MEDSIDER

VOLUME V

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF ALIVECOR, KANDU HEALTH, PROPRIO, ORCHESTRA BIOMED, MAGNOLIA MEDICAL, AND MORE

SCOTT NELSON

For more information, address Medsider, PO Box 780637, San Antonio, TX 78278.

For information about special discounts for bulk purchases, please contact Medsider at hello@medsider.com.

This book is brought to you in part by FastWave Medical.

TABLE OF CONTENTS

INTRODUCTION

Medtech is an exciting arena where you can experience the rush of a scientific breakthrough, the dizzying highs of funding success, as well as the gut-wrenching lows of unexpected pitfalls. Here, innovation doesn't come with an instruction manual.

That's why we're back with Medsider Mentors: Volume V — your backstage pass to the journeys of those who dared to bridge the gap between science fiction and accessible healthcare.

I'm hoping these mentor compilations serve as a front-row seat to a seasoned entrepreneur roundtable. If you haven't had the chance to explore our previous volumes, make sure to check them out. In each volume, you'll find a diverse crew of leaders who've overcome hurdles and achieved success in fundraising, broken through regulatory challenges, and persisted through development hiccups; veterans who'll share the inside scoop on navigating investor skepticism, mastering the art of the pitch, and turning brilliant ideas into tangible medtech solutions.

Gabriel Jones, CEO of Proprio on Doing Well by Doing Good

Gabriel Jones's CV is a choose-your-own-adventure novel across continents and industries. His vast experience includes engineering roles in Asia, high-stakes mergers on Wall Street, and tackling global healthcare challenges with the Bill & Melinda Gates Foundation. Today, he is redefining surgical precision with AI through his latest venture, Proprio. We talk about building an ecosystem that fosters collective success, navigating the ever-shifting fundraising landscape, and harnessing the power of storytelling as a leader.

Kirsten Carroll, CEO of Kandu Health on Giving Patients Agency

A quarter-century in the trenches of neurovascular disorders has honed Kirsten's expertise to a razor's edge. Kirsten tackled product life cycles and navigated industry giants like Boston Scientific and Stryker. However, her heart's calling has always been helping stroke survivors, which inspired her to found Kandu Health, a startup poised to revolutionize post-stroke care. Kandu is transforming the healthcare landscape by building a holistic ecosystem that empowers survivors and significantly improves their journeys to recovery. Kirsten talks about how innovation doesn't equal invention, the secrets of process-driven leadership, building diverse talent pools, and understanding the true needs of all stakeholders.

INTRODUCTION

Parag Gad, CEO of SpineX
on Bridging Academia and Industry

Parag Gad is an academic who saw the transformative power of science firsthand and refused to let life-changing technology languish in labs. After a 12-year tenure at UCLA, Parag ventured into entrepreneurship by founding SpineX where his team has secured FDA's Breakthrough Device Designation for two non-invasive bioelectricity devices, one for adults with neurogenic bladder, and the other for children with cerebral palsy. Parag delves into the challenges and triumphs of transitioning into medtech entrepreneurship, how to manage the steep learning curve, and alternative funding strategies beyond traditional venture capital.

Dr. David Albert, Founder of AliveCor
on Consumer-Friendly Medtech

Dr. David Albert is a physician, scientist, inventor with several patents to his name, and even a YouTube sensation! His journey took him from the hallowed halls of Duke University to the University of Oklahoma, ultimately leading to the creation of the groundbreaking Kardia brand under his company, AliveCor, which stands at the forefront of personal EKG technology. Dr. Albert shares how having realistic expectations helped his transition from academia to the entrepreneurial world, how he utilizes available resources effectively, how to build a network of allies, the game-changing effects of showing up with a prototype, and his bold approach to consumer marketing.

Shyam Natarajan, CEO of Avenda Health
on the Future of Medtech

Shyam Natarajan finished his PhD in Biomedical Engineering at UCLA and remained there as a postdoctoral scholar in the Department of Surgery before taking a remarkable leap into the business side of healthcare. As the founder and CEO of Avenda Health, he is at the helm of an innovative venture that leverages artificial intelligence and state-of-the-art imaging to transform prostate cancer diagnosis and treatment. Shyam delves into the critical aspects of understanding market needs for medical products and services, how he builds prototypes to get all stakeholders on board, and shares insights to fundraising in the complex and challenging landscape of medtech.

INTRODUCTION

Bill Colone, CEO of SinglePass on Connections that Create Companies

Bill Colone is a seasoned serial entrepreneur who has raised tens of millions of dollars for his medical device ventures over the past several decades. His extensive entrepreneurial experience, coupled with his 13 U.S. patents and background in Chemical Engineering from Arizona State University, position him as a proven veteran in the industry. Today, he is the CEO and Chairman of SinglePass, an innovative company in the field of electrocautery devices for deep tissue biopsies.

Bill shares his journey as a serial entrepreneur, his take on the venture studio approach with practical and risk-averse strategies on capital efficiency and goal-oriented planning, and how his network has been an invaluable asset throughout all of his varied startups.

Dr. Alberto Rodriguez-Navarro, CEO of Levita Magnetics on Embracing the Scientific Approach

Dr. Alberto Rodriguez-Navarro is a skilled surgeon and medtech visionary with multiple patents to his name. He is the current CEO of Levita Magnetics, a startup pioneering the next wave of minimally invasive surgeries with its groundbreaking magnetic technology.

Dr. Rodriguez-Navarro advocates for the scientific method in product development — from hypothesis formulation to MVP creation and iterative improvements based on real-world feedback. He shares his insights regarding the nuances of transitioning from clinical practice to the helm of a startup, the importance of understanding regulatory landscapes, and his firsthand experience in various roles, like sales, to better grasp the business dynamics of Levita Magnetics.

Kelly Roman, CEO of Fisher Wallace on Following Unconventional Paths

Kelly Roman, the co-founder and CEO of Fisher Wallace Labs, is an exemplar of how diverse paths can lead to groundbreaking achievements in medtech. He has made a remarkable transition from literature and marketing into the world of medtech — inspired by his work on the graphic novel adaptation of Sun Tzu's The Art of War. He now spearheads Fisher Wallace Labs' mission to knock down the stigma against mental health treatments and to help sufferers with a wearable neurostimulation device that targets issues like depression, anxiety, and insomnia.

Kelly delves into the challenges and triumphs of bringing a novel mental health treatment to the market and reflects on the importance of adaptive thinking, the power of embracing unconventional paths to regulatory approval and capital fundraising, and the critical role of focusing on the end-user experience in product design and clinical trials.

Angus McLachlan, CEO of Liberate Medical on the Benefits of a DIY Attitude

Angus McLachlan, co-founder and CEO of Liberate Medical, leverages his engineering prowess and healthcare insights to fuel innovation in medtech. With a solid foundation in mechanical engineering and a Ph.D. focused on electrical muscle stimulation for spinal cord injuries, Angus's journey from the University of Glasgow to standing at the helm of Kentucky-headquartered Liberate Medical is a story of passion and perseverance. At Liberate Medical, Angus and his team are developing a non-invasive neuromuscular electrical stimulator that is transforming the care of ventilator-dependent patients by preventing muscle weakening.

Angus sheds light on the essentials of developing a medtech startup, emphasizing the importance of a focused and resourceful approach in the early stages, as well as the necessity of deeply understanding the technology to navigate development and regulatory challenges.

Cecile Brosset, CEO of Sonio on AI-Driven Medtech

After sharpening her strategic skills at leading firms such as Bpifrance, Cecile Brosset now heads Sonio, a pioneering startup that merges AI with obstetric ultrasound. Cecile unveils the complexities she encountered while navigating the uncharted terrain of AI integration in medtech. She emphasizes the significance of an iterative approach in both team and product development, and the crucial role of an in-house regulatory group when traversing a sophisticated field like AI. Reflecting on her fundraising experiences, Cecile highlights the importance of understanding varied audiences, maintaining open communication with mentors, and the necessity of building lasting relationships for the continuous growth of an organization.

Deanne McCarthy, CEO of SwiftSure on Embracing Curiosity

As a former critical care nurse, Deanne McCarthy's understanding of challenges and patient needs in ICUs has been crucial in directing her company, Swiftsure, towards creating meaningful healthcare solutions as its CEO — specifically, improving oral care in ICU patients for a better recovery outlook. Her story is one of resilience and the relentless pursuit of pragmatic answers.

Deanne discusses the significant influence of accelerator programs in her journey, her strategy for leveraging mentors into active startup participants, and her approach to navigating the complexities of product development and regulatory challenges. She highlights the importance of harnessing curiosity, effective networking, and building strong partnerships in driving startup growth.

David Hochman, CEO of Orchestra BioMed on Building Creative Partnerships

David Hochman, founder and CEO of Orchestra BioMed, is a trailblazer in the medtech industry. With an impressive background in healthcare entrepreneurship, he has created a legacy of leading successful startups through significant mergers, acquisitions, and fundraising triumphs.

David delves into his risk-reward-sharing approach at Orchestra, and how this unique business model fosters collaboration over competition and propels high-impact technologies. We discuss the intricate process of aligning interests with global medtech giants and the critical importance of long-term strategy in driving sustainable industry innovation.

Sahil Diwan, CEO of SafKan Health on Designing Consumer-Loved Products

Sahil Diwan, the co-founder of SafKan Health, brings a fresh perspective to medtech entrepreneurship, combining his computer science background with youthful inventiveness. His journey from a young coder to a medtech CEO is driven by a personal connection — his brother's struggle with impacted earwax, which led to the creation of OtoSet, the first automated ear-cleaning device approved by the FDA.

Sahil shares his unique perspective on consumer-driven medtech, the power of design in product development, and the importance of learning from real-world data. We talk about building a business before focusing on fundraising, and how OtoSet's success on social media helped catapult the device into the spotlight.

INTRODUCTION

Greg Bullington, CEO of Magnolia Medical on Pioneering New Standards

Meet Greg Bullington, the innovative CEO of Magnolia Medical Technologies, who has significantly improved the accuracy of sepsis tests through the company's groundbreaking device - Steripath. With a rich background spanning biotech, healthcare, and software, Greg has skillfully guided Magnolia to not only create a new category with FDA, but also achieve widespread adoption of Steripath throughout the United States.

Greg discusses the critical role of robust clinical data in establishing new medical standards and how Magnolia continues to conduct studies to validate Steripath's efficacy, even after regulatory approval. He shares insights on using this data to influence entities like FDA and other government bodies in public health, and the strategic importance of maintaining and leveraging these relationships for long-term success.

Dave Rosa, CEO of NeuroOne Medical on Getting Initial Capital, Fast

With a three-decade tenure in the medical device industry, Dave Rosa is currently the President and CEO of NeuroOne, a company making strides in neurology with its minimally-invasive thin film electrode platform. With an impressive career at major strategics like C.R. Bard, Boston Scientific, and St. Jude Medical, Dave has been at the forefront of marketing, product development, strategy, and commercialization. His expertise has led to several medical device patents and the raising of over $200 million in capital markets. We discuss the vital tactics for securing initial funds, leveraging professional networks to connect with potential investors, and the importance of assembling a strong, experienced team — including board members.

Each of these conversations has been a treasure trove of insights that's enriched my journey as I steer FastWave Medical forward. I trust that this volume will offer you as much inspiration and practical knowledge as it's offered me.

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 hear and learn from next.

Best wishes,

Scott Nelson

Founder of Medsider
Co-Founder and CEO of FastWave Medical

Doing Well by Doing Good

Interview with Proprio CEO Gabriel Jones

Gabriel Jones

Preview

Gabriel Jones is a man whose journey covers diverse industries — from engineering in Japan to Wall Street mergers and acquisitions. The culmination of his hard work and versatility, however, came with his current venture, Proprio, a company redefining surgical precision through AI. Gabriel's eclectic, impressive background has equipped him with a unique framework for creating a thriving startup ecosystem, successful capital fundraising, and using public relations to his favor.

About Gabriel

Before co-founding Proprio in 2016, Gabriel's career spanned engineering, law, finance, and philanthropy across the world. He studied engineering at the University of Washington before joining Tase Kensetsu, a major civil engineering and manufacturing firm in Asia. He then moved to Wall Street to work on large-scale mergers and acquisitions for high-profile clients like AT&T and Google. After returning to Seattle, he collaborated with the Bill & Melinda Gates Foundation on global healthcare initiatives. Today, he is the CEO of Proprio, a revolutionary medtech startup aiming to improve surgical precision with AI-powered technology.

Key Takeaways From Gabriel's Experience

- To truly create a long-lasting impact, your company needs to function as a platform that benefits all its partners. Don't think of your startup as a solitary entity but as a part of a larger system where your success can uplift others.
- Raising capital is a challenge that tests a founder's skills, patience, and ability to adapt. Take a phased, incremental approach to growth, focus your efforts, implement timing cushions, and put yourself in the shoes of the investors you're pitching to.
- Marketing communications, or PR, is not an afterthought or a checkbox to tick off — it should be an integrated part of how you envision leadership, both as a tool for inspiration and a framework for building a sustainable road for your company's future.

Doing Well by Doing Good: Interview with Proprio CEO Gabriel Jones

Don’t Be Afraid to Create Your Own Ecosystem

Despite financial hardships during his childhood, Gabriel has created a multifaceted career that would baffle most LinkedIn algorithms. He views himself as an “active player,” always striving to be at the forefront of knowledge and innovation. "We have a lot of privilege just by being in this country at this moment in time with technology available to us," Gabriel reflects. "That's not enough to win the game, but you're in the game. Now you want to stay in the game."

Gabriel emphasizes the importance of not just being a product — but an ecosystem. Seattle, home to tech giants like Amazon and Microsoft, is also where Proprio is based. But Gabriel thinks that the Pacific Northwest ecosystem is missing a major medtech hub. "There's no Intuitive Surgical. There's no Medtronic here," he notes. And he doesn’t hesitate to believe he can create this ecosystem himself.

Yet, geography doesn’t have to be destiny in the 21st century. Gabriel notes that in today's virtual world, even smaller teams can harness global talent to create something remarkable.

"They're getting teams up in India of 25-50 software engineers. And then you have five people here in Seattle that are punching above their weight," he says. Size isn’t necessarily equal to impact. Even smaller teams can leverage existing technological tools to make waves in their domain.

However, even if you manage to break through, there are nuances to building a sustainable environment. To truly create a long-lasting impact, a company needs to function as a platform that benefits all its partners. Your startup is not a solitary entity but a part of a larger system where your success can uplift others. As Gabriel explains, "If you want to build an ecosystem, you have to build a platform company, which means your products have to make other products sing."

When it comes to the elephant in the room — a lucrative acquisition or an exit — Gabriel advises caution. Such endgames come naturally to companies that create value and remain committed to innovation. "Keeping your eye on the long-term goal is the way to drive that event anyway," he suggests. Don’t get lost in the grandeur of a lucrative exit; continue building something sustainable and impactful. A company that can execute on "true innovation and commercialization very well and does it many times" is most likely to succeed, according to Gabriel.

Doing Well by Doing Good: Interview with Proprio CEO Gabriel Jones

Raising Funds, Raising Stakes

Gabriel has navigated through multiple fundraising stages from pre-seed to Series B. He began by funding his startup through his own savings account, which was "rapidly dwindling" at the time. His initial boost came in the form of a $50K grant, which subsequently allowed him to raise a $1.6 million pre-seed round.

Gabriel's approach to fundraising is preparing for the unknown. "One funny thing about being a founder and CEO is if you're doing interesting, challenging things, then you're not prepared for the next job. Not fully. And the same thing is true for financing," Gabriel says. Any financial strategy that worked before won't suffice in subsequent rounds; you'll need to improve and iterate on your previous playbook with "more creativity, more hustle, more grind."

Gabriel also offers some solid pragmatic advice. In terms of timing, he says: "If you have a number in your head about how long it's going to take you to do it, add at least 50%. If you thought it was six months, it's minimum nine months." Unexpected delays, obstacles, and challenges are inevitable in any fundraising process.

On the tactical side, Gabriel stresses the need for a strategic approach. He recommends meeting only with investors who have a recent track record in your field. "Don't spend your time with people who haven't written a check in your space in more than two years. It's not worth your time". Your interactions with potential investors should be as impactful as possible, and that means doing your homework and being selective.

On another note, Gabriel makes an interesting point about understanding the investors. Founders must realize the precarious situation that venture capital firms are in. When VCs commit to investing in your startup, they need to justify this commitment to their own investors. Understanding the dynamics of this "capital call" can help you present a more compelling case.

In summary, Gabriel circles back to the importance of resilience and adaptability. The journey from Series A to Series B, in his words, is just "one more hurdle that you need to cross." As the hurdles keep coming, you need to "celebrate the ticket to play" while looking for the ticket to win.

Doing Well by Doing Good: Interview with Proprio CEO Gabriel Jones

Turn Publicity Into Promise

Conveying your startup's mission to the public is not just a marketing strategy but also a way to inspire and engage with the community.

For Gabriel, the fascinating technology and the cutting-edge science behind Proprio are just one part of the whole picture. It's also another link in his "life's work" of solving problems for humanity. That said, public storytelling is an essential part of his leadership strategy and mission for a greater purpose.

We can all agree that there are practical benefits of good PR. For Gabriel, the company culture and products are a reflection of the message he wants to communicate. He argues that a well-crafted public relations strategy not only influences the kind of talent that is attracted to the company but also shapes the quality and focus of the feedback you receive from the market.

He is also acutely aware of the challenges that come with being in the public eye. Yet, he accepts the risks of saying something controversial or facing failures publicly as inherent aspects of the journey.

Being so outspoken in the market comes with its own challenges, but rather than shying away, Gabriel embraces these challenges with what he calls the "10-second rule," which allows the team to briefly savor victories and learn from setbacks without getting bogged down. Being able to move on quickly both from celebrations and missteps, enables them to stay focused on the larger picture.

Over the next year, Gabriel and his team plan to capitalize on a pretty unique opportunity to deliver on the immense promise the company holds. This means that the next two-to-three years are about converting years of market-building efforts and technological advancements into tangible improvements in surgical interventions.

Redefining Stroke Recovery

Interview with Kandu Health CEO Kirsten Carroll

Kirsten Carroll

Preview

Kirsten Carroll is redefining post-stroke care through her startup, Kandu Health, which offers a comprehensive set of services to improve the well-being of stroke survivors and, consequently, their care partners. From her unique perspective on innovation to her emphasis on a multi-stakeholder approach, Kirsten shares invaluable lessons on breaking down monumental challenges and fostering a culture of teamwork.

About Kirsten

Kirsten is a medtech veteran specializing in neurovascular disorders with nearly 25 years of experience in the field. She holds a degree in biomedical engineering and dual master's degrees in business and public health. Kirsten has held strategic roles at industry leaders like Boston Scientific and Stryker before joining Imperative Care and co-founding Kandu Health. Her startup focuses on revolutionizing post-stroke care and enhancing the quality of life for stroke survivors through tech-enabled healthcare services.

Key Takeaways From Kirsten's Experience

- To optimize for a fulfilling career in medtech, you need to continuously develop your skill sets. Take a layered approach to your decision-making, build a robust foundation of knowledge, and then trust your gut.
- When taking on significant initiatives, adopt a process-oriented approach, break down big challenges into manageable, winnable steps, and build a team around you that is fully aligned with the mission.
- Innovation goes beyond mere invention. Focus not just on your technology but on understanding the needs of multiple stakeholders, including end users and their care partners, healthcare providers, and payers.

Redefining Stroke Recovery: Interview with Kandu Health CEO Kirsten Carroll

Knowledge Leads to Courage

One of the hallmarks of a seasoned professional in medtech — or any industry, for that matter — is the ability to make informed decisions. Kirsten's career path is a testament to her resourcefulness in that regard. And it's definitely not an innate characteristic — but a habit acquired through hard work: building a structured approach to realize opportunities.

Moving from giants like Boston Scientific to a startup like Imperative Care is a big move. Kirsten's clarity, passion, courage, and strong network of female mentors in medtech helped smooth the transition.

On the topic of courage, Kirsten offers this sage advice: "Courage can't be unfounded. It has to be grounded in experience and knowledge."

Before making substantial career leaps, it's crucial to develop a rock-solid foundation in your domain. In Kirsten's case, she spent a significant period at Boston Scientific honing her skills in full lifecycle product development, from the nuances of design control to downstream commercialization. She shares that remediating a product line while maintaining market share was an incredible challenge that helped her become a master in her domain.

Kirsten is also a strong believer in running a "great process," that is, gathering enough information to be able to make good decisions before moving on to execution. Curating all the relevant particulars before taking action helps to hone your skill sets and carries you forward in your career. But Kirsten also applies this notion on a corporate level by building great processes for organizational decision-making.

For example, she makes a point about the importance of understanding the purpose behind gathering clinical evidence: "As you're developing a clinical trial strategy, you have to start with understanding what you need the evidence for."

Different stakeholders have different needs and require different kinds of evidence to be convinced. Kirsten notes: "The more you understand what's going to get people to adopt your technology, the better you can design trials that work."

For those adventurous souls willing to venture into startups, the challenge changes from managing an existing organizational structure to creating a new one. Kirsten reflects, "It's one thing to be in operational leadership in an organization that's been around for 40, 50 years, but it's another thing to build something from scratch, build your processes, build your systems, figuring out your company and your culture."

In a startup environment, you're not just a manager or an employee: you're a culture creator, operator, and organizational architect, all at the same time.

Redefining Stroke Recovery: Interview with Kandu Health CEO Kirsten Carroll

A Blueprint for Organizational Decision-Making

Navigating the labyrinthine world of organizational leadership is no small feat, and Kirsten has done it masterfully – thanks in part to her process-oriented mindset. She tells us that tackling enormous projects isn't about facing the entire mountain at once; it's about breaking it down into "winnable steps."

But let's not overlook another key element: the people you surround yourself with. Kirsten can't stress this enough, and she doubles down by saying: “A huge part of the reason that we've been able to create Kandu, and we fundamentally couldn't have done it without this, is that we had a board and investors that were wholly bought into this mission. This isn't something you're going to do if you're not surrounded by the right people.”

In her recent experience with the spin-out of Kandu from its parent company, Imperative Care, this principle of alignment proved essential. It was all about careful planning and connecting to a broader mission of changing the course of stroke recovery.

“Our healthcare system is so fragmented,” she underlines, “If you're going to work with payers, you've got to consider the range: commercial plans, Medicare Advantage Plans, Medicaid Plans, employee benefit plans. No one person can be an expert in all of this.” That’s why you need to build a team that can do this with you.

Kirsten's advisory board is particularly noteworthy. She's assembled not just industry experts but also people who are directly affected by the problems Kandu aims to solve — stroke survivors. "Their perspectives provide invaluable insights into our clinical strategy and trial design, which helps shift mindsets about the solutions we offer," she elaborates, emphasizing the innovative nature of their services in contrast to others in the market. At Kandu, stroke survivors are included in decision-making on topics as diverse as what products to develop, how to write and present privacy policies, and who to hire.

While Kirsten acknowledges the value of establishing an exciting vision, she also emphasizes the importance of breaking it down into incremental, achievable milestones to build confidence and knowledge. With Kandu, this involved various phases. Initial exploratory spending eventually evolved into a fully independent company.

Kirsten reveals that their journey began with addressing a fundamental problem in stroke care: delayed hospital visits due to a lack of care-seeking. People experiencing stroke are often not in pain or aware of the urgency of what has happened. Over time, as they worked directly with stroke survivors, Kandu’s focus expanded to post-acute (or post-survival) challenges and the necessity of offering not just an app but a comprehensive set of healthcare services.

Redefining Stroke Recovery: Interview with Kandu Health CEO Kirsten Carroll

A Calculated Approach to Innovation

In the bustling world of medtech entrepreneurship, innovation often becomes synonymous with invention in the sense of a new device or a breakthrough technology. However, Kirsten offers a refreshing perspective that nudges us to rethink these buzzwords: "Innovation is not just about creating something new but about applying it effectively to solve significant challenges."

This is something she emphasizes in her yearly lectures at the University of California Berkeley, and it's clear that Kirsten isn't merely paying lip service to this idea — she's living it through her work at Kandu Health.

What separates Kandu from the pack isn't the technology they utilize but the profound understanding of their target audience and their needs. "We aren't digitizing something that's already being done in a brick-and-mortar setting, or trying to alter it for the better. We are rallying around a problem that needs to be solved, taking that journey, and figuring out where to go," as Kirsten puts it. This isn't innovation for innovation's sake but rather purpose-driven problem-solving.

To that end, Kirsten and her team are focused on understanding the needs of stroke survivors, care partners, healthcare providers, and payers. It's a multi-stakeholder approach that aims to demonstrate and deliver tangible value to critical players in the healthcare ecosystem.

"There was never a 'We need a digital health play,' or 'We need a services play.' It was, 'We need to serve the biggest problem and team up with that community and understand what a solution would look like.'" By focusing on well-designed clinical trials and real-world applications, Kandu is succeeding in convincing stakeholders of the service's undeniable value.

From Academia to Medtech Entrepreneur

Interview with SpineX CEO
Parag Gad

Parag Gad

Preview

Parag Gad understands both sides of the coin — the research-intensive academic world and the rigorous standards of healthcare regulation. With SpineX, he's marrying the two, aiming for a transformation in spinal healthcare. Parag delves into the intricate journey of transitioning from academia to entrepreneurship, securing non-traditional funding, and the role of regulatory milestones in building a reputable healthcare brand.

About Parag

After 12 years at UCLA, Parag founded SpineX to turn cutting-edge science into life-changing devices. The FDA has granted Breakthrough Device Designation for two of SpineX's non-invasive products aimed at improving the lives of adults with neurogenic bladder conditions and children with cerebral palsy. The company has raised $3.6 million in equity financing and has also secured non-dilutive funding from various government agencies. With ongoing multicenter clinical trials and plans for future enrollment, Parag is steering SpineX toward a new frontier in bioelectric medicine.

Key Learnings From Parag's Experience

- Moving from academia to entrepreneurship brings a whole new set of challenges. Be prepared for a steep learning curve as you navigate the various operational, financial, and technological hurdles. Surround yourself with experienced and passionate people and commit to clinical evidence to inform your decision-making. Most importantly, never stop learning.
- Building credibility is crucial for long-term success. For SpineX, FDA's Breakthrough Device Designation for its flagship products has certainly helped. Explore possible routes to demonstrating trust and remember that establishing legitimacy early on can have a lasting impact on your company's success.
- There are viable alternatives to venture capital for securing funds for your startup, such as grants, for example. While submitting them can be meticulous and time-consuming, it's not impossible to master. Illustrate both the social impact and commercial viability of your product to raise the odds for securing this type of non-dilutive capital.

From Academia to Medtech Entrepreneur: Interview with SpineX CEO Parag Gad

Transitioning From Academia to Entrepreneurship

Parag's motivation to shift from academia to entrepreneurship was that he discovered a technology goldmine that actually benefits people in significant ways. "Limiting it to a lab environment where we could treat 5, 10 individuals a year didn't seem right," says Parag.

However, transitioning from academia — or any other field — to entrepreneurship comes with its unique set of challenges, as Parag notes. For instance, bringing a product to market is significantly more complex than publishing a paper. It demands diverse skills, from R&D to fundraising. While learnings from academia or other fields can be adaptable, the key to success is acknowledging your limitations and seeking expertise to fill those gaps.

Another great way to break down the challenges of bringing a product to the market is to think about the minimum viable product (MVP) in the context of your startup. Referring to Peter Thiel's book Zero to One, Parag advises budding entrepreneurs to ask themselves, "What is the MVP, what do I need to do to get to a product that I know will work?"

Then, you can start thinking about capital efficiency, resource allocation, and engaging with potential investors. "We probably would laugh at ourselves as to what we put together for our initial alpha device, but it worked. It did the job. That one key approach (creating an MVP) was critical for us to begin tackling this problem," Parag says.

The right team is critical to launch a startup, particularly in a specialized sector like medtech. Parag highlights how his cofounder, Dr. Evgeniy Kreydin, a urologist, brought invaluable medical expertise to the table, particularly during interactions with regulatory bodies like FDA.

This expertise, coupled with a team that shares your vision and work ethic, can be a differentiated factor for a startup. Parag points out that entrepreneurship demands an unconventional level of dedication, adaptability, and willingness to tackle challenges head-on. This is especially vital for early-stage ventures and hybrid teams consisting of full-time employees and consultants. His straightforward advice to entrepreneurs is clear: Your team is your most significant asset in overcoming development and regulatory hurdles, so choose wisely.

Lastly, one of the pillars upon which you should build your venture is empirical data. Parag underscores the value of grounding business decisions in solid clinical evidence, peer-reviewed publications, and expert opinions. This not only enhances your credibility but also sets your venture on a course for sustainable market traction. By basing choices on reliable evidence, you mitigate the risk of biased decisions.

From Academia to Medtech Entrepreneur: Interview with SpineX CEO Parag Gad

Credibility as a Long-Term Asset

SpineX is set up to be a long-term, global player in the market thanks to Parag's ambition to get things right from the start. Their two flagship devices received Breakthrough Device Designation from FDA, which means the review process will be prioritized by the agency. In addition, an achievement like this can catalyze other opportunities and bring a significant amount of credibility to SpineX. "Having the Breakthrough Device Designation goes a long way," Parag says. It puts an "informal stamp of approval" on your venture, which is a paramount win for any startup in the healthcare sector.

In the early stages, every interaction with the FDA counts, whether it's a pre-submission meeting or formal review discussion. The level of professionalism and meticulous attention to detail will set the stage for future engagements. These interactions shape FDA's confidence and trust in what you bring to the table. In the healthcare space, where patient safety is paramount, this trust is a form of capital that can have long-lasting impacts on a company's success.

Therefore, it's critical to start off on the right foot. Breakthrough Device Designation is just one avenue for establishing credibility. There are alternative strategies as well, such as winning industry-specific awards, generating robust data through benchmark studies to improve patient care, securing intellectual property rights, and collaborating with well-known healthcare providers.

Taking careful, thoughtful steps in early interactions with regulatory bodies paves the way for smoother sailing down the line and contributes to building a brand in the eyes of crucial stakeholders, even if your company is not yet patient-facing.

From Academia to Medtech Entrepreneur: Interview with SpineX CEO Parag Gad

Going Beyond Venture Capital

Over the past four and a half years, SpineX has raised $3.6 million in equity. However, what's particularly noteworthy is how the company secured non-dilutive funding, mainly from government agencies like the NIH and NSF.

"With my academic background, I found that I had a knack for grant writing," Parag reflects. The skill, he explains, is worlds apart from negotiating with investors. "You have to understand that grant proposals have their own set of rules and limitations. Unlike discussions with investors, you don't have the opportunity to go back and clarify or amend your proposal. So, it's crucial to get it right the first time," Parag emphasizes. For those new to this area, Parag recommends leveraging platforms that offer grant writing coaching or even engaging specialized consultants.

When it comes to equity-based financing, the success of SpineX in attracting early-stage investors was rooted in a compelling narrative. "We were able to not only show the social impact of our medical devices but also demonstrate their commercial viability," says Parag. They simply laid out that their product is a win for everyone involved.

As SpineX is currently in the midst of a Series A round, Parag reflects on the changing economic landscape and the importance of being "realistic." It's natural for founders to harbor a strong bias toward their product, but it's essential to couple that enthusiasm with a pragmatic understanding of market dynamics. You need to adjust your expectations based on what the market can bear.

Interview with AliveCor Founder and Chief Medical Officer Dr. David Albert

Dr. David Albert

Preview

Dr. Albert is a man of many talents, blending medical expertise with entrepreneurial zeal. His company, AliveCor, is pioneering the standard for personal ECG devices that extend beyond just hardware, enveloping services and partnerships to offer comprehensive personal cardiovascular solutions. In a freewheeling conversation with Dr. Albert, we take a tour down the lanes of innovation, prototyping, fundraising, and why sometimes you have to ditch the white coat to take your ideas from the lab to the real world.

About Dr. Albert

Dr. David Albert is a multifaceted individual — a physician, scientist, inventor, serial entrepreneur, YouTube sensation, and even an adventurous surfer. His academic journey led him from Duke University, where he completed both engineering and medical graduate studies, back to his roots at the University of Oklahoma. He already had several licensed inventions when he decided to stake it all on a new cardiovascular device. The gamble led him to found AliveCor, now a frontrunner in personal electrocardiograms (ECGs) under the renowned Kardia brand.

Key Takeaways From Dr. Albert's Experience

- The transition from academia to entrepreneurship may not be seamless. You need to be realistic, utilize resources to your favor, have the right mindset to continuously learn lessons, and know how to cultivate strategic partnerships.
- The lines between medical devices and consumer marketing are not as rigid as you might think. By bringing in the right expertise, being agile, and focusing on consumer awareness and branding, you can forge a new path that is both medically sound and consumer-friendly.
- When it comes to fundraising, understand the fundamentals of valuation and don't get fixated on high numbers. Leverage a network of allies who can help you make the right connections and include tangible prototypes and demonstrations in your pitches.

Consumer-Facing Medtech: Interview with AliveCor Founder and Chief Medical Officer Dr. David Albert

Bridging the Gap Between Academia and Entrepreneurship

A physician-scientist by training and a risk-taker by nature, Dr. Albert knows the ropes of both the medical and business worlds. His wisdom, seasoned with both “bruises and pain,” offers a fresh perspective for anyone seeking to marry their academic background with entrepreneurial zeal.

First and foremost, Dr. Albert stresses the importance of having a safety net. Don’t fall prey to survivorship bias — there’s an illusion that success is almost guaranteed because we're most exposed to the success stories, while failures go largely unnoticed. Doing everything correctly doesn’t guarantee you a spot among the year's most successful businessmen.

Entrepreneurship is inherently risky, and it's essential to be prepared for unfavored outcomes. "Have a plan B,” Dr. Albert suggested.

Dr. Albert also warns about the steep learning curve. "I was incredibly naive when I started my first company. I have a master's in bruises and pain instead of an MBA," he says. While the road is challenging, each setback can be a teacher if you have the right mindset. He also points out that there are many resources today to help you start a company, such as accelerators like Rock Health and MedTech Innovator. It's worth investing the time and effort to seek out these options that can help bring your ideas to reality.

Another fundamental piece of advice from Dr. Albert is to develop well-rounded skill sets. As he wisely puts it, "Going through that process is an education in and of itself." You may have a great idea as a physician, but as a CEO, you also need experience in human resources, marketing, sales, regulatory, and manufacturing to name a few. While you may be an expert in your field, understanding the multifaceted aspects of running a business is crucial.

Lastly, but perhaps most importantly, Dr. Albert advises finding a well-suited partner who complements your skills: "Go find somebody who's done it before, who has the chops in business, who knows how to functionally start a company, and who can be side-by-side with you to implement your idea and turn it into a true innovation.”

Consumer-Facing Medtech: Interview with AliveCor Founder and Chief Medical Officer Dr. David Albert

Medtech With a Consumer Face

Medical technology and consumer-focused marketing don't naturally go together, but Dr. Albert has managed to marry the two.

Acknowledging the limits of your knowledge and experience is a first step in the right direction. Dr. Albert isn't a marketing expert, so he strategically assembled a team. "We hired the right people for our leadership team. A number of them come from Amazon, who sold things like Alexa," Dr. Albert says.

The diversity in expertise becomes particularly crucial given the complex regulatory environment in which AliveCor operates. "We're a Class II regulated medical device company. We get audited by all kinds of people," he adds. But rather than being stressed out by regulatory hurdles, Dr. Albert gets the right people on board to ensure smooth sailing.

Being adaptable to fit in the consumer market is crucial. Taking things one step further, Dr. Albert almost reinvented AliveCor's business model over the years. "We started off prescribing only from the FDA, and only over the years did we move to being able to prescribe over-the-counter, and then we have some pure over-the-counter." Industry-specific expertise is the key to driving a medical device company to such frontiers. He concludes, "We live in two worlds" — referring to the strict regulation around the medical products and their consumer-facing marketing strategy — "If you want to do that, go find people who have done it."

Having a brand identity is another important aspect of consumer-facing medtech. Some medical device companies don't need to bother with advertising if they cater to practitioners directly. However, it's not the same for over-the-counter devices. "Every day, I run into people who don't know AliveCor, but they know Kardia," Dr. Albert says

Direct-to-consumer advertising doesn't just create product sales; it builds brand capital. "The value of a brand is unbelievable," he asserts.

Consumer-Facing Medtech: Interview with AliveCor Founder and Chief Medical Officer Dr. David Albert

Show, Don’t Tell

With his humor and wit intact, Dr. Albert offers several practical and insightful bits of advice when it comes to fundraising. “Do you understand the math of 100% of zero? 100% times zero is zero,” he jokes, challenging the preoccupation many entrepreneurs have with high valuations. "At the beginning, I would encourage you to be humble — unless you just have something that you know is going to change the world," Dr. Albert advises.

Fixating on a high valuation at the cost of dilution might be a myopic approach. Although alluring, money's not the end-all, be-all in this game. Rather, aim for partners who add genuine value to the journey like a broad network, proven experience in the industry, or specialized expertise.

Now, how do you get people to not only notice your invention but also believe in it? There are a few ways to do that. One is showing people something tangible, i.e., prototypes. “We live in a ‘prove it’ industry where you have to offer proof not only to the regulators, but to your customers, or else they're not going to believe you,” Dr. Albert says.

It was exactly what he was doing — demonstrating his product — when he went viral with a simple YouTube video. Many people were excited, and many didn’t believe it was possible, to which he responded somewhat tongue-in-cheek, “You know you've made it when you have YouTube haters.”

Showing, not telling, is a strategy Dr. Albert brilliantly connects to his direct-to-consumer approach, which spans FDA, advertising, and fundraising.

The second piece of advice Dr. Albert gives is to “find allies who can help you [get your foot] in the door," whether it's a legal advisor who can introduce you to venture capitalists or a physician who can vouch for your medical device. This resonates with AliveCor's direct-to-consumer model, which has been key in building the Kardia brand through advertising, retail channels, and partnerships.

Lastly, Dr. Albert emphasizes the importance of maintaining your credibility. For him, clinical validation remains a cornerstone. "We are the golden standard, as proven by hundreds of publications," he proudly declares. Credible proof adds another layer to Dr. Albert’s fundraising strategy, offering both a competitive edge and peace of mind to potential investors.

How Data is Transforming Medtech

Interview with Avenda Health CEO Shyam Natarajan

Shyam Natarajan

Preview

Shyam Natarajan, founder and CEO of Avenda Health, started as an academic with a knack for the business side of healthcare. He now leads the charge in revolutionizing prostate cancer care. We talk about what it really takes to understand the market need for your product or service, how prototypes can be incredibly helpful in convincing relevant parties, how Shyam approaches fundraising, and what to expect from medtech in the future given current technological advancements in growing fields like AI.

About Shyam

After getting his PhD in Biomedical Engineering from UCLA, Shyam worked as a postdoctoral scholar in UCLA's Department of Surgery, focusing on minimally invasive surgical interventions. He also managed the UCLA Business of Science Center, spearheading initiatives to guide students towards non-academic career paths. With experiences like founding UCLA Innovation Week and the Inventathon, Shyam is committed to pushing the boundaries of medical technology. Avenda Health, where Shyam is founder and CEO, utilizes artificial intelligence and cutting-edge imaging to improve the diagnosis and treatment of prostate cancer.

Key Learnings From Shyam's Experiences

- **Go deep, not just broad.** Identifying a market need is only the beginning of an exhaustive investigative process. You must dive deeper to comprehend the root causes of the issue. Proceed to build a prototype only after you comprehensively understand the problem and seek mentorship proactively every step of the way.
- **Don’t overcrowd your board**. Fundraising in medtech requires a mix of politics, strategy, and clinical understanding. Be prepared to turn down offers that dilute your mission. And remember: it is a numbers game, meaning, expect to do hundreds of pitches before you secure the capital you need.
- **Cross disciplinary functions to adapt adjacent technologies**. Look for ways to synthesize advancements in other fields, such as information technology, into your product. Putting the patient at the center of your mission allows you to identify how tools from adjacent disciplines can improve your product.

How Data is Transforming Medtech: Interview with Avenda Health CEO Shyam Natarajan

Accelerate Your Progress With Prototypes

Recognizing an unmet clinical need in healthcare is table stakes; digging beyond surface level is critical. "Just because you've observed a problem, you don't necessarily know at first if it's a widespread problem or if it's associated with technology, clinical workflow, or reimbursement," Shyam candidly shares. “The wrong decision has a huge burden on both the patient and the healthcare system.”

He took nothing for granted when he decided to tackle prostate cancer diagnosis and treatment. Thanks to a PhD related to the topic, Shyam was already an expert on the issue. Yet, this didn’t stop him from interviewing around 20 people a week for almost two months. Thanks to his determined yet humble attitude, Shyam was able to truly identify all the facets of the problem.

Identifying and deciphering market needs is the first step. The next step is action: getting your prototype in the hands of end users. This is the best way to discover areas for improvement, while at the same time, showing potential partners that your idea is implementable and worth developing further.

Unfortunately, the medtech industry is notorious for long timelines due to regulations and the nature of clinical trials. "Getting a prototype out is really, really important," states Shyam. “Clinical trials take a long time and a lot of capital, but it's really cheap and really easy to come up with a representative prototype,” reiterates Shyam. A tangible prototype can fast-track getting other parties on board and moving towards your next milestones.

An intriguing aspect of Shyam's leadership is his preference to tackle challenges in-house before seeking external expertise. For instance, Avenda conducts the initial clinical trials either internally or through a university partner. The primary benefits are better control of the process and stronger relationships with clinical trial sites.

The last advice Shyam has for entrepreneurs interested in a similar path is to value mentorship and proactively seek it. Medtech isn’t an exclusive community in that regard. Shyam says, “Everyone is willing to share because we understand the challenges."

So, leverage every experienced perspective to better understand what you’re grappling with. Every road has obstacles, and mentors can help you sidestep them on your way from concept to market.

Turning Ideas Into Capital

It's one thing to come up with an extraordinary idea that'll bring relief to patients and alleviate healthcare bottlenecks. But it's quite another to maneuver through reimbursement, regulation, and fundraising.

Despite the inherent challenges, Shyam has managed to raise a remarkable amount of capital — almost $15 million. But this milestone didn't come without a host of lessons and challenges. Shyam recalls, "We were fortunate at the beginning to have a really strong group of investors that were tied to UCLA. They were basically our angels." They supplied funds as well as a foundational network and support system for Avenda Health, allowing Shyam and his team to forge their own path forward.

Shyam points out another intricate aspect of the industry: reimbursement. He shares that reimbursement was the most complicated process they encountered for a variety of reasons: It's "a mix of politics, strategy, and clinical." When you create a device that's novel, you have to figure out how to relate it to the public too. Unlike FDA guidelines, information on reimbursement isn't readily available; and your path depends on your clinical perfection, regulatory adherence, and even your company's credibility in the sector. This is where the support you get from partners and investors proves invaluable.

Shyam's overarching advice to entrepreneurs is to partner up with investors whose vision, mission, and experiences align with the project's long-term goals. In Avenda's case, the stakes are even higher as they are pursuing a Breakthrough Device Designation from the FDA, which makes the processes even more nuanced.

However, Shyam makes it clear that maintaining board control, especially in the early stages, is critical. Turning down certain investors can be a strategic move to ensure the vision of the project stays intact. It gives the company room to grow and evolve without being encumbered by external pressures that may derail its original mission. In his own words, "It's not a tradition, but it seems like every time we've gone out and raised a round, we've had to painfully say no to a term sheet in order to maintain control."

Perhaps one of the most transparent lessons from Shyam's journey is that the investor hunt is a numbers game. He candidly admits, "You just had to talk to a lot of people. I think we may have talked to 400 to 500 people."

How Data is Transforming Medtech: Interview with Avenda Health CEO Shyam Natarajan

Innovating in the Information Age

Perhaps one of the most important virtues of an entrepreneur, especially in medtech, is having knowledge in different domains and being able to synthesize it to design a coherent, patient-focused strategy. Avenda, for instance, harnessed the power of AI by aggregating multiple forms of patient-specific data —MRI scans, PSA levels, biopsy, and pathology reports — and then applying AI algorithms to generate a personalized “3D Cancer Estimation Map.”

This 3D map serves as a decision support platform. It provides a comprehensive view of how far the cancer has spread within the prostate, thereby giving doctors and patients more accurate data to make better-informed decisions regarding treatment options.

AI can mean a lot of different things — the buzzword is often surrounded by ambiguity. Its full potential unfolds even as we speak. But what's important about it, according to Shyam, is that it illuminates the incredible value of data.

Shyam believes that the road to medical device innovation is paved with devices that "learn, adapt, modify, improve over time." This suggests a new model for companies in the field, a model that regards AI not as the cherry on top but as a cornerstone. In his words, "You have to be an AI company in order to be a new medtech company." According to Shyam, data management and AI must be integral to any healthcare technology operation.

The medical device industry often progresses at a slow pace — especially when you compare it to the rapid speed of Silicon Valley. According to Shyam, there's much to learn from the latter to move at a higher pace and more efficiently. You can take this as a cue to keep an eye on tech trends and absorb what's applicable.

Lastly, for Shyam, the linchpin that holds everything together is the focus on the patient. "Always keep the patient in mind, always think about the patient because it's all about outcomes," he insists. This patient-centered approach not only serves as an ethical anchor but also as a strategic one. After all, the true merit of any technology lies in its utility and impact on human lives.

In closing, he leaves us with one of the most time-tested pieces of advice, "Be patient. Good things take time."

Interview with SinglePass CEO
Bill Colone

Bill Colone

Preview

Bill Colone, the co-founder and CEO of SinglePass, shares invaluable insights and actionable strategies for building and leveraging an expansive network, optimizing fundraising, and strategically planning for both acquisition and independent growth.

About Bill

Bill is the CEO and Chairman of SinglePass, a company developing an electrocautery device for deep tissue biopsies. He previously headed Spinal Singularity, raising over $11 million for product and clinical development. He was VP of R&D at Direct Flow Medical and the President of Endomed, which was sold in 2005. Bill also served in multiple leadership roles at Endologix and holds 13 U.S. patents with more pending. He earned his bachelor's in Chemical Engineering from Arizona State University, where he later served as an Associate Faculty Member and sits on the advisory committee for Chemical and Materials Engineering.

Key Learnings From Bill's Experience

- Your network is an extension of your company. You can leverage it at every stage — from idea to development, to launch, and even to exit.
- The venture studio approach has proven to be lucrative for Bill's multiple startups. Maximizing the use of limited funds, effective outsourcing, and planning for an early strategic exit can be more profitable than the traditional venture model.
- Grounded in realism and continuous feedback, Bill has a systematic approach to being a serial entrepreneur: keeping risk at a minimum while utilizing capital extremely efficiently and strategically keeping the end goal in mind.

A Roadmap to Serial Medtech Entrepreneurship: Interview with SinglePass CEO Bill Colone

Connections as a Competitive Advantage

You've probably heard the saying, "Your network is your net worth." Bill is living proof of that. He has accumulated a wealth of connections throughout his career, and it provides him with a competitive edge. As Bill puts it, "When you do anything for so long, you create a lot of relationships. SinglePass actually came about from something that I did 15 years ago."

You might assume that a seasoned entrepreneur like Bill can afford to take a step back from networking at this point in his career. Not quite right. He shares: "I try to go to every single Orange County medical device meeting. Even the ones in the evening where I'm tired and have worked all day". This is undoubtedly characteristic of the best company builders in the medtech space.

In fact, this mindset is how he connects with people who provide crucial domain expertise, including the best consultants in the field. For example, with SinglePass, Bill had the privilege of choosing from a pool of consultants who had specific expertise in electronic device regulations.

Investors, as you can imagine, are another critical part of an entrepreneur's network. Bill doesn't only proactively attend meetings to increase his contact list, but also keeps his existing investors close, by keeping them in the know. He is also quite open about his fundraising activities and the company's progress. He regularly updates his investors on milestones and challenges. "We let everybody know what we were working on and what we think is coming," he says. Transparency with investors builds trust and can lead to further opportunities down the road. "I'm shocked at the number of investors I have that say 'the other companies I've invested in have never sent me an update.' So I periodically let them know where we stand with everything, and the value of that is incredible."

When it comes to conquering complex regulatory hurdles, Bill's network again plays a significant role. For example, Bill relied on an extensive network of experienced partners and consultants to prepare for entering the European market. Notably, they had previously received EU MDR approval for other Class III devices, providing a level of confidence and expertise to navigate the process. His team had a robust relationship with their notified body and an authorized representative who was highly familiar with the kind of medical device they were bringing to market, a cautery-based device in this case. "We were able to enter the European market because of our connections and experience, and because we received great feedback from an authorized rep who essentially guided us through the process," Bill added.

A Roadmap to Serial Medtech Entrepreneurship: Interview with SinglePass CEO Bill Colone

Why the Venture Studio Model is Compelling

Traditional startups often have full-time employees and cumbersome overhead expenses. But Bill's venture studio framework offers an alternative pathway, cutting through complexities to deliver promising medical technologies in record time and at a fraction of the cost.

In contrast to the traditional approach of renting office space, building clean rooms, and hiring large teams, Bill's group operates with a different approach. He describes it succinctly: "We always have a single employee, which is the CEO. Everything else is contracted out." This minimalist approach extends to every aspect of the business — no rented buildings, no full-time staff, resulting in extremely lean operations. Beyond cost-savings, Bill's model has another, less discussed advantage: agility in the face of external disruptions, such as supply chain issues. "Right now, I don't get charged unless I have the CMO doing work for me. If I had full-time employees, I'm paying them even while we're waiting six weeks for something to come in," Bill notes.

Bill is not a proponent of exorbitant funding rounds; his formula is based on capital efficiency. "What we like to do with the first round of funding is to get to human trials," Bill shares. Following this, a priced round of funding is targeted to achieve key regulatory milestones and a limited market release. According to Bill, this approach "eliminates or reduces the risk dramatically for strategics, both from a regulatory and commercial perspective."

"The seed round was a million and a half. The Series A was two and a half million.", Bill shares about his funding cycle with SinglePass. This is modest compared to the significant amount of capital raised for most medtech startups, but he also points out: "If you have less capital in, an early exit can still be a really big win for all of the founders and early investors."

The venture studio model may not be universally applicable. Bill admits this himself: "This may not apply to more complex devices, so I wouldn't say every company should start like this." However, Bill's approach has been consistently successful for multiple startups.

A Roadmap to Serial Medtech Entrepreneurship: Interview with SinglePass CEO Bill Colone

A Guide to Serial Entrepreneurship

Bill is a proven startup operator and has an outline that he applies to all his businesses.

It's his rule not to raise an enormous amount of capital, which according to Bill, increases the risk. Instead, his plan is clear: "We choose an ideal exit window. More importantly, we have a lean, but solid budget. What will it take for us to get to the first human trials? We'll close the seed round once we get those dollars."

Once the seed money is in, the focus is on getting into human trials. According to Bill, it proves to investors and key stakeholders that the venture has legs.

Following the seed round, Bill looks to a Series A to fulfill multiple objectives. "The priced round will get us through both regulatory approvals and a limited market release," he says.

SinglePass is a great example considering it's positioned for both acquisition and independent commercialization. Bill recommends founders strategically plan for acquisition from the onset, but he also runs his startups as if they aren't going to be acquired. This way, the company is flexible based on the interest it generates among potential acquirers or growth-stage investors.

While you're in the midst of it all, it's also important to stay grounded. Bill's overarching advice to newcomers in the field is "be realistic, understand it will take a while, and listen to feedback." For example, when it comes to your pitch deck, Bill's take is: "Show it early and often, and you will ultimately arrive at a version that addresses what the investors are looking for." Bill added jokingly: "I think I was on pitch deck number 42 for SinglePass before we closed the recent raise."

Lastly, he circles back to the importance of networking — "It's a never-ending part of your job," Bill says. Even if you're tired, or you think you've met enough people, Bill would probably tell you to get out there and shake some more hands.

Childlike Curiosity and the Scientific Approach to Medtech Startups

Interview with Levita Magnetics CEO Dr. Alberto Rodriguez-Navarro

Dr. Alberto Rodriguez-Navarro

Preview

Discover Dr. Rodriguez-Navarro's journey — from his childhood fascination with using magnets to clean the inside of his turtle tank to leveraging this concept into a cutting-edge magnetic surgery platform. As a surgeon-turned-CEO, Alberto discusses what to consider when starting a new business, how to hone your framework when transitioning from the clinic, and early-stage strategies to ease the road to FDA approval.

About Dr. Rodriguez-Navarro

Dr. Rodriguez-Navarro is not only a skilled surgeon but a medtech visionary with multiple patents to his name. Today, he's the driving force behind Levita Magnetics, a startup aiming to make surgical procedures as minimally invasive as possible with their advanced magnetic technology.

Key Learnings From Dr. Rodriguez-Navarro's Experience

- **Prioritize the scientific method from the beginning**. Focus on effectively forming and testing your hypotheses. Begin with an MVP, gather real–world feedback, and then improve it in the most capital–efficient way.
- **Transitioning from the clinic to a startup demands adopting a different mindset**. Trust your abilities, but be receptive to feedback. Before delegating responsibility, dive into the roles yourself, as Dr. Rodriguez-Navarro did by becoming Levita's first sales rep.
- **Think like the FDA**. Both the entrepreneur and the FDA share the same goal: creating and validating a safe and effective product. Adopting this mindset will help you recognize the constraints of those on the other side of the regulatory table.

Childlike Curiosity and the Scientific Approach to Medtech Startups: Interview with Levita Magnetics CEO Dr. Alberto Rodriguez-Navarro

Nail the Basics

Levita Magnetics is an example of how remembering the basics can lead to profound breakthroughs.

Dr. Rodriguez-Navarro reminds us that medtech isn't about reinventing the wheel. Instead, it's about asking the right questions and finding the best ways to answer them. It comes down to creating a hypothesis and then determining the quickest, least resource-intensive way to test it. Before diving into elaborate plans and broad objectives, remain "laser-focused" on the key questions you need to answer, so that you don't only conserve resources but also expedite time-to-market.

With almost a decade–long experience in the field, Dr. Rodriguez-Navarro is aware that not all products, even those with stellar results in preclinical studies, translate well in the real world when used on actual patients.

This is especially the case in surgery.

"The idea is to develop a safe product that works, and the only way that you can really test that is in clinical experience," says Dr. Rodriguez-Navarro. That's why it was important for Levita to conduct human clinical trials as early as possible. "The true measure of a product's efficacy isn't confined to lab environments but comes alive in actual surgical settings."

Once the safety of the product was ensured, Levita strategically leveraged patient trials to further product development. Instead of pouring resources into developing the most advanced system in the lab, Dr. Rodriguez-Navarro promotes starting with a minimum viable product (MVP). By placing this MVP directly in the hands of surgeons, Levita could verify that their innovations were both theoretically sound and practically impactful. As he aptly puts it, "To truly gauge a product's worth, you should aim to offer surgeons a safe, functional MVP and then listen closely to their feedback."

Another fundamental principle for Dr. Rodriguez-Navarro is tapping into your unique strengths and resources. In Levita's case, this was the location. In its quest to speed up research without compromising quality, Levita chose to conduct its studies in Chile. While operating at a faster pace, it still adhered to U.S. standards to ensure the research met the highest quality benchmarks.

"Figure out your advantages, and use them for your company," Dr. Rodriguez-Navarro advises.

Lastly, a warning from Dr. Rodriguez-Navarro to those who might want to follow a similar path, "If you're going to conduct studies outside the U.S., always maintain strict ethical standards. Things can be more flexible abroad, but any lapses can come back and bite you. Don't try to take shortcuts, but instead, do the work."

Check Your Ego at the Door

Transitioning from clinical practice to entrepreneurship requires a change in mindset. The world of surgery demands precision, confidence, and trust in one's expertise. As a surgeon, you may be used to being the ultimate decision-maker in an operating room. But you need to shed that ego to become a successful entrepreneur, as your new environment introduces its own challenges that require adaptability, an open mind, and above all, a sales mindset.

"You have to trust in yourself, but not be impermeable to new comments or how to improve," Dr. Rodriguez-Navarro advises, underlining the crucial balance between confidence and humility. He embodied his own advice by rolling up his sleeves and becoming Levita's first sales representative. This first-hand experience allowed him to understand user needs, gauge what resonates with buyers, gather real-world feedback, and refine Levita's offering accordingly.

Such an ego check extends to fundraising, too. "You need to construct your track record to ensure you deliver on what you are promising," Dr. Rodriguez-Navarro emphasizes. While you might assume that a groundbreaking product or an impressive resume would make fundraising a breeze, he offers a reality check, "You will hear a lot of no's. It's part of the process." But this is where persistence is crucial. You need to accept rejection as a part of the journey and grab every piece of feedback as a golden opportunity to improve.

Moreover, in the tight-knit world of medtech, it's crucial not to burn bridges, as today's 'no' could be tomorrow's introduction to a potential investor.

Lastly, while many entrepreneurs dream of an acquisition, Alberto believes in the power of a long-term vision and building a standalone company. Instead of only focusing on an exit, he has plans B and C to guide Levita to its future. Viewing the company as the endgame itself communicates two things to stakeholders: first, you're committed to innovation; and second, you will offer genuine value, as you truly believe in your project and are committed to seeing it through.

Think Like the FDA

Both the entrepreneur and the FDA share the same goal: creating and validating a safe and effective product.

According to Dr. Rodriguez-Navarro, you need to adopt the mindset of a regulatory official. This will help you recognize the objectives and constraints of those on the other side of the regulatory table. In other words, it will help you be empathetic towards the regulatory representatives who share the same end goal as you.

For starters, even your very first prototype should be developed according to safety considerations. See the product from the FDA's point of view to identify whether it's aligned with their requirements from the start. The primary objective should always be the development of a product that is safe and works as intended. If, at any point, a product doesn't align with these criteria, it's imperative to re-evaluate and refine. As Dr. Rodriguez-Navarro advises, "If it's not safe for any reason, well, go back and improve it."

Secondly, building a bridge of trust with regulatory agencies is imperative, and the keystone of that bridge is transparency. Dr. Rodriguez-Navarro's guidance is crystal-clear, "Don't try to hide anything from regulatory bodies. In the end, it always shows up somehow." A breach of trust can jeopardize the entire venture.

Ancient Wisdom Meets Modern Medtech

Interview with Fisher Wallace CEO Kelly Roman

Kelly Roman

Preview

Kelly Roman, co-founder and CEO of Fisher Wallace, shares his career leap from literature and marketing to pioneering a novel approach to the treatment of mental health. Kelly and his team at Fisher Wallace are combining deep-rooted strategic insights with advanced technological innovation to revolutionize mental health with a wearable brain stimulation device. Kelly shares what he learned on his journey, touching on the value of unconventional thinking, the importance of making mental health treatments more accessible and less stigmatized, and the potential of decentralized clinical trials.

About Kelly

Kelly Roman is a Harvard graduate with an English major who took an unconventional path to medtech inspired by his experience co-authoring the graphic novel adaptation of Sun Tzu's "The Art of War." As co-founder and CEO of Fisher Wallace, he spearheads the development of wearable brain stimulation technology aimed at providing relief from depression, anxiety, and insomnia.

Key Learnings From Kelly's Experiences

- Adaptive thinking and the willingness to explore alternative approaches can yield great results. Whether you're tackling FDA regulation or capital fundraising, leverage your resources and real-world experience to get to your goals quicker.
- Be mindful of the obstacles standing in the way of your device's potential utilization, no matter how efficacious it is. The only way to create change and ensure long-term market success is to prioritize the needs, comforts, and desires of your end users.
- Don't be afraid to consider remote trials for a cost-effective and expedient approach to FDA clearance or approval, particularly in the field of mental health research.

Ancient Wisdom Meets Modern Medtech: Interview with Fisher Wallace CEO Kelly Roman

Think Outside the Box: Alternative Paths to Regulatory and Fundraising

Traditionally, the FDA's approval processes can be notoriously rigorous and time-consuming. But, depending on your product, there might be multiple ways to reach your goals. For the wearable Fisher Wallace Labs was designing, Kelly and his team pursued an Investigational Device Exemption (IDE) path, which enabled them to introduce their device to the public earlier than expected.

Of course, they can't commercialize Oak until it's been approved by the FDA. However, having IDE approval allows Fisher Wallace to use their device for clinical studies or pilot research programs, as long as there's informed consent and monitoring.

This approach enabled Fisher Wallace to begin gathering data while simultaneously raising awareness in the market. A notable example of this strategy in action is their recent collaboration with the Seattle Police Department, where they enrolled 200 police officers to test the device and provide feedback.

Another unconventional approach Kelly took was crowdfunding. While typical in the realm of consumer products and SaaS, crowdfunding isn't the go-to fundraising strategy for most medtech companies. Yet, for Kelly and Fisher Wallace, it made sense.

"When we launched crowdfunding, we already had 50,000 customers," Kelly shares. These customers were people who had already tried the device themselves in the study programs. They believed and trusted in the technology. Counter to what some investors think is "dumb money", Kelly candidly notes, "That's very smart money in the sense that they know a lot about the technology."

However, Kelly does offer a word of caution for other medtech entrepreneurs," If we had not had all those customers, I don't think we would have been successful. Some companies are spending 70 cents on the dollar by using platforms like Facebook ads to try and get investors. That's a pretty tough thing to do."

While crowdfunding can be an effective route for some, it's not a one-size-fits-all solution. For it to work, a company needs to have an established customer base and a strong, genuine connection with its audience.

Ancient Wisdom Meets Modern Medtech: Interview with Fisher Wallace CEO Kelly Roman

Making Mental Health More Approachable

The best products are often those designed to be simple and rooted in user feedback. The evolution of the Fisher Wallace's device, moving from its initial design, which Kelly humorously refers to as "Radio Shack style," to the much more user-centric Oak 2.0 was in this exact spirit.

Kelly states. "Our path is as much consumer product as it is medical." By focusing on the consumer experience, Kelly and his team were able to extract invaluable feedback from their version 1.0 device users. "Even if you have the best device that addresses major problems, if users aren't comfortable or happy using it, you'll face challenges. It's essential to consider how users feel and interact with your product," he shares.

Kelly hired top-tier talent for Oak, commenting: "Eric Fields, the industrial designer behind the first Nest thermostat and various Beats products, joined our team. We also brought on Alloy Product Development, an engineering firm that has worked on all of Beat's products."

One significant change they made was to move away from visible wires and AA batteries. The Oak 2.0 uses a lithium-ion rechargeable battery to eliminate the need for external wires, which didn't have as much to do with the efficacy of the product as it had with its goal to improve its user-friendliness. Kelly shares, "There's plenty of medical devices in which personalization is not as crucial. But an interesting analogy is when someone has a cast on, it becomes a whole different thing, people sign it and draw little pictures, and then it becomes a personal object."

Personalization is even more important when offering a product that tackles mental health issues. The goal for version 2.0's design was to create a stylish wearable that users would feel comfortable, even proud to be seen wearing, without the need to conceal it.

Kelly points out that the cost of manufacturing Oak 2.0 will be higher. However, he's also convinced that its improved design and functionality will not only help reduce the stigma often associated with mental health devices but will also make it easier to market. Because their users tend to be lifetime customers — some even owning multiple devices for different residences — the investment in continuous product development is justified. He anticipates that customers will likely update their devices every three years, similar to the upgrade cycles seen in consumer electronics like smartphones.

As a person who has suffered from undiagnosed ADHD for years, Kelly stresses the importance of destigmatizing mental health issues and treatments, especially in a post-pandemic world, and advocates for people to self-reflect and seek help when needed.

Ancient Wisdom Meets Modern Medtech: Interview with Fisher Wallace CEO Kelly Roman

Tips for Executing Decentralized Trials

Clinical trials are the bedrock of advancement in medtech. How you approach and execute them can significantly influence a device's path to market. Kelly offers an intriguing perspective on decentralized clinical trials, illuminating the merits and challenges of his progressive approach.

To begin, Kelly underlines the importance of engaging with the FDA, no matter how you're managing your trials."If you're going after an FDA indication, the first thing is you should go meet with the FDA."

Kelly shares: "Mental health is a great area to run remote clinical trials." Partnering with Climb, a company with experience in vaccine trials, and Synapse, a CRO, Fisher Wallace has been able to harness the power of simple yet efficient communication tools such as SMS, which ensures high engagement — something indispensable in remote trials.

One might wonder about the legitimacy of these trials, but Kelly's confidence stems from impressive results. "We beat placebo at every time point — week one, two, and four. We had a massive response rate by week four." However, some challenges remain, and Kelly is forthright about the roadblocks. FDA, for instance, is keen on getting more extensive data before they are fully convinced.

While remote trials can be faster and often less expensive than traditional methods, they're not exactly cheap. Kelly highlights that the costs approximated is around $4,000 a patient for their trials. And while the costs can vary based on the complexity and nature of the study, the key is to ensure value for every dollar spent. Kelly also emphasizes the comparative advantages of this type of trial: they are still faster and less expensive than working with a big institution.

Of course, it's not all about cost-efficiency. For a successful decentralized trial, you need to understand and value the participants. Kelly's most significant feedback from their experience is simple: "Don't underpay." Compensate your participants for their time and effort fairly so that you get higher compliance and lower dropout rates.

What we can conclude from Kelly's experience is that as medical research expands its horizons with decentralized trials, it's becoming evident that a mix of clear regulatory communication, technology that enables efficiency, and a genuine appreciation of participant contributions will shape the future of clinical trials. By placing participants at the heart of the process, not only can you streamline research but also work towards better, more inclusive medical solutions.

Interview with Liberate Medical CEO Angus McLachlan

Angus McLachlan

Preview

Co-founded by the ingenious Angus McLachlan, Liberate Medical is developing a breakthrough device that synchronizes with a patient's breathing pattern, significantly reducing atrophy of the respiratory muscles for those on mechanical ventilation. We talk about Angus's do-it-yourself philosophy, how a deep understanding of the technology you're developing gives you leverage across multiple functions, and the nuances of pitching to investors.

About Angus

Angus McLachlan, co-founder and CEO of Liberate Medical, has a rich academic and professional history that intersects engineering and healthcare. Originating from Scotland, Angus began his academic journey in mechanical engineering at the University of Glasgow. This laid the foundation for his PhD research focused on electrical muscle stimulation for spinal cord injuries. His innovative work gained the attention of Apellis Pharma, leading to a collaboration that propelled the launch of his own company, Liberate Medical. Liberate is pioneering a non-invasive neuromuscular electrical stimulator to prevent muscle weakening in patients who rely on a ventilator to breathe.

Key Learnings From Angus' Experiences

- During the early stages of development, there's not an endless budget to play around with. Narrow your focus to only the core functionality that is needed, leverage existing resources creatively, and cultivate the internal passion of your team to drive innovation.
- Rely on your in-house expertise for specialized work. A deep understanding of your product makes you the best person to oversee development or handle conversations with regulatory bodies.
- Effective communication is vital in finding good capital partners. Learn to read the room for each pitch and adjust your narrative accordingly to best convey your message. Once you secure favorable investors, keep them in the loop and maintain a constructive relationship for long-term support.

A Self-Starter's Guide to Medtech: Interview with Liberate Medical CEO Angus McLachlan

Smart Prototyping on Limited Funds

Early-stage companies with limited funds and grand ambitions have to use their resources strategically.

First things first, you need to understand the core features of your technology and focus on perfecting them. Here are the two questions you need to answer clearly: What is the main purpose of your device? Does it do it effectively?

In Angus's words, "In the early versions of the prototype, I do think it's very important to work out what's really the core, unique functionality with your technology." For Liberate Medical, this is synchronizing stimulation with a patient's breathing pattern. By focusing on this central aspect, Angus and his team were able to purposefully direct their limited resources, securing maximum impact from every investment.

Angus shares, "We just had to make sure we could get the device working, do its unique thing, and show that that unique thing was beneficial to patients."

Once you know your product's basic functionality like the back of your hand, there's room for creativity. That being said, it's still important to keep a pragmatic attitude and try to leverage existing resources. For example, Angus ingeniously adapted a stimulator that was already commercially available to Liberate's specific needs instead of starting from scratch.

He recalls, "We were able to avoid having to develop the whole stimulation circuit and get IEC testing for that stimulation circuit, which is a time-consuming and expensive process. We were able to avoid all that to get to our first prototypes and first clinical data. That was a huge time saver."

Similarly, they used bifurcation cables to connect two smaller electrodes, creating the size they needed, and used a cheap 3D printer for the user interface — UI is important, but not in the initial stage. These practical solutions enabled them to create affordable, functional prototypes. Even though they weren't the epitome of elegance, these first versions validated what VentFree was capable of doing.

Once they achieved positive results in pilot trials, Liberate's focus expanded beyond their product's core capabilities. Angus recalls, "After we did those pilot trials, that's when usability became much more of the focus of the product development." By being strategic with their changing priorities throughout the device's development cycle, Liberate was able to address all aspects of the end product.

Lastly, the challenges for new technologies don't end when you prove their efficacy. You also need to promote the integration into existing medical workflows. That's when it's crucial to put yourself in the shoes of the end-users. Angus says, "We wanted to learn from them (physicians) as much as possible about their current workflow. Then we design the device around that to make sure it's as easy as possible to use."

A Self-Starter's Guide to Medtech: Interview with Liberate Medical CEO Angus McLachlan

To Outsource or Not

In the start-up ecosystem, operating with a lean approach is not a one-size-fits-all strategy. The best path forward often depends on the nuances of what you're developing, and while outsourcing might seem tempting, it comes with its pitfalls.

For example, when developing the alpha and beta versions of your product, one thing you need to do is to iterate quickly based on evidence and feedback. Here, full control might yield better results. Angus points out, "You just have to keep trying things to get something that works. That can end up being really expensive, even with a great outside contractor."

Angus also challenges the conventional approach of outsourcing regulatory initiatives right away. Case in point: Liberate doesn't have a regulatory consultant. Such an absence might seem atypical to other companies, but Angus leans into his strengths and successfully capitalizes on in-house expertise before considering external assistance. He leads crucial conversations with regulatory bodies by drawing upon his clinical experience from his PhD days. He says, "You can pay a consultant to do the predicate analysis, but it's not that hard. You can also just work it out yourself, find the product codes, find devices, etc. And you're probably doing more thorough research, just because it's your baby."

To do it yourself as Angus advises, you first need a thorough understanding of your device. Then, Angus recommends writing regulatory submissions as much as you can, especially on the technical aspects of your product, since you know the technology better than any external consultant ever will. This makes you the best person to have informed and fruitful conversations with regulatory bodies.

Angus shares, "We really had to know the literature so we could convey why we thought it was important both to clinicians or investors."

In the spirit of tackling challenges hands-on, Angus's approach extends beyond Liberate's immediate product development. The onset of the COVID-19 pandemic put Liberate in a precarious position, as it did with countless startups grappling with supply chain chaos and stringent travel restrictions. The team's proactive stance and Angus's leadership allowed Liberate to overcome these hurdles. They were able to obtain an Emergency Use Authorization (EUA) during the pandemic. Remarkably, Liberate Medical was in production by September 2020.

A Self-Starter's Guide to Medtech: Interview with Liberate Medical CEO Angus McLachlan

Speak the Language of Your Investors

When you're raising funds, effective communication is a must. One tenet of any successful communicator is their ability to fine-tune the messaging based on their audience. When speaking to different investor groups, like VCs or angel investors, tailoring your pitches accordingly is always a good practice. While Angus is a technical guy who knows all the mechanisms of his device inside and out, he's capable of simplifying it all for his audience. He understands that his investors come from diverse backgrounds and may lack specialized knowledge, so he adjusts his pitch to make the complex comprehensible for them.

For example, Angus shares, "The initial rounds were all angel groups or individual angel investors. They're not all experts in medical devices or intensive care or respiration." But as VentFree matured and Liberate approached its Series B round, the company's target shifted towards venture capital groups. Angus emphasizes: "As you get speaking to more VCs, the level of the depth of detail they go into and the technical discussion is a bit more intense." VCs bring heightened scrutiny and diligence to the table and you need to be able to address that when needed.

Persistence is another cornerstone of fundraising success. "For any fundraiser, you just have to speak to a lot of investors. I would love to say it was a quick process, but it was not. You just have to keep hearing a lot of no's", Angus shares. However, the challenge doesn't end once you secure the funding. Moving forward, it's important to foster and maintain strong relationships with your investors.

"We've always done a regular shareholder update. That's been extremely helpful. We had pretty good insider participation and they've been extremely supportive over the multiple rounds of funding that we've done," Angus disclosed. Such a relationship can determine the future of your company, not only in terms of your immediate fundraising goals, but also when it comes to long-term success.

Lastly, Angus imparts another nugget of wisdom for those looking to secure funding: don't overlook grants. Procuring grants is a detailed, elaborate process, maybe even more so if you're not coming from an intensive academic background like Angus. However, they are extremely beneficial, especially as they are non-dilutive and can often bridge crucial funding gaps.

Connecting the Dots Between Medtech and AI

Interview with Sonio CEO
Cecile Brosset

Cecile Brosset

Preview

Cecile Brosset Dubois shares her transition from renowned consulting firms like Bain & Company to leading her own medtech startup, Sonio, a startup that focuses on enhancing obstetric ultrasound with AI. We touch on her strategic approach to product development, the importance of an in-house regulatory team, her drive for meaningful work, and effective tactics for fundraising.

About Cecile

Cecile Brosset Dubois began her career in 2005 at Capgemini, later advancing to Bain & Company. Her strategic insights as Head of Strategy at FSI - Fonds Stratégique d'Investissement - and her pivotal roles at Bpifrance set the stage for Cecile's entrepreneurial journey. At Kamet Ventures, she embraced the startup world before co-founding Sonio, a company dedicated to revolutionizing obstetric ultrasound through AI technology.

Key Learnings From Cecile's Experiences

- The guiding principle both in product development and team building is the same: progress is iterative. Aiming for perfection, while a worthy goal, should not paralyze the journey towards improvement. Be tenacious and don't give up.
- Having an in-house regulatory team that understands both the product and the ever-changing landscape is a must, especially if you're utilizing new, AI-based technologies.
- Whether you're commercializing or fundraising, understand your audience and keep an open dialogue with experienced entrepreneurs. Focus on building relationships and leveraging them for growth.

Connecting the Dots Between Medtech and AI: Interview with Sonio CEO Cecile Brosset

Iterate the Imperfect, Step-by-Step

In medtech, the goal is to create a flawless product as fast as possible. However, you should acknowledge that perfection is not something you can achieve immediately – or even quickly.

"We didn't build the full platform in one go," says Cecile, emphasizing her methodical, incremental approach to product development.

Sonio started as a single diagnostic tool that served in a clinical support capacity. The initial version went through multiple, iterative phases based on both user and regulatory feedback, serving as a ground for subsequent modules.

"It really informed our roadmap as well as our decisions on how to structure the team," says Cecile. The goal is to be both capital-efficient and agile, learning as you go.

It's also important to establish a flexible organizational structure that allows you to iterate rapidly. For instance, with Sonio, data science, product development, clinical, and regulatory are all under one roof. This allows Sonio to "really anticipate what would be expected from a regulatory standpoint early enough in the process" and pivot accordingly, says Cecile. For example, some modules of their software are not regulated like typical workflow solutions. "We developed continuously and iterated with our users while we adapted the AI modules to regulations," she added.

In essence, Cecile believes that perfectionism should not halt progress: "At BPI, I kept hearing that you should keep iterating, which means making incremental changes; in this sense, not doing it perfectly is the right path."

This step-by-step approach doesn't just apply to building a product. It also applies to putting together a team.

"Hiring is a mix of testing and trusting," says Cecile. Her approach to team building is analogous to dating, but in a professional context. The hiring process is a period of mutual evaluation, where both parties assess each other. The employers, for instance, evaluate whether a potential team member would fit within the company's culture and work dynamics over a given period. This allows both employers and candidates to gauge their compatibility before making a long-term commitment.

Even though recruitment was a learning process as well, Cecile knew one thing from the very beginning: the key to assembling a great team lies not just in technical qualifications but in shared values and goals. In line with that, her team-building criteria are simple enough: "I like to go fast. I'm ambitious. So basically, if they fit those criteria, usually I know that we're going to get along quite well."

In line with that, she pays attention to how reactive people are, gauging their commitment to the mission and their willingness to move fast. "You don't join a startup if you don't want to work hard and challenge yourself," she adds.

Connecting the Dots Between Medtech and AI: Interview with Sonio CEO Cecile Brosset

Iterate the Imperfect, Step-by-Step

AI holds incredible potential to revolutionize healthcare. However, it's a rapidly evolving field and even regulatory bodies like FDA are playing catch up to the ever-updating AI algorithms. It’s a challenge to find established regulatory pathways that serve as precedents, which is why Cecile advocates for having an in-house regulatory team that understands both the intricacies of your product and the shifting landscape of regulations.

Cecile learned this the hard way. Sonio started out by employing external consultants, only to realize that "if you don't understand what the product does, you're not going to get it right," she mentioned. In other words, outside consultants simply lacked the insights necessary to effectively drive the regulatory process forward.

Recognizing the need for specialized, internal expertise in regulatory affairs, she recruited a seasoned professional from the industry. This proved especially helpful when external advisors, even advisors who had worked at FDA before, were uncertain regarding Sonio’s chances of gaining approval. But their in-house expert – Florian Akpakpa – who had a deep understanding of the product, was undeterred and has successfully led the company down the path of eventual FDA approval.

The takeaway lesson here is that when working on novel technology, it’s invaluable to have someone on your team who really understands your product and the various regulatory guardrails.

And don’t forget that the regulatory landscape is always changing. New guidelines come into play, and what worked last year might not fly today. That’s also why having someone on the inside who's up-to-date can be a lifesaver.

Connecting the Dots Between Medtech and AI: Interview with Sonio CEO Cecile Brosset

Right Audience, Right Approach

Launching a sophisticated product is no small feat. Cecile and her team at Sonio succeeded by first understanding their audience — both customers and investors — and then figured out how to keep them loyal to the cause.

Starting with customer engagement, Cecile attributes her startup's initial success to their winning market segmentation. They didn't just try to sell their diagnostic module to anyone who'd listen; they knew their early audience was specialized diagnostic centers in fetal medicine, which is why they specifically targeted those centers.

Once you've got the right target, the next step is customer engagement or, as Cecile calls it, 'customer success'. "Onboarding people on your software, making sure that they're happy with how it works, and helping them use it in a clinical context is incredibly important," she says. An important point that Cecile emphasizes is that the sale itself is only the beginning of your relationship with clients. Helping customers get the most out of your product is what will eventually solidify the bond.

Effective communication is just as crucial in fundraising as it is in customer engagement. In Cecile's experience, her first pitch didn't resonate with investors at all. "I shared my vision and project consistently, yet it was initially met with rejection," she recalls. The breakthrough came after consulting with two seasoned entrepreneurs. They helped Cecile refine her pitch to capture the essence of the business case in a more compelling way.

"It wasn't about changing the reality but about framing our story to align with their priorities so that they feel comfortable investing. I pitched the same company, same vision, same plan, but just a little differently in a slide deck. And then we started receiving checks like a month and a half after that," Cecile recalls.

Beyond the right type of communication with investors, it's important to keep the channels open with those who've successfully navigated the fundraising waters before you. "I really had to partner with serial entrepreneurs that have succeeded in fundraising in the past. And they were the people who helped me build the right pitch deck and understand what investors were looking for," Cecile comments.

Lastly, remember that although it's never easy, fundraising typically gets a little less challenging with each successful round. For example, Cecile's third round had investors approaching her, a far cry from the hurdles she experienced the first time around.

Her ultimate bit of advice is: "Be well-accompanied by experienced people who want to help you. If you have a project that you believe in, don't give up. There are always going to be people that will trust you."

From Nurse to Medical Device Entrepreneur

Interview with Swiftsure CEO
Deanne McCarthy

Deanne McCarthy

Preview

Deanne McCarthy's journey from bedside nursing to entrepreneurship is a compelling story of determination, curiosity, and building vital networks. She unpacks the invaluable role of mentors and connections, her insights on accelerator programs, and how her initial lack of startup experience gave her the tenacity to seek out and validate collaborative partners.

About Deanne

Deanne, founder and CEO of Swiftsure Innovations, was a critical care nurse before deciding to make the switch to medtech entrepreneur. With Deanne's commitment to empowering nurses and enhancing patient outcomes, Swiftsure has assembled an adept team and a robust group of advisors that has enabled the company to move incredibly quickly across key functions like product development, regulatory affairs, and commercialization.

Key Learnings From Deanne's Experiences

- Good accelerator programs will allow you to tap into a wealth of expertise. Don't be shy about converting your mentors into active players in your startup.
- Not knowing everything is perfectly okay. Harness your curiosity in every facet of your venture to ensure you find the right resources to reach your milestones.
- Don't be afraid to ask for favors. And to reciprocate, approach your network with a spirit of generosity.

From Nurse to Medical Device Entrepreneur: Interview with Swiftsure CEO Deanne McCarthy

Nurturing Ideas in Collaborative Soil

A lot of people have good ideas, but they seldom act on them because knowing where to start is not second nature to everyone. Although Deanne had no prior entrepreneurial experience, she was able to move forward with her idea extremely quickly. Deanne attributes much of her readiness to the foundational skills and network she acquired at the Creative Destruction Lab (CDL), an equity-free accelerator.

It was there that she was able to access a cadre of seasoned advisors. But that's not all — Deanne is a natural collaborator. Thanks to that skill set, she was able to turn these mentors into active participants in her startup's journey, shaping everything from the company's initial funding round to forecasts and business plans.

"The first thing that we did was outsource product development," she explains. Swiftsure partnered with a certified Canadian medical device design company, Ironstone. There, she was able to accelerate the development process by pressure-testing each iteration with external consultants, some of whom ended up working for Swiftsure full-time.

"I'm not a quality expert. I definitely went out and learned as much as I could about all of the different work streams that are necessary," Deanne says. During the peak of COVID, Deanne and her team adopted a hands-on approach to product testing, enlisting ICU nurses for real-time feedback.

"We would videotape everything and then have a systematic interview with each of the end-users to unpack questions that the design team had," Deanne explains. "We did that five different times and having insights from these really experienced, smart nurses was invaluable," she adds.

Accelerators can sometimes be a mixed bag. They demand time and energy, and not every startup walks away with a golden ticket. For Deanne, however, her experience with CDL was an invaluable opportunity to collaborate with others in the industry and find people who were interested in propelling her idea forward.

With the non-dilutive funding she was able to garner, Deanne quickly moved on to building a regulatory plan and early prototyping. She advises, "If you're at an early stage, reach out and get to know all non-dilutive funding grant options that are out there and engage with those organizations early. It takes a lot of work and a lot of time to get non-dilutive funding, but it's well worth the effort."

In the end, her stint at CDL proved to be a game-changer, setting the gears in motion and expanding her network in ways she never imagined.

From Nurse to Medical Device Entrepreneur: Interview with Swiftsure CEO Deanne McCarthy

From Curiosity to Confidence

Deanne's nursing background fueled her curiosity and the desire to make methodical decisions at each step.

She acknowledges that they were fortunate to progress so quickly, considering Swiftsure's team was working remotely during the pandemic. But Deanne did what it took through regular check-ins with key consultants, always thinking about a Plan B, and keeping various options open in every area, ensuring there were alternatives in case something didn't work out.

When it came time to choose the right product development partners, Deanne was thorough: "We did interviews with four or five different product development shops, had conversations with companies they had worked with, found and talked to businesses that they didn't give us as references, etc." After deciding to partner with Ironstone, she enlisted a quality expert to attend meetings and pressure-test everything.

On the clinical side, Deanne applied an unexpectedly pragmatic lens: sales. "Your clinical sites need to think what you're doing is interesting, worthwhile, and compelling," she explains. Just like most organizations, hospitals have multiple priorities. "You need to find out who's able to move as quickly as possible and who's got the right plan in place," Deanne advises.

Deanne approached regulatory challenges with the same rigor: "I felt that was a risky area of the business, so I wanted to make sure I talked to as many people as possible." She invested in three different regulatory opinion memos and consulted with four additional experts. "Some would argue that I spent more than I should have on that aspect of the business, but I felt I needed to do it," she shares.

Building a partnership with your investors is also critically important. Deanne says, "Have investors who believe in you and who you can be candid with about what's working well, what isn't working well, and where you need support."

She has the right partners now, but getting to this point wasn't easy for her. Deanne admits to initially feeling awkward, almost as if she was asking for a favor because her startup needed money. Her discomfort shifted over time as she gained more experience, assembled a competent team, and achieved key milestones. "I go into conversations with potential investors now, excited to tell them about this incredible investment opportunity," she adds.

From Nurse to Medical Device Entrepreneur: Interview with Swiftsure CEO Deanne McCarthy

How to Cultivate the Right Support

Embarking on a startup adventure is never a solitary mission. Deanne knows that all too well. Her venture was bolstered by the rich network she developed, especially through her experience at CDL. "We ended up having some really great mentors who stayed with us throughout the program. And one of our mentors ended up being the lead of our pre-seed round," she explains.

The initial step is making contact, but to truly harness the power of your network, you need to build lasting relationships. And while you might not always be in a position to give back immediately, that's perfectly fine. As Deanne puts it with a chuckle, “I find myself constantly asking for favors. I'm excited to one day be in a position to return favors for other people because, at this point, I'm always asking.” And even if you don’t have the means to reciprocate, it’s okay. Reaching out with a good question often yields good dialogue.

At the core of successful networking is a spirit of generosity, something Deanne has experienced firsthand. "People have been incredibly open and generous with their time," she recalls. This willingness to connect, share insights, and offer support has been a crucial element in her entrepreneurial journey. In Deanne’s own words, "It's overwhelming how many good people are out there that are willing to just lend an ear, hear what you're up to, and see if they can help.”

Beyond personal connections, Deanne encourages leveraging every possible network or platform. “You need to talk to a lot of people to find who they are — they’re out there and often really generous with their time."

Winning Together in Medtech

Interview with Orchestra BioMed CEO David Hochman

David Hochman

Preview

David Hochman, the maestro behind Orchestra BioMed, shares his journey from conceiving the idea of the company to accelerating high-impact technologies through risk-reward-sharing partnerships with leading medical device companies. David shares his take on driving successful collaborations, operational excellence in R&D, and the importance of a long-term strategy for sustainable industry innovation through aligned incentives.

About David

David, founder and CEO of Orchestra BioMed, has over two decades of experience in healthcare entrepreneurship, venture capital, and investment banking. He has a history of leading successful medical startups, including Orchestra Medical Ventures and Accelerated Technologies. As Chairman of Motus GI and former board member of Corbus Pharmaceuticals and PROLOR Biotech, David has been instrumental in advancing medical technologies, contributing to significant mergers & acquisitions, and many fundraising successes.

Key Learnings From David's Experiences

- Embrace creativity in structuring partnerships and business models. The nature of collaboration depends on you and your partner organization's vision, capabilities, and long-term goals. When done right, sharing risks and rewards can be highly productive.
- Having robust operational capabilities enables you to generate more clinically meaningful data. The more impactful the data, the more value you can build.
- Prioritize a long-term outlook over short-term gains. Do not cut corners in favor of reaching certain milestones, especially in clinical trials that ladder up to your regulatory strategy.

Winning Together in Medtech: Interview with Orchestra BioMed CEO David Hochman

Partnerships With Shared Risks and Rewards

David's journey began with a noble goal: to create medical devices that generate profits while making a meaningful impact on society.

As the landscape evolved, David skillfully borrowed and adapted the risk- and reward-sharing concept from the biotech industry, reshaping it for medtech. It’s the main principle Orchestra BioMed operates on.

What sets Orchestra apart from other medtech companies is its collaborative business model. They are not investors, nor an accelerator. David says, “We're going to be an operating business that has the ability to execute research and development and clinical programs.” They are breaking down barriers that often exist in discussions with large strategics. Instead of the traditional stilted conversations centered around potential acquisitions, Orchestra looks for ways to collaborate long-term.

Orchestra’s programs are wholly-owned subsidiaries of the company. They meticulously structure each one, complete with legal, financial, and operational frameworks. A joint steering body ensures the alignment of interests, facilitating efficient decision-making. Each program is unique and requires the Orchestra team to tailor their approach for optimal flexibility.

Their partnership with Medtronic, for example, has proven to be quite successful. The AVIM technology has been adeptly integrated into Medtronic's pacemaker devices after thorough testing. “We worked with them very carefully to design the trial that we got the approval for, and the partnership has the potential to expand to other indications," David explains.

Forming win-win partnerships should be the goal, but it's essential to weigh all factors before joining forces with another company. A well-thought-out collaboration can be very productive, but others can be risky.

David summarizes: "It wasn't easy to put together, but I will say it's going really well — we've accomplished a lot in a year, and we're excited about what we'll accomplish over the next couple of years and so on."

Winning Together in Medtech: Interview with Orchestra BioMed CEO David Hochman

Meaningful Data Should Steer the Wheel

The robust infrastructure Orchestra has built with its networks makes it capable of conducting research, development, and clinical trials very efficiently.

David emphasizes the critical importance of meticulous clinical trial design. "We worry incessantly about clinical trial design because it has to be right. It's about creating robust, meaningful data that benefits patients, doctors, and businesses alike."

Currently, Orchestra is running a few large-scale studies involving hundreds of patients each. Their Backbeat program with Medtronic is a notable example. It’s designed to help people with cardiac pacemaker implants who also have uncontrolled hypertension. What's unique about it is that it's a true randomized double-blind study, which is not easy to execute in the medical device world.

Orchestra’s focus extends beyond regulatory approval; they are committed to creating a therapy that genuinely benefits patients, physicians, and businesses. They have full control of the study design, which empowers them to ensure that the trial aligns with these broader objectives.

In David’s words, “We're not done just because we got to a regulatory milestone. We have to care about not just data good enough for approval, but data good enough to guarantee that this is really something that is good for patients, good for doctors, and good for business.” He understands the pitfalls of short-term decision-making and the allure of cutting corners to move quickly, so David stresses that one needs to stay on course, even when the journey is long and challenging.

In the grand scheme of things, Orchestra envisions not only improving healthcare but also reaping the rewards of their efforts. They anticipate earning royalties from every device that Medtronic sells with their therapy. Given that over a million patients worldwide receive pacemakers each year, and an estimated 70% of them also suffer from hypertension, this revenue stream holds immense promise. This is attributed, in large part, to their steadfast commitment to generating meaningful data that substantiates their therapy.

Winning Together in Medtech: Interview with Orchestra BioMed CEO David Hochman

Thinking Long-Term Pays Off

One of the key lessons that David imparts is the importance of maintaining a long-term perspective. Some short-term decisions may seem necessary to reach immediate milestones. However, “Cutting corners is going to come back to haunt you, ” David emphasizes.

The traditional venture model is focused on investments resulting in a short- to medium-term exit. David's vision extends beyond that and recognizes that significant value can continue to accrue after a potential exit. By embracing revenue-sharing models, Orchestra seeks to capture a more substantial portion of this long-term value, ultimately delivering greater returns and creating lasting revenue for its shareholders.

One other area where long-term thinking is crucial is when it comes to clinical affairs. David shares, “There are short-term decisions that you can't undo. Making hasty choices in clinical trial design, prematurely sharing information, or rushing the commercialization of a product in an attempt to meet revenue milestones can have lasting consequences.” The goal is not just regulatory approval but generating robust, meaningful data that benefits patients, physicians, and businesses alike.

Five years into its journey, Orchestra has achieved significant results and remains committed to realizing its vision of transforming healthcare through creating value with its long-term partnerships.

How to Get Users to Fall in Love with Your Product

Interview with SafKan Health CEO Sahil Diwan

Sahil Diwan

Preview

Sahil Diwan brings a youthful, creative energy to medtech entrepreneurship. His company, SafKan Health, is automating ear wax removal, easing the burden on both patients and physicians. We talk about consumer-driven medtech, the power of design, garnering experience from real-world data, focusing on building the business before fundraising, and how OtoSet went viral on social media.

About Sahil

Sahil Diwan, a first-generation immigrant and fast-moving entrepreneur, is the co-founder of SafKan Health. With a background in computer science from the University of Oregon, Sahil's entrepreneurial journey began early. He was already coding at the age of 16 and building startups during his college years. Sahil's venture into medical technology was inspired by his brother Aadil's struggle with impacted earwax, leading to the idea for OtoSet, the first automated and FDA-cleared ear-cleaning device.

Key Learnings From Sahil's Experiences

- Design is about so much more than just looks; it shapes how people see your product, how they use it, and even how they feel about it. Aim to craft something that's not just easy on the eyes, but also easy to use, avoiding complex features that could overwhelm your users.
- Facing FDA's rigorous guidelines shouldn't be considered a regulatory hoop to jump through. Getting actively involved in the process, with a top-notch consultant by your side, can lead to some key learnings you may not have otherwise anticipated.
- Building a solid business foundation is often more challenging than raising capital. Managing a medtech startup involves juggling market demand, product refinement, and team-building, all the while balancing day-to-day operations. When you zero in on the fundamentals, funding gets a lot easier.

How to Get Users to Fall in Love with Your Product: Interview with SafKan Health CEO Sahil Diwan

Design is Everything, and it's Never-Ending

In the world of medtech, and most other industries, design is more than aesthetics: It's about how end users interact with the product and how they perceive it. And ultimately, user experience carries a lot of weight in the adoption rate of any given product.

In the early days of OtoSet, Sahil and his brother undertook the design side of the mission from a practical standpoint. They needed to translate medical needs into a user-friendly device.

The foundational design of a medical device means understanding clinician and patient needs without putting the regulatory requirements aside. Sahil says, "We brought a totally novel ear-cleaning device to market. But the real learning is this: How to continuously iterate on a device that clinicians will use every single day on patients."

The team at SafKan Health recognized early on that, given clinicians' demanding schedules, introducing a new tool can be challenging. Therefore, medical technology shouldn't come with a steep learning curve. "If your medical device isn't intuitive or easy to use, your training has to be hands-on or hours long," Sahil emphasizes. Such a lengthy process is unfeasible, especially in a busy clinical setting.

So how do you successfully, and efficiently, refine the design of your product? Sahil's first answer is real-world testing. "We bring in patients all day, every day to our office and offer free ear cleaning. We're learning a lot about how small tweaks can make a big difference in a product's workflow and usage," Sahil comments.

Once you've set the foundation in place, the next step is creating an emotional connection. Packaging, for example, is something Sahil places importance on. The unboxing experience has to be special, for example. "You want them (physicians) to be excited that they have a new product in their office and you want them to be excited to use it," Sahil mentions.

OtoSet boasts a sleek and intuitive design, resembling a pair of stylish headphones. The transparent compartments on each side allow you to visibly track the clean water as it flows into each ear and then emerges with earwax debris in a separate container. Thanks to the device's stylish design, and partly thanks to the oddly satisfying visuals of the whole process, OtoSet became a viral sensation online, hitting 150 million views without a cent spent on consumer marketing. The viral fame led to a surge of patient interest on their website, offering Sahil valuable insights into managing growth effectively.

On that note, SafKan Health experienced the immense potential of social media. He advises other entrepreneurs not to shy away from, or underestimate, the power of social channels. Far from just being used for entertainment, platforms like Facebook, Instagram, and TikTok can be powerful tools for education, marketing, and brand-building, reaching audiences far and wide.

Use Regulatory Guardrails as a Forcing Function

Although there are other medical devices to clean earwax on the market, FDA's requirements for OtoSet were still stringent, necessitating a full 510(k) submission.

Sahil says, “We are one of the youngest teams ever to receive 510(k) clearance for a medical device”. There are a few lessons Sahil gleaned through this experience. The first one was simple enough: bring in top talent. He praises his consultant Alison Komiyama for her crucial role in navigating FDA's requirements and ensuring compliance.

Yet, Sahil and his team weren't just bystanders. They were actively involved in the process, absorbing every detail. Sahil's advice to aspiring medtech entrepreneurs is straightforward: “Find a great regulatory consultant and don't be afraid to learn and do a lot of the work yourself.”

Their proactive approach didn't stop at addressing regulatory hurdles. They were hands-on at clinical trial sites as well, partnering up with both a Contract Research Organization (CRO) and experienced clinical advisors. When it comes to studies, Sahil keeps two pillars in mind: meticulous data collection and insights from real-world experience. “We used our clinical trial sites as a way to collect data for our 510(k), but then also to start getting real-world experience,” says Sahil. For example, he was there when the device's head strap broke on a trial. It was a simple snag, but it could have been a trickier setback — a reminder of the unpredictability in product development.

For Sahil, collaboration with clinicians who are keen on using and improving the product is crucial. "I don't really care if they have the biggest name in their space, I care if they're going to actually take the thing and put it on their patients and use it and tell me how to make it better," he notes.

Reflecting on the journey, Sahil concludes, “Honestly, I think going through that 510(k) process and all the effort and time it takes was well worth it. It helped us develop a much better product.” He also advises other founders in the medtech space to build a strong foundation in clinical affairs and establish market demand before seeking substantial funding. “You have to have significant momentum to raise a meaningful round,” he says.

How to Get Users to Fall in Love with Your Product: Interview with SafKan Health CEO Sahil Diwan

Build Up a Business Before Raising Funds

Sahil, a first-time entrepreneur, quickly realized that laying the foundation of a solid business was a mightier challenge than fundraising. He says, "To me, raising money was actually easier than everything that comes with building an actual business."

Before you attempt to raise a serious round, you have to find ways to be capital-efficient. During the early stages, Sahil and his brother were quite prudent with their budget — a critical skill in the time and resource-intensive process of launching a medical device. He recalls, “When we did the Dreamit program, we were sleeping in $35 hotel rooms, my brother and I both. That's how we scraped by.”

Another lesson Sahil had to learn the hard way was managing market demand. "We had so much demand that we ended up selling too many too fast," he shares. Having so much demand sounds like the dream for an emerging startup. However, failing to manage it risks your company’s reliability and trust, which is far more important than hitting short-term milestones. Therefore, thoughtful scaling and controlled growth are important

Post-launch, the team needed to develop a playbook for broader adoption. For that, Sahil collaborated with early adopters to refine OtoSet, tailoring it to fit workflows and market needs before scaling up. This allowed them to enhance the product while strengthening relationships with key stakeholders.

And when it finally came to capital raising, Sahil shares, “I have to mention how much I learned from all the rejection.” Every ‘no’ comes with some sort of feedback, and the team was on point in addressing those gaps. Do not take rejection as definitive and maintain communication with your potential investors. Sahil recounts how some initial skeptics returned, impressed by their progress and willing to invest

Sahil’s overarching advice is to balance fundraising with day-to-day business operations. Maintaining focus on the business is critical, even while raising funds. Contrary to what you might be thinking, challenges in raising capital do not diminish with each successive round. In early fundraising, ”You're trying to sell a story or a world that doesn't really exist yet,” Sahil explains. However, he cautions that subsequent funding is equally challenging, each situation presenting unique obstacles that must be navigated in tandem with the business's evolving needs.

How to Secure Widespread Adoption of Novel Technology

Interview with Magnolia Medical CEO Greg Bullington

Greg Bullington

Preview

Greg Bullington, co-founder and CEO of Magnolia Medical, offers firsthand insights on establishing a new standard of care with Steripath, a device designed to enhance sepsis testing accuracy by reducing blood culture contamination. He talks about the pivotal role of robust clinical data, why Magnolia is still running studies even after proving their device's efficacy, and how to use the results to successfully convince different entities such as FDA and other government bodies in public health.

About Greg

Greg Bullington, co-founder and CEO of Magnolia Medical, is a leading figure in the development of Steripath, a revolutionary device that dramatically improves the accuracy of sepsis tests. Greg's previous expertise includes leadership positions across biotech, healthcare access, and enterprise software. Over the last decade, Greg has shaped every facet of Magnolia's success, from creating their own category and navigating the regulatory landscape with FDA to collaborating with the U.S. Congress to accelerate the widespread adoption of Steripath to help avoid the preventable error of false-positive sepsis misdiagnosis.

Key Learnings From Greg's Experiences

- You need solid data, repeatable results, and a technology that remains relevant over time when trying to shift the paradigm in healthcare. Simply demonstrating a device's functionality isn't sufficient; continuous validation and persuasion of diverse stakeholders are key to widespread acceptance.
- Effective communication strategies are crucial when introducing a novel technology. Magnolia found itself educating not only FDA but also enlightening the broader market about Steripath's significance, ultimately owning its innovative market leader role, changing the standard of care for sepsis testing accuracy.
- Positioning a device as the standard of care requires backing from government entities, which are often inundated with proposals from various parties. Knowing how to tell a compelling story with irrefutable data proving device efficacy can push your device higher up on the priority list.

How to Secure Widespread Adoption of Novel Technology: Interview with Magnolia Medical CEO Greg Bullington

Repeatable and Sustainable Data as the Bedrock

Concentrating on validated performance data, repeatability, and sustainability from the onset is critical to build support and gain traction in the healthcare market. Introducing new technologies in healthcare often meets skepticism – and sometimes, rightfully so. To overcome this, you need to start with solid facts. In Greg's story, establishing a bulletproof foundation has been crucial in demonstrating the validity of Steripath to FDA, end users, and the government entities they are collaborating with today.

When Magnolia was first founded, they spent years gathering data at three major hospitals in Seattle to gain a comprehensive understanding of the efficacy of their invention to validate their core hypothesis.

Greg emphasizes, "You can't over-invest in trying to get direct end-user feedback and to have as many cycles as you can out in the field to collect that, as opposed to making decisions in a vacuum around a conference room table with a whiteboard."

During the early periods following Magnolia's inception, the team collected samples from tens of thousands of patients using their ISDT technique, by manually separating the initial sample from the rest. The results were clear: ISDT delivered a significant reduction in false positives, however, nearly a quarter of positive results were still false positives.

Confronted with the numbers, Greg pondered, "What if we invented a completely new device, a sterile end-to-end blood collection platform, so the only thing we test is the blood, not blood mixed with contaminants?" Today this device — Steripath — exists.

The idea was great but it had to be supported by empirical data. Steripath's efficacy was initially tested through three major independent clinical trials that proved its superiority over common manual processes. In fact, one large-scale clinical trial at Stanford University demonstrated a 100% reduction in false positives over 11,000+ patient sepsis tests. "We have demonstrated that this is a preventable error," Greg notes.

Nevertheless, demonstrating a device's effectiveness is just the first step toward its commercialization. Success requires constant commitment. As Greg puts it, "You're going to have to convince the next segment or the next cohort of people that you're targeting, whether it's physicians, nurses, other clinicians." He continues, "I could easily name five or ten technology platforms that have hundreds of peer-reviewed publications behind them and still struggled mightily."

Having hospitals adopt your product is not a straightforward path even with strong clinical validation. Hospitals have a long list of potential improvements to address and therefore have to pick and choose what to focus on. To have them prioritize your solution, you need more than a few peer-reviewed publications showing its efficacy. Greg shares, "Direct, significant, quantifiable data demonstrating preventable morbidity and mortality. Those are the kinds of things that should come to the top of the list."

On their mission to make Steripath the standard of care amongst U.S. hospitals, Magnolia Medical operates within multiple parallel swim lanes encompassing clinical evidence, process improvement, training, and software development for tracking and quantification. On top of all this, their team is collaborating with government organizations to accelerate the adoption of ISDD as the new standard of care.

How to Secure Widespread Adoption of Novel Technology: Interview with Magnolia Medical CEO Greg Bullington

Working With FDA to Establish a New Category

Getting FDA to recognize a new product category is no small feat. It involves not only having a robust, reliable device but also presenting rigorous data and a commitment to ongoing validation. Simply understanding, validating, and trusting your technology isn't enough; you also need to effectively demonstrate its merits to the authoritative bodies to secure their buy-in.

Magnolia pioneered the Initial Specimen Diversion Technique, followed by the invention and development of the corresponding device, the Initial Specimen Diversion Device (ISDD). Both are now individual categories, the latter having earned recognition and endorsement from CLSI, CDC, and other medical societies. The ISDT was a manual technique they developed using off-the-shelf parts. Using this technique, the Magnolia team got the false positive sepsis test results down to about one-in-four. The ISDD – Steripath – is a significant leap forward, delivering results ten times better than the manual process.

“As the pioneers in the space that we're developing and commercializing, we have the obligation and the opportunity to educate FDA on this particular challenge,” Greg shares.

The journey involved presenting robust data that highlighted the significance of Magnolia’s solution, the potential benefits it brings to patients, medical staff, and the overall healthcare system, as well as securing support from other proponents of Steripath, like bipartisan members of the U.S. Congress, which Greg has skillfully managed to get on board.

Yet, working with FDA to establish a new category for ISDD and Steripath was only the beginning for Magnolia. Regulators are not the only stakeholders that you need approval from. When you create a new medical device category, you also have to educate the entire market about its value and its impact on improving patient outcomes.

“Regardless of how simple your technology is, you've got to be creative in terms of how you illustrate and educate to get all of the various stakeholders aligned and on board with your mission. That's the communication challenge side of it,” Greg notes.

Magnolia's robust data, as well as Greg’s thoughtful and intentional targeting of the right government entities, has been critical in supporting Steripath’s widespread adoption. They achieved collaboration with key opinion leaders and authoritative bodies, including the Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), National Quality Forum (NQF), Clinical & Laboratory Standards Institute (CLSI), and Veteran Affairs (VA) Administration.

To convince such entities to support you in your mission is a huge triumph for any medtech company. But to achieve that, you need bullet-proof scientific evidence. You need to know how to get people to pay attention to your cause. Finally, you need to educate the market and the key stakeholders in the community, demonstrating that your solution’s benefits far outweigh the costs.

How to Secure Widespread Adoption of Novel Technology: Interview with Magnolia Medical CEO Greg Bullington

Securing Widespread Support for Novel Technology

Magnolia's strategic partnerships with diverse government entities, ranging from CMS to political leaders, have been crucial in establishing Steripath as a standard care practice in U.S. hospitals.

Greg elaborates on their approach, "It really comes back to the data and evidence as the foundation." He acknowledges that government officials and agencies, wary of past dealings with less credible organizations, demand robust, incontrovertible data before giving their support. This need for credible evidence has led Magnolia to invest heavily in clinical research, which in turn has facilitated productive conversations and engagement.

Steripath doesn't just offer marginal improvements; it brings a drastic reduction in false positive results for sepsis tests. Such a significant improvement in diagnosis and the subsequent outcomes can be quite a persuasive narrative for government agencies that work on healthcare quality. For example, every member of Congress has a significant number of constituents who are affected by a misdiagnosis of sepsis, for whom the congressperson serves as a representative in the government. By targeting this affected population, Magnolia has been able to establish vital communication channels and exert influence with key government representatives.

Greg summarizes, "The combination of the data, the magnitude of the solution, and the understanding that this is something preventable that's harming folks within every district in the United States — and around the world — each and every day, has been a compelling narrative and a compelling opportunity for driving the support that we have from the Senate, the House, as well as the VA, CMS, CDC, NQF, CLSI, and all the other organizations we have worked over the time."

Greg believes that success in the early stages of a business is about making robust connections as much as it is about having robust, reliable empirical evidence. And at the end of the day, the connections you make really come down to playing the odds — Greg calls it a "law of large numbers game," especially in the nascent stages. He suggests treating every single interaction as a potentially game-changing moment. It's about addressing every meeting, every conversation, and every introduction as if they could lead to a breakthrough opportunity.

The efforts the Magnolia team undertook with such big institutions to help promote Steripath's adoption represent monumental successes towards enhancing patient care, improving the healthcare system, and of course, fulfilling Magnolia's mission as a company to continue solving big problems in healthcare.

Your Network is Your Net Worth

Interview with NeuroOne CEO
Dave Rosa

Dave Rosa

Preview

Dave Rosa, President and CEO of NeuroOne, is a seasoned leader in the medical device industry with over thirty years of experience. NeuroOne is developing high-definition, minimally invasive neurology devices utilizing its unique thin-film electrode technology. Dave discusses critical strategies to secure initial capital even before early development and regulatory milestones are achieved, how to leverage networks to connect with potential investors; and the importance of assembling a supportive and experienced team, including board members.

About Dave

Dave Rosa, President and CEO of NeuroOne, brings over three decades of experience in the medical device industry. His career spans several key roles at major firms like C.R. Bard, Boston Scientific, and St. Jude Medical, focusing on marketing, product development, strategy, and commercialization. Dave has several medical device patents to his name, has served on numerous corporate boards, and raised over $200 million in the capital markets. He holds an MBA from Duquesne University and a BS in Commerce and Engineering from Drexel University.

Key Learnings From Dave's Experiences

- Securing initial capital requires more than just a great idea; you'll need to make tangible progress like prototype development and hitting pre-clinical milestones. You can leverage local organizations and social media to target potential investors like angels, large companies interested in emerging technologies, and investors who already have a foothold in your domain.
- Embrace open communication for various purposes, including investment, consultation, and support. Surround yourself with a supportive and experienced team, including board members.
- Opt for shorter regulatory paths like the 510(k) to swiftly navigate through approvals. Focus on technologies with clear predicates to avoid regulatory complexities. Plan your timelines realistically, anticipating possible delays and iterations along the way.

Your Network is Your Net Worth: Interview with NeuroOne CEO Dave Rosa

How to Secure Initial Capital, Fast

"Way back in the Stone Age, when I started in this business," Dave quips, “you could raise money based on a concept.” However, a viable medtech venture now demands a progressively rigorous set of milestones such as functional prototypes, animal and human data, regulatory clearances, and even actual revenue. The shift is clear: investors these days are far less willing to take big risks compared to a decade ago.

This elevated early angel investors to pivotal players, filling the gap left by venture capitalists' dwindling willingness to take on early-stage startups and the risks they carry.

In this context, Dave advises pursuing conversations with strategics early. Even though NeuroOne did not have a final product design, it did meet the growth initiatives of Zimmer Biomet — a multinational medical device company. “They were willing to take a chance on us,” Dave reports. Thanks to the perceived fit, NeuroOne secured a $3.5 million accelerated milestone payment from Zimmer Biomet for EVO sEEG.

Dave also suggests researching the societies and organizations that may help startups, budding companies, or small businesses. Drawing on his experience in Minnesota with organizations like Medical Alley, Dave shares that these groups often have connections to early-stage and institutional investors and can even assist in talent acquisition.

“The fastest way to get money for me has always been to find a network,” Dave suggests. However, he also recognizes that not every entrepreneur has established connections. He shares his own experience of leveraging social media platforms to connect with investment bankers and analysts, “There were a number of relationships that have been really helpful in finding small pockets of money.” Getting your face and story out there can end in fortunate encounters.

Another potential class of investors is the large corporations. They are always on the hunt for smaller companies in the hopes of finding the next growth platform. It’s important to be consistent in your messaging, however. “Keep saying the same thing so that you're able to capture people's interest,” Dave advises. “I was very skeptical, but I have become much more active on social media, and it’s enabled introductions to physicians, some of whom are entrepreneurs themselves, who are interested in investing in technology in their area, as well as other large corporations.”

In Dave’s experience, looking into the investors of competitive companies could prove fruitful, as they may be interested in making additional investments within the same sector. “If they already like the space, and if they're already invested in the space, they may want to make a second bet in the same space,” Dave explains.

Your Network is Your Net Worth: Interview with NeuroOne CEO Dave Rosa

Why Your Network is Your Net Worth

Dave knows how to reach out to people, and it's important that you do, too. This includes engaging with someone to invest, to get them on board with your idea, to consult them, or just to check in.

Let's start with fundraising. Dave's knack for networking played an important role in securing initial funding for NeuroOne. He points out that there are people out there managing high net-worth individuals' money, who are willing to make smaller bets in companies that are at early stages, and Dave was successful in finding them.

He even reveals that, at one point, NeuroOne was operating on a month-to-month basis, completely depending on those small investments. He says, "The formula is, get out in front of as many people as you can, find the people that have relationships with family-run offices or who manage high net-worth individuals, and you can find out who those people are by reaching out, whether it's investment bankers, colleagues, or friends."

Being open to talking to people has other benefits, too. As the CEO, you're the ultimate decision-maker in a company, and it can feel quite lonely and draining at times. "When things go wrong, it will be your fault, whether it is your fault or not," Dave says. You have to remember that you don't have to know everything. Instead, surround yourself with supportive and experienced people. Dave emphasizes, "Put your ego aside, learn as much as you can on the way up, and hire people that have more experience and skill than you."

Inevitably, you'll make some wrong calls. What's crucial is learning from these missteps and moving forward, rather than getting bogged down. Dave continues, "You need to have a support network, friends, colleagues, a mentor to bounce things off and keep your sanity. It's the loneliest job that I've ever had in the world, and I've had it now for quite a while."

The significance of having the right people on your board cannot be overstated. As Dave puts it, "The wrong board, or even just an individual member, can really derail the company." You need to be fastidious when choosing who joins your company, especially your board.

Your Network is Your Net Worth: Interview with NeuroOne CEO Dave Rosa

Realistic Clinical and Regulatory Strategies

Investors don't want to take big risks, full stop. That means if you fail to prove the safety and efficacy of your device, you risk losing the prospects of investment. This is where it gets close to a zero-sum game. "There are so many investors over the years that have been burned investing in a great idea that never got through FDA," Dave notes.

To mitigate such risks, Dave's first strategy is opting for a shorter regulatory path, like the 510(k). It's a tactical decision that'll help you navigate the regulatory waters more swiftly.

A second tip to avoid getting stuck in the regulatory labyrinth is focusing on technologies that have predicates, or in Dave's words, "devices that have already been cleared by FDA that you feel you're comparable to."

Despite favoring the 510(k) pathway, Dave approaches it with the rigor of a PMA. He highlights the importance of collaborating with individuals experienced in similar devices and formerly affiliated with FDA. Working with people who have been in the trenches, who know both the business and the regulatory field inside out is of prime importance. He summarizes, "I try to find consultants that are former FDA employees or reviewers that were in the space that I'm in. I also try to find the people with the right attitude who'd say, 'Tell me what you want to accomplish, and then I'll tell you if we can get there and what the opportunities are and what the risk is.'"

The last piece of advice Dave offers regarding navigating the regulatory and clinical landscape is making sure your timelines are realistic. He says, "Don't cut yourself close on what you expect the clearance times to be." In other words, you need to be prepared for possible delays, revisions, etc. Respect the marathon nature of this race and be prepared for the long haul while keeping your eyes on the finish line.

About the Author

A self-described medical device and health technology enthusiast, Scott is co-founder and CEO of FastWave Medical, a cardiovascular startup that has successfully closed on nearly $20M in capital in less than a few years.

Scott is also a co-founder of Crossfire Medical, an early-stage, venture-backed company focused on the chronic venous insufficiency arena.

He founded Medsider in 2010 with one simple goal: help ambitious doers learn from experienced medical device and health technology entrepreneurs. Scott's 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

The chief aim of Medsider is to help ambitious doers learn from proven medical device and health technology entrepreneurs. These experienced founders and CEOs will show you how to:

- Improve your commercialization plans.
- Enhance your regulatory submissions.
- Strengthen your reimbursement strategies.
- Streamline your R&D efforts.
- Raise capital for your startup.
- Advance your network and career.
- And much, much more!

On a monthly basis, tens of thousands of people consume Medsider podcasts and articles. Folks just like you — men & women, CEOs & entrepreneurs, leaders & teammates, and many others who are interested in ensuring their success within the broader healthcare ecosystem. Learn more at **medsider.com**.

VOLUME V

MEDSIDER MENTORS

MEDSIDER















SCOTT NELSON