to thoroughly understand the market you're entering by interrogating your stakeholders with an open mind.
- Develop a deep understanding of your market, not just in terms of what your technology can do, but how it fits into the existing healthcare ecosystem. Understand the specific medical and economic environment, as structural dynamics, such as regulatory requirements, reimbursement policies, and standard of care procedures, can either hinder or facilitate the adoption of your product.
- Consistent investor communication is crucial for securing funding. When it comes to pitching, you have to be able to tell an engaging story. Use every opportunity, regardless of the outcome, as a learning experience. Analyze what worked, what didn't, and why. Continuously refine your pitch to ensure it not only tells the right story but also resonates with potential investors.

The Simplest Device is Often the Best Device

Despite his background in the complex field of deep brain stimulation (DBS), Reinhard has come to appreciate the value of simplicity.

As Conor Mulrooney, co-founder and COO of Phagenesis, who developed the Phagenyx system, always says, “What's important is not what your device can do, but what it can do for the end user.” In contrast to DBS, where different specialists handle the device implantation and patient care, Phagenesis benefits from a simpler treatment process: the same professional who sees the patient can apply the therapy and monitor the results, leading to a very direct feedback loop. Such simplicity not only makes the device safer but also increases the chances of market adoption. Reinhard observes, “Because the same person who is applying the therapy sees the outcome, this encourages the same user to then treat more and more patients because the positive feedback loop is very convincing.” While Phagenyx might seem underwhelming in its lack of advanced features, that simplicity is precisely what makes it safe and effective.

Reinhard’s philosophy is that “The simplest device is often the best device.” The device might be complex internally, but its external simplicity is what matters to the user.

In the early stages of the company, Prof. Hamdy used off-the-shelf lab equipment to validate whether electrical stimulation of the pharynx—the muscular tube in the middle of the neck—could effectively improve swallowing in dysphagia patients. By doing so, the team understood the mechanism of action before designing a product tailored to it. Then, the focus was on making the therapy as easy as possible to apply. The catheter is designed similarly to a nasogastric feeding tube, which speech pathologists and nurses are familiar with, so they can use it with minimal training. It works just like a standard feeding tube but with the added functionality of neurostimulation.

The point is to create a product that integrates smoothly into existing practices and yields efficacious clinical results. This way, you minimize disruption and maximize adoption. And the way to do that is to spend quality time with the end users—observing and listening with an open mind. Reinhard advises, “Just be in the corner of the room, watch what they're doing, take a lot of notes, because that's going to guide you to the best design solution.”

How to Change the Status Quo

Reinhard has had the opportunity to work on different novel technologies throughout his career. One of them was Medtronic's DBS therapy. "It's oftentimes really fun to work on this stuff, but also very challenging because you're trying to attempt to change the status quo," he shares.

For him, introducing a disruptive piece of technology starts by first understanding the audience and the market needs, and then the specific barriers that might hinder adoption. Reinhard eventually adopted a "market access checklist" built on three foundational pillars: structural barriers, therapy readiness, and physician adoption. Here's a rundown:

Structural barriers: Clearly identify the patient demographics that will benefit from the therapy and the indications you're solving for. Understand economic incentives like Diagnosis Related Group (DRG) codes and relative value units (RVUs). Then, you collect robust clinical evidence supporting the benefits of the therapy. This forms the basis of market adoption and shapes the clinical strategy.

It's important to note that these factors can have both positive and negative impacts. For example, in the U.S., in cases of severe dysphagia in stroke patients, if the patient cannot safely swallow by the second week of care, the standard procedure is the surgical placement of a Percutaneous Endoscopic Gastrostomy (PEG) tube. This invasive procedure not only extends the patient's hospital stay due to recovery but also brings additional risks and costs. Phagenesis offers an alternative that can prevent the need for a PEG tube, presenting a strong incentive for early adoption in the U.S. market. On the other hand, in Europe, patients with similar conditions can be discharged with a less invasive nasal gastric feeding tube, which translates to less of an immediate incentive for adopting Phagenesis' therapy.

Therapy readiness: Assess how easily the therapy can be integrated into current practices and how simple it is to train staff to administer it. The complexity of the therapy, complication rates, and safety risks can greatly influence its adoption.

Physician adoption: Understand who will apply the therapy, who prescribes it, and who refers it. Make their job easier, not more complicated.

Foster Relationships Through Compelling Storytelling

Phagenesis closed a substantial Series D round earlier this year of over $40 million. Reinhard says, “You're always fundraising, basically, and you should start long before you need the money.” You need to build relationships with investors who ideally follow not just your company's growth but also your personal development as a leader, observing how you meet or exceed the commitments you've set.

It’s also crucial to find the right financial partners who are not just interested in your sector but are also at the right stage in their fund's lifecycle to support you. Ideally, you want investors who are early in their fund lifecycle. Reinhard emphasizes, “That basically means the first two, three, or four years max of the specific funds.” This gives them ample time to engage with your growth and see a return on their investment before their fund closes.

In addition to these strategies, you must master another skill: storytelling. In the business context, this means distilling complex ideas or technology into narratives that are easy to understand.

When you’re fundraising, the first respondent you’ll encounter at a VC firm is often someone junior—an associate who preliminarily assesses your fit. The goal is to communicate your story so compellingly to this associate that they can relay it to the investment committee with the same punch. In essence, your job is to make this person able to pitch their partners on your behalf behind the scenes.

Mastering this is an art that takes time. It’s best to treat each pitch as a learning opportunity and never a waste of time. Reinhard’s tactic is to **start with low-stakes investors**, who might not be the perfect fit—they provide a rehearsal space to test your presentation in a real-world scenario without repercussions. Even if your pitch doesn’t land, you can refine it with the feedback you get without the pressure of losing a crucial investment opportunity.

The Right CEO Profile

“You need to ask yourself as a CEO, as the company enters new phases, am I still the right person for this role? Do I still have the best profile to lead and drive the company’s best interest? It’s probably the most difficult question because it's about yourself.” says Reinhard.

As Phagenesis gears up for scaling commercialization in the United States, Reinhard – based in Europe – discussed this challenging decision with the incoming Series D investors. "Would a CEO based in the United States be better suited?" Together they concluded that, under the circumstances, stepping down was best for the next phase of the company.

After handing over Phagenesis to his U.S. based CEO successor, Reinhard is looking forward to new opportunities later this year.

Managing Critical Risks in Early-Stage Medtech

Interview with Instylla CEO
Amarpreet Sawhney

Amarpreet Sawhney

Preview

Amarpreet Sawhney has developed advanced biosurgery technologies, leading to several FDA-approved products, including surgical sealants, spacers, and drug delivery systems. Today, he is the CEO of a few companies, including Instylla, which is developing polymerizing liquid embolics. These embolics can be used to shut down the blood supply to hypervascular tumors and control bleeding. Amar shares his frameworks on risk assessment for medtech startups, tips on clinical study design, and how to prioritize indications when working on platform technologies.

About Amar

Amarpreet Sawhney is a serial entrepreneur and renowned inventor with over 120 patents. Today, he's the CEO of a few innovative life sciences companies, including Instylla, Rejoni, Sealonix, and Pramand. His previous ventures include Ocular Therapeutix, Augmenix, and Confluent Surgical. Amar's FDA-approved inventions include ReSure Sealant and Dextenza for ophthalmology, DuraSeal for neurosurgery, FocalSeal for lung surgery, Mynx for femoral puncture sealing, and SpaceOAR for prostate cancer radiotherapy. Together, they have impacted over 8 million patients globally.

Key Learnings From Amar's Experiences

- Understanding and mitigating risks early on is essential. Don't take on too many risk factors simultaneously, especially those outside your expertise. Choose ideas with immediate, clear value propositions over those with long-term, cloudy outcomes. Creating a "wow moment" with demonstrable results will likely result in market pull vs. market push.
- When designing clinical trials, ensure your primary endpoints align clearly with the core function of your technology. You can have cascading secondary endpoints, but you must start simple and layer in sophistication only after your key goals are established.
- Pick your initial indication wisely. A strong start can set the stage for future success, while a misstep can hinder your platform's potential. Identify areas where there's a real, pressing need and a hungry market. Aim for something that has the potential to be disruptive, instead of implementing minor tweaks to existing solutions.

Managing Critical Risks in Early-Stage Medtech: Interview with Instylla CEO Amarpreet Sawhney

Picking the Right Battles

Amar has worked on many early-stage companies from their inception, so he knows quite a bit about starting off with limited capital. His guiding principle for the product development phase is understanding risks and uncertainties. He identifies six major areas when evaluating whether a medtech idea has legs:

1. Market understanding: A large, well defined market.
2. Technology validation: An impactful technology that is differentiated and can make a significant change.
3. Team capability: A go-getter team—in Amar's words, "not just a bunch of academics stumbling through the processes."
4. Financing: Capital to make it happen.
5. Clinical and regulatory pathway: A roadmap for your particular clinical pathway and funding to sustain it.
6. Reimbursement environment: Who will cover the cost? Insurance, government programs, or self-pay? Is there an existing reimbursement pathway? Do you need a new billing code? Does your product fit within an existing DRG?

Amar adds, "Sometimes you have to almost start from the sixth one first."

Obviously, tackling too many risks simultaneously lowers the probability of success. "If you were to apply 50% probability to the success of each one of these items, tackling more than three, you only get a 12%," Amar explains. You must target projects with immediate, clear value propositions without unnecessarily high risk exposure.

What makes a value proposition clear and immediate? Consider a sealant for a cerebral spinal fluid leak. You can see the leak stop right away. This makes the value proposition clear and immediate. On the other hand, it's hard to see immediate results with, say, a drug for Alzheimer's disease, as improvements in memory are subtle and can be influenced by natural aging. It can take years to determine if the drug is effective. Although the size of the market for Alzheimer's disease can justify the investment, if the market opportunities are similar, the wise choice to make, for the sake of example, is the sealant, according to Amar.

Amar also underlines that products addressing acute, unmet needs are more likely to succeed as the market will "pull" them or actively seek them out. You should aim to create a "wow moment" in practical settings and make the immediate impact of the product evident and impressive. As a startup that naturally lacks the marketing muscle of large companies, you must rely on strong market pull. If you follow Amar's advice and focus on desperate and obvious needs, you land in an audience that actively seeks your product rather than needing to be convinced to adopt it.

Logical Clinical Study Design

Amar’s approach to designing clinical studies has evolved significantly over the last 20 years. In the past, separate pilot and pivotal studies were the norm for him, often adding significant time to the development process. Now, he prefers adaptive studies that incorporate a pilot phase within the larger study. This allows for early data submission and feedback from FDA, resulting in faster progression into subsequent phases. “For some of my new companies, we do a pilot study on 10, 15 patients, report back to FDA, and we negotiate the overall protocol for the remaining patients.”

When setting up a trial, Amar emphasizes that the primary endpoints should closely align with the device’s main function. For instance, when developing an embolic, the primary endpoint should be something that directly reflects the device's purpose, i.e., cessation of blood flow. Endpoints that are further away from the device’s primary action, such as tumor regression, introduce more variables and noise, and in turn, reduce the likelihood of success.

Now, this doesn’t mean you can’t have cascading secondary endpoints. But you need to start with directly achievable goals and progressively move to more complex ones. It’s important to ensure that your primary and secondary endpoints are logically structured in a stepwise fashion.

The other thing that has changed over Amar’s 20 years in the industry is the landscape for conducting global trials. Europe was once a favored location for initial studies thanks to its regulations. But the recent MDR changes have altered things significantly. Amar now considers locations like Australia, New Zealand, Kenya, and Mexico, depending on the study’s specific needs and regulatory frameworks. Amar says, “You can get into first-in-man sooner in those other geographies.” Still, it's crucial to choose locations known for sound science and credible data when submitting to the FDA. “If you go and do it from some less established, less rigorous country, then the data may not be as believable,” he explains. Understanding each country’s regulatory advantages and challenges is critical to ensuring that the trial data is both credible and acceptable.

Trial success heavily relies on finding motivated clinicians who can effectively handle the device and are committed to the study. This is especially important in international settings, where challenges in logistics and communication can arise. A dedicated and capable investigator can make a significant difference in the outcome of the study.

Initial Indication Paves the Path

When you have a platform technology, picking the suitable initial indication to pursue, is critical. “If you have a platform and you pick the wrong place to start, your platform will be thrown out; the baby will be thrown out with the bathwater. Nobody wants to revisit it if you fail,” he explains.

When choosing an indication, Amar’s advice is to focus on areas with significant need and existing market demand. For example, Instylla’s first indication is to address hypervascular tumors. Amar saw a clear market need and the potential for substantial improvement over existing treatments. “People are willing to spend a lot of money on treating tumors, and there's already a fair amount of products being sold right there,” he notes.

Amar also warns against relying on incremental improvements, as they are often insufficient to change entrenched behaviors. A product that offers only slight improvements over existing solutions may struggle to gain adoption due to the effort required to change established practices. Instead, Amar advises aiming for significant advancements that clearly demonstrate superior outcomes.

Lastly, aiming for a truly compelling result is crucial for gaining traction in a competitive landscape. “When a doctor uses your technology, they should see immediate, impressive results and say ‘I’ve been cutting steak with a butter knife all my life, and you suddenly hand me a Ginsu knife’, that’s what you’re looking for,” Amar explains. Such an impact can capture the attention of practitioners and stakeholders and open the way to widespread adoption.

Validating Demand in Medtech

Interview with Pristine Surgical CEO Bryan Lord

Bryan Lord

Preview

Under Bryan Lord's leadership, Pristine Surgical has developed Summit, a fully integrated single-use, digital arthroscope with 4K resolution. Bryan shares the story of how he evolved his career to become a medtech entrepreneur and the lessons he learned along the way—about how to protect your competitive advantage, how to achieve market pull vs. market push, and the importance of collaborating with experienced mentors.

About Bryan

Bryan Lord started his career as a "deal guy" – originally a tech lawyer in Boston, and always involved in startups. With a wealth of experience across various technology sectors including semiconductors, enterprise software, and medtech, and spanning roles in corporate finance, technology licensing, and M&A, he's now President and CEO of Pristine Surgical. Before Pristine, Bryan also founded three venture organizations: New Venture Advisors, Orthopedic Venture Partners, and Innovation Alliance.

Key Learnings From Bryan's Experiences

- Building a strong competitive moat goes beyond securing patents. True differentiation lies in the unseen details—your trade secrets, software code, and unique manufacturing processes. While patents are valuable, it's the proprietary knowledge and execution that truly fortify your position in the market and give you a significant competitive advantage.
- Validate market demand before falling in love with your technology. Engage with potential stakeholders, including physicians, ASCs, administrators, and technicians, to refine your value proposition. Train your sight on simplifying complex processes to offer substantial operational benefits.
- To survive the medtech minefield as a startup, one of your most important tasks as a CEO is to surround yourself with good advisors and mentors who will help you refine the company's story. It's also imperative to own your circumstances and make the best of them, moving your venture forward by always maintaining momentum.

Building Moats Around Your Business

Others in the industry have attempted to achieve what Pristine finally achieved with Summit. But many eventually left the pursuit, concluding the technology was too nascent.

“The neat thing about where we are is that, when you cross that chasm onto the commercial side of it, you see a good moat, you see a long development pathway that means what you've done is hard. That, on this side of it, is a real strength,” shares Bryan.

What creates these moats are a few things. First, is motivation: not every player is eager to disrupt the status quo. It takes a perfect storm of risk capital, talented people, and effective execution to disrupt an industry with an innovation. For incumbent firms, there’s also an opportunity cost to developing new technologies, which Bryan observes, is often overlooked in the industry. Startups can focus 100% of their efforts on their new pursuit. “This is a project and a type of technology that docs have wanted for a long time and that the market has been very interested in,” he shares.

Second, and more specifically, Bryan believes that there are multiple ways to build your moat. The most obvious is patents. He also believes that for Pristine, trade secrets and software can arguably be even more important than patents. You can't solely rely on patents to maintain a technological and competitive edge. With a device with complex digital capabilities like Summit, you have the opportunity to keep sophisticated manufacturing techniques to yourself and develop significant advantages with software code as well.

Validating Demand in Medtech: Interview with Pristine Surgical CEO Bryan Lord

Market Pull vs Technology Push

There is a common pitfall in innovation: falling in love with your technology before verifying if there's actual market demand.

Bryan knows that it's very hard to spot a disruptive medical technology when it's at an early stage. "With that humility, your job is to look for market responses, pay close attention, and think soberly about them," he says.

As a doctor-founded company, Pristine rigorously validated the market need by engaging not only with potential users but also with ambulatory surgery centers (ASCs), administrators, staff, and technicians as well.

Getting to the right value proposition took iteration and feedback from the market. But Pristine's efforts to understand both physician and facility needs paid off. For example, initially, Bryan believed infection control would drive the adoption of their technology. However, it turned out that the real burden was the cost of the current technology, the complexity of service and sterilization of existing equipment, and inefficiencies that come with both. And ASCs are rigorous about process improvement, efficiency, and cost reduction, so Summit solves a fundamental need and interest for its customers.

This is why Pristine developed Summit, a device that eliminates 35 sterile processing steps and replaces it with just one: plugging in a new, single-use device. Such a simplification in workflow offers a substantial operational advantage and gives Pristine a great competitive edge. As Bryan elaborates, "What we're doing is delivering the same, if not higher quality image, but also at a lower cost and with a simpler process flow. It's truly disruptive to the marketplace."

Validating Demand in Medtech: Interview with Pristine Surgical CEO Bryan Lord

The Role of a Startup CEO

Medtech has its own specific challenges. For example, finding product-market fit is very different in comparison to unregulated environments where you can ship a product with bugs and iterate based on feedback. Here, the product must be trusted and meet certain regulatory standards before it's used in medical settings. In such a demanding environment, your most important job is to surround yourself with good advisors and a high-quality team.

Guided by their CCO Dave Carey’s "aim small, miss small" principle, the Pristine team staged a three-phase product rollout: first in-human use, followed by a limited market release, and finally a full nationwide launch. By doing so, they were able to refine the product while directly engaging with healthcare providers.

Fundraising also presents unique obstacles for startup CEOs, particularly in this current market. Bryan notes the importance of focusing on the substance rather than the aesthetics of fundraising. He says, “Ultimately, the most important thing is to be responsive to the circumstances that are around you." That means, for example, if the market is down by 50%, a down round might very well be the best option moving forward. “Keep it moving with headwinds, with tailwinds, with sidewinds, but keep moving down the track and leave the aesthetics to people who don't have anything else to do,” Bryan emphasizes. His parting advice to young entrepreneurs is simple, “Work from where you are today. Deploy that capital smartly and efficiently, build your syndicate, your relationships, lean into those investors, bring them on your board, and get to the next milestone for your next round.”

“Entrepreneurship is about creating and selling a vision, and enjoying that process,” Bryan adds. And he admits one probably doesn’t need multiple advanced degrees to do that. However, “Having that background gives you the confidence and courage to go do something that hasn't been done before.”

Identifying and Mitigating Key Risk Factors in Medtech Startups

Interview with Adona Medical CEO
Brian Fahey

Brian Fahey

Preview

Brian Fahey, CEO of Adona Medical, is leading the development of the Adona Interatrial Shunt, a smart implant designed to manage heart failure. This adjustable shunt, integrated with bi-atrial pressure monitoring, helps regulate blood flow between the heart's upper chambers and enables remote monitoring of patients. Brian talks about the importance of identifying and mitigating medtech's three major risk factors, how to assess ideas strategically, and how to approach investors and potential M&A transactions.

About Brian

Brian Fahey is the CEO of Adona Medical, a Shifamed-portfolio company he co-founded with Amr Salahieh. Before Adona, Brian founded a critical care company, Niveus Medical. He also spent time at J&J Innovation, specializing in drug-device products for oncology, and contributed to the leadership team at Arrinex, a neuromodulation company in the ENT space. An alumnus of the Stanford Biodesign Innovation Program, Brian holds a Ph.D. from Duke University.

Key Learnings From Brian's Experiences

- There are three major risk factors in medtech: product-market fit, technical feasibility, and clinical validation. When assessing your idea, the first thing to do is to try to talk yourself out of it. Once you reach a point where you can't argue any further, you may have something solid. From there, your goal should be to identify the areas with the highest risk factors and those that are quickest to mitigate.
- Pioneering innovations can be substantially rewarding, but the trade-off is they often demand longer, more complex clinical trials. Mitigate clinical risk by studying the pathways of predicate technologies to refine endpoints, patient populations, and more. True disruption requires a product that's not just better, but significantly transformational.
- Be selective in fundraising: Consider your sector, stage, and the size of the round you're after in order to focus your energy on your best prospects. Transparency and consistent communication build trust and enhance your brand in both fundraising and M&A processes.

Identifying and Mitigating Key Risk Factors in Medtech Startups: Interview with Adona Medical CEO Brian Fahey

De-Risking and Assessing the Viability of an Idea

In the medtech startup world, the name of the game is risk mitigation in order to secure future capital. But choosing the right battles is a challenge in itself. “Oftentimes people try to tackle the wrong types of risks,” Brian says, and this prevents entrepreneurs from having a clear way forward. For him, technical feasibility, clinical validation, and product-market fit are the primary areas of concern.

Product-market fit is a factor you need to address during your idea stage. As an entrepreneur who has spent considerable time with the Stanford Biodesign Innovation program, Brian has been able to develop a keen sense for legitimate gaps and whether an idea is worth pursuing. He advises, “You’ve got maybe five chances to do something in your entire professional career. Ask yourself, ‘Are you going to wager 20% of your career on this idea?’”

When evaluating an idea, his strategy is to try to talk himself out of it until he runs out of counterarguments. To follow his footsteps, examine the following five carefully: clinical need, potential market size, regulatory roadmap, reimbursement landscape, and the identity of potential buyers. A holistic view will provide a clearer picture of the opportunity.

Another rule of thumb Brian shares is to think with the end in mind. He evaluates, “If we are successful, who is this a must-have product for among the big strategics?” In Adona’s case, there is a significant number of global strategic players competing for new therapies in cardiology – specifically heart failure. Competition can lead to more lucrative exits in the cardiovascular sector, as well as provide the flexibility to work with partners that align with the vision.

Once you decide on an idea, you’ll need to move on to other critical aspects. Brian admits, that as a leader with a technical background, it’s easy to hyper-focus on technical risk. For example, jumping straight to a prototype. However, “Investors often don't worry about the prototype,” says Brian, “they're worried about market risk or about pricing or reimbursement.” That’s why it’s important to shift energy to risks that could impede progress – such as securing funding or building a regulatory roadmap – because, as Brian says, “Humans, with the right funding, generally have an ability to figure the technical things out.”

To be a fundable company, you need to understand your potential investors’ sensitivities and make sure early development mitigates the risks that optimize your chances of winning them over. Engaging with potential investors early is a good starting point to get to know them and their concerns. However, you need to be thinking about product-market fit and technical risks simultaneously. “It might make more sense to jump three steps forward and then work backward,” Brian adds, if that is what it takes to address the most critical aspects early on to “unlock your path forward.”

Identifying and Mitigating Key Risk Factors in Medtech Startups: Interview with Adona Medical CEO Brian Fahey

Learn from Others When Building Your Clinical Roadmap

Developing a pioneering device requires going the extra mile. And undoubtedly, your risk-reward tolerance comes into play. Brian shares, "I would not want to be on a very long clinical and regulatory journey unless I had the ability to learn something from others along the way." This is not advice per se, but a personal preference. For example, if your project requires a PMA pathway, you shouldn't shy away from it, given that you fully understand the timeline and implications.

Novel devices can be incredibly rewarding to work on, but they require a demanding clinical validation phase. Nevertheless, they are often the ones that move the needle the most in the healthcare industry, and even if you’re not going to conduct such trials, you should always be learning from those who do.

In Adona’s case, the fact that heart failure patients are particularly diverse makes study design more nuanced and challenging relative to some other sectors. That’s why Brian champions studying successful and failed projects to refine clinical endpoints, patient populations, and data collection strategies. This is one strategy he employs to help mitigate clinical risks, by learning from others' experiences.

However, Brian points out that while following in the footsteps of the pioneers in a therapeutic area can reduce some clinical or market risks, it often transfers risk to the technical domain. To make a significant impact, you need a team of top-tier innovators and a product that’s remarkably better than existing solutions. In his words, “We have to aim to be like 500% better than everything else. Because if you're only 30% better and five years late, that's not enough to disrupt the ingrained momentum of the pioneers in the space. If you're going to be truly late, you have to be transformational.”

Fundraising and Partnerships: Time is an Asset

Contrary to the common advice of "go talk to everybody," Brian champions a time-conservative approach to forging collaborations.

In his book, it's essential to be selective about who you talk to when raising capital. “Focus your time on being well-prepared for your best shots,” Brian advises. Your best shots depend on your sector, your stage, and the size of the round you’re after. “Narrow down your list to the people that you think are most likely to invest,” he suggests.

You should also pace what information you want to exchange at each interaction. “Your only goal on a first meeting is to get a second meeting. You're not getting a check that first day. So don’t give them 30 slides,” explains Brian. To build a strong foundation at the first meeting, it’s enough to show them you are credible, personable, relatable, receptive, and have a compelling insight into a problem that is real and have a solution that has potential.

Getting comfortable with risks and addressing them head-on is another key aspect. For Brian, it’s important to admit the risks objectively rather than trying to refute them. Being transparent about risks and discussing mitigation strategies strengthens investor confidence.

Brian also believes it can make sense to consider bringing in strategic investments if they adds value, such as access to facilities, partnerships, or physician relationships. Such investors can accelerate your company’s growth. When accepting deals, "Know what you're getting into," Brian advises. It’s crucial to be clear about any rights associated with the investment, such as board seats, observer roles, or walk-away clauses, and make sure they align with your goals and strategies.

Building credibility and trust is also paramount in M&A. A big global company will spend quite some time and effort on due diligence to see behind the curtain of your company. Still, everyone knows that they can’t surface everything. That’s why your trustworthiness is an important variable in this process.

On M&As, Brian shares, “It often feels like progress is slow until suddenly everything happens at once.” That’s why moving the needle by starting conversations as early as possible is important. Early introductions might not guarantee an acquisition, but they help in building relationships and trust. This also applies to investors. Communicating your milestones and delivering on them enhances your credibility, especially for younger entrepreneurs. Brian advises thinking about your company as a brand and engaging with your community and stakeholders with that mindset.

Nothing Matters as Much as Execution and Iteration

Interview with Wyndly CEO
Aakash Shah

Aakash Shah

Preview

Wyndly is a telehealth company that helps people overcome their allergies with personalized treatment plans that can be followed from home. Aakash Shah, the CEO, shares insights on simplifying healthcare access by meeting patients online and emphasizes the importance of learning by doing to accelerate personal and business growth. Aakash also talks about the power of storytelling when engaging customers and investors, and of how to leverage video-based social media to reach both consumers and decision-makers effectively.

About Aakash

Aakash Shah co-founded Wyndly, a telehealth company specializing in allergy immunotherapy, with his cousin, Dr. Manan Shah, and participated in Y Combinator W21. As the CEO, he's led the company from early inception through product development and eventual commercialization. Aakash holds dual degrees in Computer Science and Cognitive Science from the University of Virginia. Outside of Wyndly, he often presents on healthcare, telehealth, and startups, advises entrepreneurs, and hosts the Founders and Builders podcast.

Key Learnings From Aakash's Experiences

- Focus on streamlining healthcare processes while adhering to changing consumer behavior. Digital health is a ripe market where you can provide convenient, accessible solutions that align with modern consumer demands, and reduce barriers, be it financial, geographical, or logistical.
- Experiment constantly and learn by doing. Practical experience is invaluable; the nuances of any endeavor, including business, are best understood on the fly rather than through theory alone.
- Craft a simple, straightforward pitch to convey what you're doing and why it matters to your customers and investors. Don't use technical jargon; it's often confusing for your audience. Continuously refine your narrative based on your experience with how it lands. Storytelling is a skill that can be learned and it is vital for a CEO to attract customers, inspire a team, and persuade investors.

Nothing Matters as Much as Execution and Iteration: Interview with Wyndly CEO Aakash Shah

Simplify Healthcare for Broader Adoption

Patients often jump through hoops when seeking medical advice for minor issues. To see a doctor, the all-too-common scenario is to take time off work, endure long waits, pay copays, and then only get limited face-to-face time with a physician. That's why the first instinct for a vast majority is to turn to the internet, pointing to a shift in patient behavior.

Today's consumers are digital natives accustomed to the convenience of online services. As Aakash puts it, "People are taking health into their own hands. Everyone wants to be the guardian of their own health." He also observes, "What we're seeing is that the vast majority of people, the first thing they do is they Google their symptoms, or they ask ChatGPT, or they look on TikTok to see who else is experiencing this. So that's how most people find us."

Embracing telehealth and digital tools to provide accessible care has proven to be a winner in today's healthcare environment. Plus, platforms like Amazon have conditioned users to expect products and services delivered right to their doorstep. To catch this wave, Aakash's advice is to aim to streamline processes, cutting out the unnecessary steps that frustrate people. In Wyndly's case, after a lot of experimentation, the team streamlined the patient experience to three steps within which they got access to a personalized, at-home allergy treatment plan.

Digital channels can reduce the barriers to entry—whether they're financial, geographical, or logistical. By leveraging them, you can open your services to a broader audience. Convenience should be at the forefront of your offering so that it's easy for your users to integrate your solution into their lives.

Nothing Matters as Much as Execution and Iteration: Interview with Wyndly CEO Aakash Shah

Action Trumps Theory

For Aakash, taking initiative and learning by doing is paramount. "You can't learn how to cook by watching food TV," he notes, "There's just so much little nuanced bits and pieces that you really only get by doing." For him, harnessing the power of constant experimentation accelerates both personal growth and business development.

Aakash is all for trial and error to find the most effective business model for scaling. He explains, "It's constantly experimenting until you realize, okay, this is how the buyer wants to interact with what we're doing."

For example, Wyndly tested many models, including having patients talk to an online allergy consultant first, before they figured out, “People already knew how to buy diagnostic kits online.” For Aakash, this was an unlock, “The more confusion you can avoid, the easier it is for people to understand how you're going to get them from their current state to their happy place.” And this is how Wyndly decided that the first step in its customer journey was to ship the allergy test kit. Finding the optimal model is vital, as for Aakash, speed and agility are non-negotiables for success. "Nothing matters as much as how quickly you're able to execute and iterate," he says.

"You get to choose how quickly you want to learn. If you try something new once a month, you'll learn 24 things in two years. If you do something new every week, that's 104 things." He points out that consistent experimentation brings exponential benefits. The difference between 104 and 24 learnings is not linear; there’s also the compound growth you're gaining on top of it.

“The most fun part is it feels good to get better at stuff,” Aakash shares. “Just get started, and then you'll start getting better. And it doesn't matter because at the end of it, you'll be like, ‘Awesome. I now have skills I didn't know I had before.’"

Nothing Matters as Much as Execution and Iteration: Interview with Wyndly CEO Aakash Shah

A Simple Message Goes a Long Way

Raising capital, especially when you're just starting out, can be approached in many different ways depending on whom you're reaching out to and what your goals are. For example, you can secure funding from a bank, i.e. take on debt—although landing a $10 million loan isn't easy. Alternatively, you might consider private equity firms; they'll invest in your company, often buying 30–40% ownership. Venture capitalists are the more obvious route, but many entrepreneurs begin by reaching out to friends and family.

While it's true that fundraising is a numbers game, you have to have a good pitch. Aakash says that simplifying their message from "sublingual immunotherapy" to "permanent lifelong allergy relief," resonated immediately. "You've got 30 minutes with someone; you spend 15 teaching them how to pronounce "sublingual." Not quite what you want to be doing," he shares. This is a prime example of how confusion leads to churn. To engage both customers and investors, you need a clear and straightforward message.

It's also important to refine your pitch based on feedback, to improve how stakeholders see your value proposition. Aakash approaches pitching to investors like running a series of A/B tests: "You should be changing your story every five meetings. And then at the end of the 50th meeting, you've done 10 iterations. You've improved 10 times," he says. However, he's also quick to caution about reading the signs. If you've talked to 500 people and still haven't received a check, "Then you're probably doing something really, really wrong."

Aakash advises entrepreneurs to hone their storytelling abilities. "Get good at bringing people into what you're doing and why you want to do it. It's a learnable skill," he asserts. Effective storytelling is important in attracting customers, inspiring teams, and persuading investors.

Nothing Matters as Much as Execution and Iteration: Interview with Wyndly CEO Aakash Shah

Social Media is Not Just for Consumer Businesses

Over the past 20 years, we've witnessed an explosion of new marketing channels. SEO, Facebook, social media, podcast advertising—none of these existed in 2000. Yet, many in the B2B space hesitate to leverage these platforms. Aakash emphasizes, "Algorithms are really good at getting your message in front of the right person nowadays."

So, if you're talking to people, if you're selling to people, you need a social media presence. And not just any presence; it needs to be video-based. "Video is where we're currently seeing the ability to get real reach, especially on TikTok and YouTube Shorts," he notes. Once you see what's working, you can expand to LinkedIn, Facebook, and other platforms.

Aakash shares his own experience, "We were just trying to talk to patients and democratize the allergy visit experience. I literally just put a camera in front of my co-founder and said, 'I have a cat allergy. You're the allergist that I'm seeing. Tell me about it.' And we were just recording that and putting it out. And we naturally saw that this was getting hundreds of thousands of views. And now we're doing millions of views per year."

Creating content doesn't have to be a massive time sink. Aakash highlights that your investment on it compounds over time. Interestingly, many of their B2B customers started as individuals who engaged with their content. "They got an incredible experience, and then they're like, 'Okay, I'd like to bring you into my 20-provider practice,' or 'I'd like to bring you into my chain of private equity-backed offices.' And that's because decision-makers are still people," Aakash shares. Whether you're in B2B or B2C, your potential customers and partners are online, consuming content, and making decisions based on what they see and hear.

Building Resilience Through Rejection

Interview with Transverse Medical CEO
Eric Goslau

Eric Goslau

Preview

Eric Goslau is the co-founder and CEO of Transverse Medical and has a background rooted in commercialization. Transverse Medical is developing the Point Guard Cerebral Embolic Protection Device, designed to prevent strokes during cardiovascular procedures by protecting the brain from debris that can enter the bloodstream during these interventions. Eric shares how his background in sales helps him manage all aspects of the company, how fundraising cycles have worked for him, and his philosophy when it comes to product development: the enemy of good is perfect.

About Eric

Eric Goslau has 29 years of experience in leadership, commercial sales, marketing, product development, and entrepreneurship. He is the co-founder and CEO of Transverse Medical and a co-inventor of their Point Guard Cerebral Embolic Protection Device. At Transverse, drawing from his extensive experience, especially in commercialization, Eric oversees all aspects of the company, including fundraising, clinical planning, regulatory strategy, and product development. He has successfully raised over $14 million through innovative financing strategies.

Key Learnings From Eric's Experiences

- A technical background is great for a CEO, but sales experience adds unique value. It sharpens the skills needed for initiatives like creating clear, stage-specific execution plans, staying focused on measurable progress, and handling setbacks with persistence. Ultimately, a CEO’s job is to sell an idea—both to investors and the team.
- You'll get money from different places like family offices, high-net-worth individuals, and angel investors. Don't worry about sticking to traditional labels, just get the right amount of money for where you are. Having a lead investor who can back you across multiple rounds is helpful. This entity or firm can guide other investors and support you through each stage of growth. Ultimately, remember that fundraising is a cycle. Start each stage with the next in mind.
- Don’t get stuck aiming for perfection. Get into the market faster with a “good enough” device for early traction and investment. For that, move to clinical trials as soon as possible to learn and iterate based on real data. If you can, start with a simpler version to meet regulatory requirements, then refine and expand in phases to build momentum and attract support.

Building Resilience Through Rejection: Interview with Transverse Medical CEO Eric Goslau

Apply a Sales Mindset to Your Startup

Beginning with his first job at J&J after college and continuing through various roles in the medical device industry, Eric carried the bag in sales for most of his career. “Sales people make the best early-stage CEOs,” he says. This is primarily because it takes perseverance to follow through a sales cycle and see a project through to success.

Eric’s sales experience helped him understand the full process of taking something from concept to acceptance, and he applies this same mindset to fundraising, product development, team leadership, and managing investor relationships. He shares, “Those of us who sold understand that there's a cycle that you have to go through,” pointing to the practical benefits of sales knowledge in managing a company’s growth and strategy—where it’s paramount to build a step-by-step process.

In sales, “99% of the time, you hear ‘no’,” he shares. However, constant rejection builds your ability to persevere. He says, “As an early-stage CEO, there are many types of CEOs, and one of them is going out and raising funds. But a lot of times, as an early-stage CEO, you're put in a position where not only are you fundraising, but you're also running a process to develop a product. You're leading the team and helping that aspect of it. Maybe you have early shareholders or investors. Now you have to manage them. So now you have public relations in there. All of those tie back to the sales cycle experience: running that process at different stages, being able to address people's concerns and gripes.”

Running a company is no different. Most aspects of a sales cycle is transferable to fundraising. Working with investors, especially non-VC investors, requires patience and the ability to explain things simply, a skill honed by years of managing varied client perspectives. At the end of the day, what you’re selling is an idea.

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Your Fundraising Rounds Aren't Always Clear-Cut

Although having a step-by-step approach is useful, it's important that you remember early-stage fundraising doesn't always follow a neat, structured path like "seed," "Series A," and so on. It's often a combination of funds from different sources, like friends, family, high-net-worth individuals, and family offices. Each of these comes with its own challenges and timeline.

"When you get a lot of investors at different levels, small checks versus medium checks to big checks, it's hard to get shareholders to a point where they understand where you're going and where you need to be," says Eric. That's why his advice is to focus on securing the right type and amount of funding for each stage rather than getting tied to traditional round labels.

Eric chooses between VCs versus other options based on the amount of capital he needs. For larger raises in the range of $50 to $150 million, especially for multibillion-dollar markets, venture capital is often the best route. However, for smaller raises, you'll need to get creative. "The sources are out there, but you have to dig deep to find them."

For example, if you only need $500,000 for early animal testing, don't go collecting 50 small checks. Eric suggests, "Try to find that one angel investor who can fully fund it or combine it with non-dilutive funding. It's going to be a lot easier to manage."

He also notes that for smaller-scale projects with a more limited pathway—say, raising around $10 million for a specific technology—you're likely better off targeting angel groups or family offices instead of VCs.

For non-VC investors like angels or family offices, Eric suggests keeping explanations simple, as these investors may not have medtech backgrounds. Patience is key with non-VCs, as they often require more hand-holding to understand the tech. Also, securing a lead investor early on—someone who can provide continuous support through multiple rounds—is always beneficial.

To survive the fundraising cycle, Eric's strategy is to plan each funding round with the next one in mind—raising capital is an ongoing cycle—guide investors through this process, and secure their commitment in a methodical fashion.

Building Resilience Through Rejection: Interview with Transverse Medical CEO Eric Goslau

Know When a Device Is Good Enough

Transverse was founded in 2012, with seed round funding to kick off the development of Point Guard. After testing about 50-60 prototypes, they built the first-generation device and conducted a first-in-human clinical trial in Germany. However, adjustments were needed. By 2019, the team began redesigning the device, but the pandemic in 2020 slowed things down. Thankfully, a non-dilutive grant from Colorado and inside investor support helped keep them afloat while they finalized the Point Guard 2.0 design.

The team is now refining the device. Their goal is to learn from past challenges and ensure Point Guard meets clinical and FDA standards, especially given that the only approved device in this space, Sentinal, was approved despite failing its primary clinical trial endpoint. This caused skepticism among some physicians about the feasibility of the idea. Appointing Dr. Ian Meredith, a former Boston Scientific Chief Medical Officer who played a key role in the acquisition of Claret Medical's Sentinel device, as a board director has been a big win in boosting Tranverse's credibility and sharpening their insight as they approach their pivotal trial.

During this phase, it's crucial that the team focuses on a streamlined, achievable goal. As a co-inventor, Eric has seen the risks of aiming for perfection in device development, which he believes can slow down progress. "The evil of good is great," he says.

It's essential to quickly introduce a device into clinical testing. Simulations can't fully replicate human use, a lesson Tranverse learned from its first-generation Point Guard device. So it's crucial to see how the device performs in real-life conditions.

Eric recently helped found and joined the board of Secure Closure, a medtech startup developing a device for large-bore vascular closures. With high failure rates in existing products like Abbott's Perclose and Teleflex's MANTA, the need for this type of device was clear, but reaching the ambitious goals they set was going to be challenging. Eric advised a step-by-step approach: secure a 510(k) or PMA clearance on a simpler version first. He believed this would expedite market entry, build momentum, and attract early investors. And it proved true: by phasing development, the team could gain traction while preparing for a more advanced version down the line.

Now, the team is applying the same strategy to Point Guard 2.0. Eric insists, "Get it in, test it as fast as you can in all the different types of models, but you just won't know what you have until you put it into a human. If you can get there quick and fast, then you can start that process again." He also adds,"At the end of the day, time is money. If you don't have any money, you're going to run out of time real quick."

How to Build a Delightful Experience for Your Customers

Interview with Somnee CEO
Tim Rosa

Tim Rosa

Preview

Tim Rosa is the CEO of Somnee, a company developing wearables based on personalized neuroscience to improve sleep quality. Tim shares insights on building and scaling successful brands based on real customer experiences, keeping messaging clear, and using brand strategy as a business foundation. He also shares why solid data and clinical evidence in OTC products are essential and how he generates value out of ongoing research.

About Tim

Tim Rosa, CEO of Somnee, is leading efforts to improve sleep through personalized neuroscience. Previously, he was the CMO at Fitbit, where he played a key role in establishing the health and fitness wearables category. He built the organization's global marketing function, contributing to the sale of over 140 million devices in 100+ countries. Additionally, he helped drive the company's IPO and its eventual $2.1 billion sale to Google. Tim has also advised and worked with major brands like Electronic Arts, 2K Sports, ESPN Video Games, and Jasper Health.

Key Learnings From Tim's Experiences

- Building a brand as you build your company is crucial. To do this, put yourself in your customer's shoes and analyze available data, such as forums, customer support logs, and other feedback sources. Develop a product roadmap that addresses any friction points you discover. Throughout the process, ensure your messaging is as clear and simple as possible.
- A brand is more than just marketing; it's the foundation of your business strategy. Building a brand means creating an experience that connects with your audience. To achieve this, focus on what matters to your customers. Stay in tune with consumer trends, like the shift toward being more informed and empowered, and align your decisions accordingly. Make your brand strategy central to everything—from product design to business choices—to build loyalty and drive growth.
- Clinical evidence in OTC categories can help you create something that truly changes the game within your industry. Aim to build products that solve real problems in a measurable way. Invest in ongoing R&D to refine and adapt your solution continually and prioritize data accuracy and clinical evidence to gain trust and differentiate yourself from competitors.

How to Build a Delightful Experience for Your Customers: Interview with Somnee CEO Tim Rosa

Be the End Customer

When Tim took the helm at Somnee, he set out to rebuild the company from the ground up—revamping everything from the brand to the product itself. For Tim, brand isn't just about marketing; it's the core of business strategy, and it influences everything—product development, team recruitment, decision-making, and every touchpoint along the customer journey.

"There's definitely no silver bullet when it comes to giving a company a complete makeover," he explains. "For me, I become the end customer." Tim emphasizes, "No matter what industry you're in—whether it's consumer, enterprise, or healthcare—you need to understand who your end customer is and what their experience is like."

He emphasizes, "It's about understanding your friction points, eliminating them, and bringing delight and joy to the user experience. Sometimes it's as simple as beautiful design, communicating things in a way that's very easy to understand, and adding more in layers because obviously, you're going to have people that want more information."

When Tim joined Somnee, he saw that the team was talented, but there was a lot of friction—especially in how they communicated the service. He knew that in healthcare, simplicity, accessibility, and clarity were essential. So, his first goal was to make the user experience simple and intuitive while explaining complex technology in a way that everyday consumers could easily follow, understand, and internalize. "I told them, 'Look, my mom in Michigan needs to understand what we're talking about.' That's the bar. It's about communicating to everyday consumers without diminishing the science behind it," he explains.

So, how do you become the end customer? Tim starts by analyzing data, identifying points of frustration, and then building a product roadmap to address these issues. With his OTC device experience, he immerses himself in customer feedback—reading forums, customer support logs, and other sources of user-generated information.

Tim stresses the importance of truly understanding the end customer as a foundation for any successful business. Whether you're an executive, a scientist, or in another role, it's crucial to know your audience—whether that's a consumer, an employer, or another stakeholder.

It's not enough to have groundbreaking technology; you need to marry it with brand and product experience to make a real impact. Tim believes that achieving this balance is what ultimately separates game-changing products from those that fall short. As he puts it, "You need to win hearts and minds."

How to Build a Delightful Experience for Your Customers: Interview with Somnee CEO Tim Rosa

Win Customers Over with a Holistic Brand

A brand's purpose is to build an emotional connection with customers. Tim's experience at Fitbit only serves to illustrate this important lesson—the company perfected the device's user experience, which ended up driving word-of-mouth marketing and helped them build a loyal community.

Fitbit owes its success to the team's decision to make the user experience simple and relatable. By focusing on featuring the simple and familiar goal of taking 10,000 steps a day, they created an easy-to-understand and motivating message. This approach helped them stand out against competitors like Nike, whose FuelBand used the less intuitive concept of "fuel points," which many consumers didn't understand. As Tim puts it, the clarity and simplicity of Fitbit's message gave them a strong advantage in the market.

To build a strong brand and business, Tim advises entrepreneurs to start thinking about PR early and to plan strategically. "I plan in three-year cycles," he says. "Anything beyond that is just guessing." He believes that having a clear vision and a structured timeline is crucial for building momentum and achieving long-term goals.

For Tim, brand is the foundation of all decision-making, from product development and engineering choices to recruiting a team and eventual go-to-market commercialization approaches. It's important to make your brand the focus from the beginning, so that it guides all aspects of growth.

To win the hearts and minds of your customers, it's essential to follow trends in evolving customer behavior. The shift has accelerated, particularly after the COVID-19 pandemic. One unexpected positive outcome for OCT devices was how it opened people's minds to science and the validation of technology. In healthcare, there's now a growing trend of empowered consumers taking control of their health. With the popularity of long-form health content and influencers like Andrew Huberman and Peter Attia, it's clear there's a strong demand for scientific information—provided it's presented in an accessible way. This means companies must prioritize educating consumers with validated, accurate information that aligns with their health needs and experiences. Tim says, "I'm working to change how people think about neurotech and neuroscience because there's so much more education and research available now."

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Win Customers Over with a Holistic Brand

The shift in healthcare is now focusing on the consumer. It used to be about securing deals with employers or healthcare providers, but today, you need the end consumer or employee to use and benefit from your product," Tim explains. This consumer-centric approach is why he puts the brand at the center of everything.

When Tim took the helm at Somnee, he relocated the manufacturing. He reasoned that, from a business perspective, having manufacturing close to the U.S. offers advantages in speed, cost, and development, and allows teams to be on-site quickly. This decision also benefits Somnee's image. Tim says, "Personally, if I'm putting something on my head, I prefer it not to be made in China—it's just my preference. I believe the quality of working with contract manufacturers outside of China is noticeably different."

How to Build a Category-Changing Product

One path to building a company is to launch a product that fits into an existing ecosystem. Alternatively, there are those who aim to change the entire industry with their solution.

What sets Somnee's device apart from the others in the market is that it's a closed loop: it both diagnoses and treats. "There are very few products in the world that are closed-loop and provide this level of outcome," Tim says. This is precisely what he saw in Somnee—a product that offers real, measurable results and can change the sleep industry. He envisions a future where, instead of doctors prescribing sleeping pills, they prescribe Somnee. Over 600 doctors have already recommended the device, and the goal is to move beyond consumer wellness products to healthcare solutions that physicians can formally prescribe.

On his way to eventual FDA approval, Tim is now focused on building a product based on reliable, precise data. He notes that while earlier generations of wearables like Fitbit, Oura, and Whoop raised awareness about general health, they often struggled with accuracy. "The painful part of 1.0 is bad data in, bad data out," he explains. Whereas with Somnee, the focus is on delivering clinical-level data that consumers and healthcare providers can trust.

Somnee's technology has been developed by neuroscientists over seven years. Unlike sleeping pills, which can affect various parts of the body and brain, Somnee treats sleeping problems without side effects. To be able to do that, collecting accurate data is paramount. Tim emphasizes that where you collect data matters greatly. For example, heart rate measurements are more accurate when taken from the chest. Similarly, for sleep, Somnee uses a headband because sleep is managed in the frontal cortex of the brain. By positioning the device on the forehead, Somnee ensures it captures the most relevant and precise data for neurostimulation. "We're using clinical-level technology because we need that level of accuracy to perform the therapeutic neurostimulation," Tim explains.

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How to Build a Category-Changing Product

By prioritizing clinical evidence, Somnee sets itself apart from competitors and builds credibility. And to stay ahead, the company invests heavily in ongoing research and development. With four sleep labs in their California office, Somnee replicates the same technology used in Dr. Matt Walker's lab at UC Berkeley. "We're constantly conducting research and trials—whether it's on personalization, different stages of sleep, or different consumer cohorts," Tim shares.

For entrepreneurs, the takeaway is clear: staying innovative means committing to constant learning and adaptation. Investing in research, testing, and understanding your customer's specific needs leads to more precise and compelling solutions. It also positions your brand as a leader in innovation and expertise.

The Power of Quality Data

Interview with CorVista CEO
Don Crawford

Don Crawford

Preview

Don Crawford is back on Medsider. After he led Sapheon to a $238 million exit, Don joined another startup: CorVista Health. CorVista is developing a non-invasive medical device that uses advanced machine-learned algorithms to detect heart conditions, such as coronary artery disease and pulmonary hypertension, right in a doctor's office. Don talks about the need for focus in startups, the importance of precise data collection, and the value of transparency and respect within teams. He also shares his approach to hiring and building a top-notch group of people.

About Don

Don Crawford's career began at Medtronic, followed by progressively senior sales and marketing roles at Guidant Corporation, Ventritex, and Intermedics, including overseeing a $100 million international cardiovascular business. Known for his results-driven leadership and focus on team collaboration, he's now president & CEO of CorVista Health. Previously, he led Sapheon, a venous device company, to a $238 million acquisition by Covidien.

Key Learnings From Don's Experiences

- In the startup world, there's no room for inefficiency. Spreading your efforts too thin can be risky. Choose a focus—one that aligns with your company's strengths—and direct your efforts there.
- Precise, clean data is the backbone of any data-driven technology. With high-quality data, everything else—whether solving a problem or training an algorithm—becomes much simpler. Keeping things in-house gives you the control you need to design trials carefully and ensure accuracy and reliability at every step. It also lets you connect directly with potential users, gathering valuable insights, building trust, and refining your technology based on real-world feedback.
- Transparency and mutual respect among team members are crucial for an efficient startup. Be open about goals, challenges, and successes, and show respect for everyone's ideas and contributions. When hiring, prioritize flexibility and growth. Start by bringing in consultants or part-timers to assess their fit before committing to full-time roles.

Don’t Spread Your Research Thin

CorVista’s early work was processing physiological signals—electrical, hemodynamic, and imaging—with a team of data scientists who had no prior experience in medical devices. They collaborated with a doctor, gathered signals, and, on a modest $2 million budget over two or three years, demonstrated that their technology could potentially detect abnormalities in the body.

Achieving this in such a short time and with limited resources was no small feat. Don credits this success to the team’s commitment to remain focused. While the company holds patents in cardiology, neurology, and oncology, they chose to focus on cardiology, because, in medtech, resources and time are limited. As Don puts simply,” The key to a small company is to stay focused.”

So, how do you decide how to narrow down your focus? For CorVista, their research pointed the way. The team identified coronary artery disease (CAD) as not only one of the most critical global health issues but also an area where their technology could make a significant impact. Despite decades of treatment options, CAD remains a leading cause of death globally. The efforts in reducing mortality rates have unfortunately made limited progress. This lack of impact is what drew CorVista’s attention to CAD. Don explains, “If you take the energy, the three-dimensional electrical energy produced by a heart, you can detect signals that are being released from the body; we could interpret those signals and see a difference between a disease state versus a healthy state.”

This focused approach also improved resource efficiency. If Don hadn’t chosen to concentrate on a single indication, the team wouldn’t have been able to demonstrate hard evidence of their technology’s capabilities with just a $2 million budget.

Moreover, a focused strategy helps maintain regulatory and quality standards. At CorVista, implementing a quality management system early on—specifically tailored around their target indications—ensured consistency and compliance throughout product development. Don emphasizes, “From the time I joined CorVista, everything was done through a quality management system, almost as early as employee number two or three.”

In short, by zeroing in on cardiology and building a solid foundation early on, Don was able to develop a powerful, targeted solution with limited resources. Thanks to their concentrated efforts, CorVista filed 180 patents, with 81 already granted—a substantial base of intellectual property built from the early days of AI and machine learning in an emerging field.

Commit to Clean Data for Clearer Diagnostics

"The key is that in data science, poor data is like garbage in, garbage out. But if you put in really great data that you collected, you know exactly where it came from and that it was clean and clear, then you can actually obtain or decipher information about that data very well," Don shares. This focus on data quality has been central to CorVista's mission of creating a technology that accurately diagnoses CAD and PH.

You don't have to be a data scientist to appreciate the value of high-quality data. Without it, you risk compromising the accuracy and credibility of your findings. To avoid this, CorVista made a decision early on—they managed their trials internally instead of outsourcing to CROs. Don explains, "We did so internally because the data was so important; we had to make sure that data was pristine." Keeping this function in-house gave CorVista full control over the data collection process, and the integrity and precision they needed. This also allowed CorVista to build direct relationships with end users—physicians and clinicians who would eventually rely on their diagnostic system. Working closely with their future users, CorVista could gather valuable feedback and insights while strengthening trust and understanding within their target market.

The sheer volume and precision of the data collected were also critical. Through FDA-sanctioned clinical trials, CorVista gathered information from over 11,000 patients, building a robust dataset to train and refine their algorithms. This extensive database allowed them to differentiate between healthy and diseased states with impressive accuracy. "We can detect significant coronary disease…and the lack of significant blockage with a 99% negative predictive value," Don states. This high level of accuracy is only achievable because of the well-structured, high-quality data they collected.

Today, the CorVista System delivers immediate, actionable results. In a doctor's office, the test takes only three minutes, with no invasive procedures or radiation involved. Don explains that their system collects over 10 million data points per patient and processes these through cloud computing to generate a report that helps physicians diagnose conditions like CAD and PH. The simplicity and speed of this workflow make advanced diagnostics accessible even at the primary care level.

In short, when it comes to your approach to clinical studies, make every effort to maintain control over the process to guarantee the quality of data. Managing trials internally ensures not only clean, reliable data but also fosters direct engagement with end users. By being on the ground with it, you gather valuable insights, build trust, and refine your technology based on real-world feedback. With quality data and user engagement in place, everything else—whether solving a problem or training an algorithm—becomes much easier.

How to Build the Right Culture for Your Company

For Don, the foundation of CorVista's culture is transparency and respect. He says, "If you're a shareholder, you have my respect, and you certainly have our transparency." This approach extends beyond investors to team members as well. By valuing employees' ideas and being transparent about the company's goals and challenges, CorVista has created an environment where people feel involved and appreciated, which fosters the collaboration and innovation startups need to thrive.

Building this culture, however, requires more than just talking about values; it demands consistent action. Don emphasizes the importance of engaging your team actively, especially in a small company. "I've always been really, really strong about the teamwork requirement," he says. "It didn't matter what function you were—clinical, regulatory, or research—we were all working together to solve the problem."

These values are reinforced through regular team meetings and workshops, even when working remotely. "We've been using Zoom for meetings long before it became the norm during COVID," Don says. In every interaction, he ensures the team knows the company's values are more than just words on a wall. When issues arise, they're addressed directly. "We would take a time out and actually talk about it, bring someone over to the side," he adds. Such a hands-on approach ensures that problems are resolved quickly, and everyone stays aligned.

This proactive engagement also extends to hiring. Don uses a phased approach, which was especially helpful in the early stages of the company. Instead of immediately bringing on full-time employees, CorVista initially hires consultants to test whether they are a good fit for the long term. For example, they brought in a legal advisor as a consultant to handle early legal work. After a period of successful collaboration, he transitioned into a full-time role. This method allows CorVista to manage resources efficiently while ensuring that new hires align with the company's culture.

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How to Build the Right Culture for Your Company

In a startup environment, where resources are often limited, employees need to be flexible and take on multiple roles. To accommodate this, Don has implemented a "player-coach" system. New hires start as hands-on contributors—"players"—and as they gain experience, they evolve into leadership roles as "coaches." This system keeps the team lean and adaptable as the company scales.

Integrating functions within this lean team structure is another priority. At CorVista, clinical, marketing, and operations work closely together to ensure that product development is aligned with both customer needs and regulatory requirements. "Clinical had to be embedded in the team," Don notes, highlighting the importance of collaboration across departments. This setup allows CorVista to respond quickly to challenges and continuously refine its product, maintaining efficiency and alignment throughout development.

Move Fast Early, Slow Down When It Counts

Interview with Neuspera CEO
Steffen Hovard

Steffen Hovard

Preview

Steffen Hovard, CEO of Neuspera, has spent over 30 years in medtech. At Neuspera, his team is developing a novel, less invasive device that uses neuromodulation to treat conditions like overactive bladder. Steffen talks about confirming market fit before investing, building an early network for key hires and investors, aligning development speed with each phase, engaging with regulators early, and taking a steady, relationship-driven approach to fundraising.

About Steffen

Steffen Hovard spent two decades at Coloplast, where he held various senior leadership roles that contributed to the company's growth, including the acquisition of a Minneapolis-based urology business. With deep expertise in the space, he has consistently driven growth and innovation across multiple functions, positioning himself as a leader of leaders in medtech, with board roles at Medical Alley and AdvaMed. Today, he's driving forward Neuspera, a company developing advanced neuromodulation technology for urology applications.

Key Learnings From Steffen's Experiences

- In medtech, development timelines can stretch over a decade. Before pouring resources into an idea, it's crucial to confirm its relevance and market potential and then get the right people on board.
- Align your pace with the development stage you're at. Move fast in early development but slow down and be thorough in the clinical stages. Then, be ready to go full throttle when commercialization approaches. Start thinking about market access from the start, as early decisions can impact later commercialization. Bringing in the right specialists upfront for coding, coverage, and payment planning can smooth the path to market.
- Take a steady, strategic approach to fundraising. Perfect your pitch and refine your story to make a strong impression. View each investor interaction as a long-term relationship rather than a one-time opportunity; stay in touch, and show consistent progress. Above all, bring energy and resilience to each pitch—persistence can turn a "no" today into a "yes" tomorrow.

Move Fast Early, Slow Down When It Counts: Interview with Neuspera CEO Steffen Hovard

Lay the Groundwork for Success

Running a medtech startup is a huge undertaking. Timelines often stretch over a decade, and the resources required are intense. One of the foundational steps, Steffen explains, is ensuring the market opportunity is large enough to justify the commitment. “If the problem you’re trying to solve isn’t really big enough to be attractive, it will be really hard to raise capital,” he notes. In any startup—and especially in medtech—it’s essential to make sure that solving this problem truly matters. Steffen suggests asking yourself, “What happens if you don’t solve it? Will the world really be in a worse place?”

Once you validate the market need, getting the right people involved early on can help pave a smoother path forward. “Having that nice balance between somebody with the external customer perspective and somebody who thinks about the technology, being able to marry that up early on, I think will minimize the number of stumbling blocks that you will come across,” he shares. Bringing in industry experts—particularly physicians—on board from the start provides invaluable, real-world insights and adds credibility as the product eventually reaches other stakeholders.

“The world is big, but it’s very small at the same time,” Steffen notes. A handful of key stakeholders often form the core opinion pool in a field. When you have relationships with these insiders, he adds, “Whoever checks into your idea, they will go to those people.” And having these people on your side makes gaining traction easier when it’s needed most.

Of course, none of this matters without a solid technical foundation. From his experience at Neuspera, Steffen knows that proving the technology works is essential. Having a founder or lead engineer who can take charge of technical validation is invaluable. “The work that our founder did with the fundamentals was just amazing,” Steffen shares. And that solid foundation is exactly what he’s building on today.

Move Fast Early, Slow Down When It Counts: Interview with Neuspera CEO Steffen Hovard

Get the Pacing Right

One of Steffen's main takeaways is understanding and committing to the time medical device innovation takes, especially the clinical and regulatory pathways. Medical device companies, particularly those with Class III products like Neuspera, have to contend with long timelines and extensive regulatory scrutiny. "Accept the time it takes," Steffen emphasizes.

In the early technology development phase, moving quickly is paramount. During this stage, you can experiment, iterate, and even fail fast to arrive at a working product. However, once the clinical and regulatory processes come into play, the pace needs to change. "Be thoughtful, be cautious when you get into the clinical work and when you get into the regulatory work," he explains. This stage isn't one where you can "move fast and break things." For Steffen, rushing to hit milestones is a mistake; instead, he focuses on maximizing value during the maturity process as the milestones approach.

Steffen also suggests thinking about market access as early as possible because decisions made during the development and clinical phases can impact commercialization down the line. "You might actually be able to capture information during the clinical trial that can either help you or make your market access more complicated," he advises. Bring in the right specialists early on for coding, coverage, and payment mapping.

Once regulatory milestones are achieved, in Steffen's words, "Prepare to accelerate on the back end."

One of the most effective ways to approach regulatory work thoughtfully is by engaging with FDA from a relationship-building perspective rather than treating the process as a checklist to complete. Understanding their concerns and engaging them proactively—rather than skipping steps in hopes of moving faster—is the best strategy. This way, you lay a strong foundation, which can smooth out future interactions with the agency.

While specialized consultants can play a valuable role, Steffen advocates for developing internal teams in regulatory and clinical areas rather than relying solely on external help. With a core team that understands both the product and the clinical challenges it addresses, a company can present itself more confidently and navigate regulatory and clinical hurdles with consistency and depth.

Move Fast Early, Slow Down When It Counts: Interview with Neuspera CEO Steffen Hovard

Bring Energy to Your Pitches

Fundraising takes serious energy, and it's easy to drain yourself by pushing through without a strategy. Steffen suggests slowing down and taking mindful steps when seeking capital to make sure your story is rock solid. When pitching to investors who hear dozens of ideas, your message needs to hit hard and fast. "Slow down, make sure that you get the story right, and pressure test it a couple of times before you go out," he emphasizes. For a story that stands out, focus on three elements: a big opportunity, a clear and easy-to-understand differentiation, and a well-defined pathway to market and potential exit. To keep momentum, Steffen advises, "Be thoughtful of building it out in a time frame where you don't wear yourself out because it takes substantial time, and you have to invest just a ton of energy. You have to be super present for every single one of them."

But there's more to fundraising than just perfecting the pitch. For Steffen, building relationships with investors over time is invaluable. He points out that it's rarely a "yes or never" situation, so it's essential to view initial meetings as the start of a journey. "Maybe they're not really in a Series A mood at that point, but maybe come back in the B round and then make sure that you build on a positive story that you established in the beginning." In other words, stay in touch, demonstrate your progress, and keep proving the value of your vision—persistence can pay off in unexpected ways down the line.

Tap into industry networks and associations, such as AdvaMed, to help build connections and credibility, especially if you're new to medtech. Not only do these organizations give you exposure to key stakeholders, but they're an easy entry point for building industry ties and getting your name out there among relevant players. Leverage warm introductions wherever possible. A direct referral from a trusted connection can go much further than a cold message. "Make sure that you have people on your side who are prepared to put in a good word for you," he advises.

Finally, Steffen brings a classic sales mindset to fundraising, a skill he honed in his early days doing cold calls. The key is resilience, he shares, "Even if you get a 'no' many, many times, know that the next one may be the 'yes' you're looking for. You don't need a lot of them. You just need a few." It's about bringing energy to each pitch, even after the hundredth one, because the right investor might be just around the corner.

About the Author

A self-described medical device and health technology enthusiast, Scott is the co-founder and CEO of FastWave Medical, a venture-backed cardiovascular startup developing differentiated intravascular lithotripsy (IVL) systems for calcific artery disease, a market valued at over $9B.

Scott is the founder of Medsider and was named one of MD+DI's most influential medtech voices to follow in 2024. His work with Medsider has been featured in publications like Forbes, Mass Device, MedCity News, and MD+DI.

Scott is also the founder of Joovv, one of the leading photobiomodulation brands in the world, and 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.

About Medsider

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- Streamline your R&D efforts.
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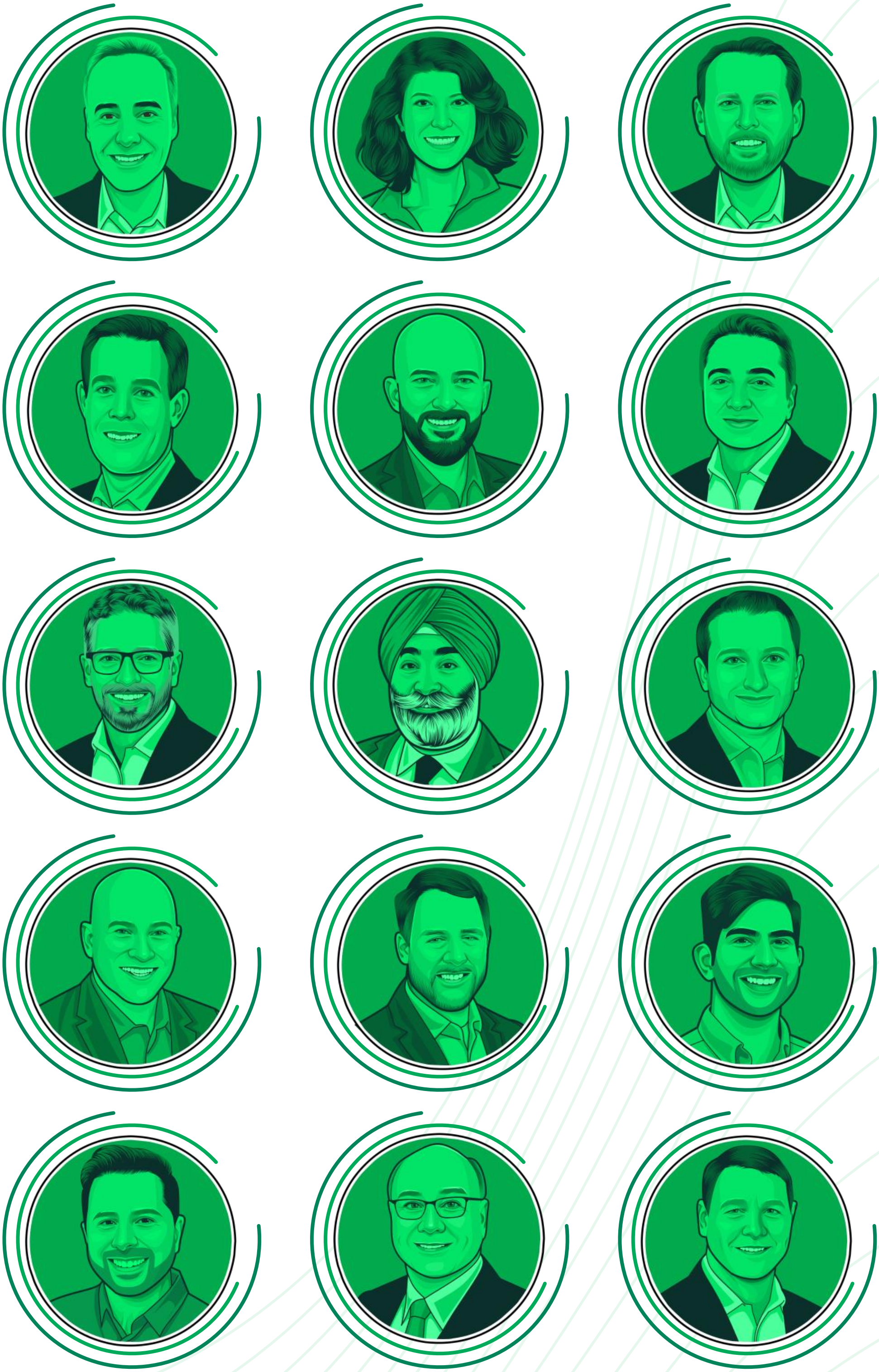

SCOTT NELSON