

STANFORD BYERS CENTER FOR
BIODESIGN

● byers center for
biodesign

 Stanford MEDICINE



STANFORD
BUSINESS

Stanford ENGINEERING



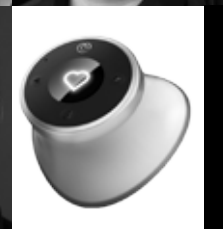
An easy to use, non-surgical therapy that offers immediate results for women with loss of bowel control.

— **Eclipse System**
from Pelvalon



A more durable and reliable ventilator that's a fraction of the cost.

— **Portable Ventilator**
from OneBreath



A fast and portable device to diagnose coronary artery obstruction.

— **CADence™ System**
from AUM Cardiovascular



An advanced device that activates the muscles of bedridden patients to prevent weakness and deconditioning.

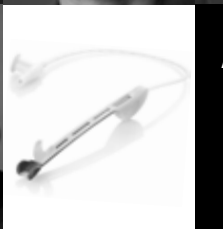
— **Muscle Stimulation System 110**
from Niveus Medical

Welcome to the future of health care



A system for improved monitoring and control of asthma in children.

— **Asthma Management**
from Tueo Health



A safe, cost-effective way to reduce the risk of pneumonia in intubated patients.

— **Sherpa Suction Guide**
from Ciel Medical



A proven, drug-free solution to stop night terrors in kids.

— **Sleep Guardian**
from Lilly



Young innovators don't know how hard it is to bring new technologies to patients. That's why they're exactly the right people to do it.

— **Paul Yock, MD**

Fifteen years ago, we founded Stanford Biodesign on the belief that innovation is a discipline—a process that can be learned, practiced, and perfected. Our vision was to create an ecosystem of training and support for Stanford students, fellows, and faculty with the talent and ambition to be health technology innovators. We also wanted to give them the knowledge, skills, mentoring, and network it takes to actually deliver innovations to patients.

From the start, we knew our approach had to be interdisciplinary. We found the ideal home at Stanford Bio-X, with its connections across the Schools of Medicine, Engineering, and Business. We also realized we had to leverage our location in Silicon Valley and engage world-class mentors who were willing to share their insights and expertise with our trainees. Starting with a team of just four fellows, we soon added graduate and undergraduate classes, multiple teams at Stanford and abroad, and faculty training and seed grant programs.

On the following pages you'll learn about some of the incredible things our fellows and students have accomplished so far. Our fellows have invented technologies that have treated more than half a million patients—and that's just from projects they initiated during their training with us at Stanford. As they've gone out into the world to continue their careers, they're creating and delivering new solutions that will help millions more.

Some alums have even gone on to start new Biodesign training programs at their universities or within their companies, further expanding the pool of young innovators. And many universities have used our approach and teaching materials to create their own programs. Our net impact—and our multiplier effect—is clear.

But there's a lot more to do. We're entering a new era of health economics, where innovators must create new technologies that don't just enhance health, but also increase value. We need to prepare our fellows for a new environment where traditional funding mechanisms and business strategies no longer work. And as we move toward a global health marketplace, we need to learn new lessons in affordability and efficiency from the developing countries that are joining the innovation ecosystem.

These are big challenges, but thanks to the generosity of our donors, the support of our friends in Silicon Valley, and the vision of our University leaders, we've officially been designated the Byers Center for Biodesign at Stanford. This is a major step forward and will help us continue to train fellows, faculty, and students as we expand our economic, global, and policy initiatives. However, we still need donors, advisors, mentors, and friends who understand the challenges we face in health care and are excited by the opportunities.

Help us launch the next generation of innovators—bold young men and women who see constraints as opportunities and will find exciting new ways to improve health and wellness for people everywhere. **Help us invent the future.**

Paul Yock, MD

Director, Byers Center for Biodesign

*The Martha Meier Weiland Professor in the School of Medicine
Professor of Bioengineering and, by courtesy, of Mechanical Engineering*

the biodesign process:

Three simple steps—identify, invent, and implement—turn the arduous, complex, and risky undertaking of health tech innovation into a disciplined, step-by-step process that works. Each year, Biodesign offers an intensive fellowship to 12 innovators with backgrounds in medicine, engineering, and business. Grouped into three teams, these fellows are immersed in a specific area of patient care at the Stanford Health Care hospital and clinics.

During the first three months, the fellows **identify** important unmet clinical needs. By directly observing the full cycle of care from diagnosis and treatment to recovery and billing, they discover problems and opportunities. They watch what's done and how it affects the provider, the patient, and the system, while asking pointed questions that challenge the status quo.

“**Biodesign develops true innovators who will create the future of health care delivery.**”



— **Vic McCray, MD, '11**
President & CEO
Ocular Dynamics, LLC

They identify hundreds of needs without judging or prioritizing. Then, the fellows filter the list with rigorous objectivity, taking everything into account—from the stakeholders affected by that need to how much potential there is to improve care or save money by solving it. It's an intense and iterative process with progressively deeper dives

into the needs that have the most potential. Ultimately, they arrive at the two or three most promising needs which—if they can be solved—will have a major impact on health and wellness.

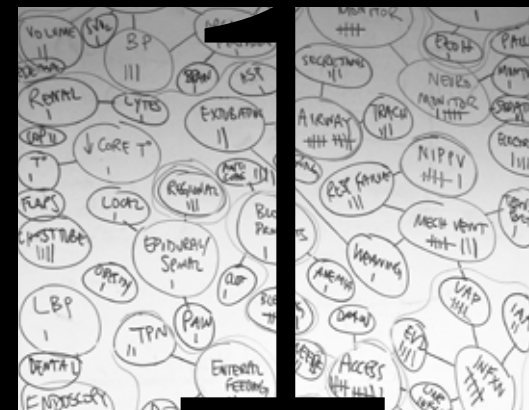
Next, the fellows begin to **invent**. They brainstorm hundreds of potential solutions for each need. Then they organize their ideas and compare them against the selection criteria for each need. During this step, they quickly create a series of rough prototypes so failures emerge early and iteration can lead to better solutions.

The concepts are further filtered as the fellows research everything from intellectual property issues to reimbursement and regulatory pathways. Finally, the best idea wins against many worthy competitors—it's all about survival of the fittest. The process guarantees a concept that has the best chance of reaching patients.

The next step is to **implement** the winning concept. The fellows keep prototyping and testing their technology while developing plans for patenting and regulatory approval. Here, we bring in the “varsity players,” industry mentors with deep business knowledge that help fellows explore market potential and funding sources.

In the end, each team will have an invention and execution plan that's ready to be pitched to any VC. And once they're trained in the process, fellows can use it again and again, anytime, and in any setting. That's the real power of the Biodesign process. It creates more than just innovative products. It creates innovative people.

michael ackermann: one innovator's success story



identify

“During the first three months, my team and I observed patient care at Stanford ophthalmology clinics. While we identified more than 300 unmet needs, it seemed like every third patient we observed had dry eye. Nearly 25 million Americans suffer from this disease. Most treatments focus on inflammation on the surface of the eye, but that doesn't address the root cause. We found that the condition is undertreated and that there aren't many options for patients.”

The most novel part of the Biodesign process is this first stage—identification. Having a systematic way to look at and assess needs for clinical importance and commercial relevance is priceless. I used to think, ‘I have this hammer, now I've got to find a nail.’ But the Biodesign process taught me a different way of thinking about innovation.”

“**If it were not for Biodesign, there is just no way I would be in the leadership position I'm in today.**”

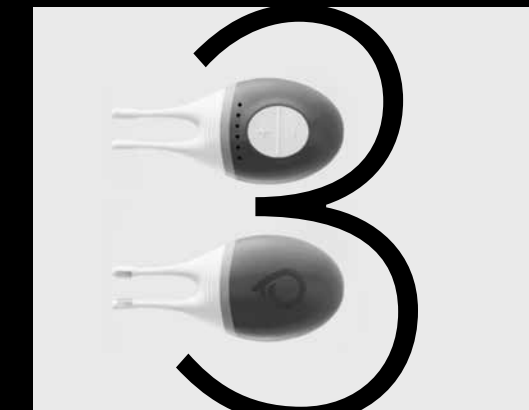
— **Michael Ackermann, PhD, '11**
Founding CEO, Oculève
Vice President of Neurostimulation, Allergan



invent

“Once we'd screened all the viable needs and decided to focus on dry eye, we spent months brainstorming and testing treatment ideas. Because I have a background in electrical stimulation, I wondered if the body could be stimulated to produce tears naturally. Turns out, it could be.”

At first, we thought it should be an implantable device (pictured above). But through many iterations and further testing, we found we could create a non-invasive technology to send painless micro-electrical pulses to the lacrimal gland in the nasal cavity. And it could be controlled by the patient. By taking a non-invasive approach, we knew we could reach many more people and do so with less complications, at a lower cost.”



implement

“Seeing the potential benefit to millions of dry eye sufferers motivated me to take this product (pictured above) to market and start a company called Oculève. We were recently acquired by Allergan for \$125 million and we've treated more than 400 patients in clinical studies to date, with very promising results.”

Since the fellowship, I've trained more than 300 people in the Biodesign process, coached 43 others, been named on nine issued medtech patents, and founded another start-up that has raised \$600,000 in funding to date.”



“

Health tech innovation needs to start and end with the patient—not the technology. That’s exactly what the Biodesign innovation process teaches people to do. Too many inventors get so excited about solving a big problem, they leap at the first good solution that presents itself without fully understanding all the aspects of the underlying clinical need and downstream challenges. Given the high stakes of medtech innovation, it’s vital to master this process so you can avoid many of the common pitfalls.

— **Josh Makower, MD**

*Co-Founder, Stanford Biodesign
Founder & Chairman, ExploraMed
General Partner, NEA*



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Biodesign develops and enables the next generation of innovators to rethink medical device development for the rest of their careers.

— **Tom Krummel, MD**

*Co-Director, Stanford Biodesign
Chair Emeritus, Department of Surgery
Stanford University*



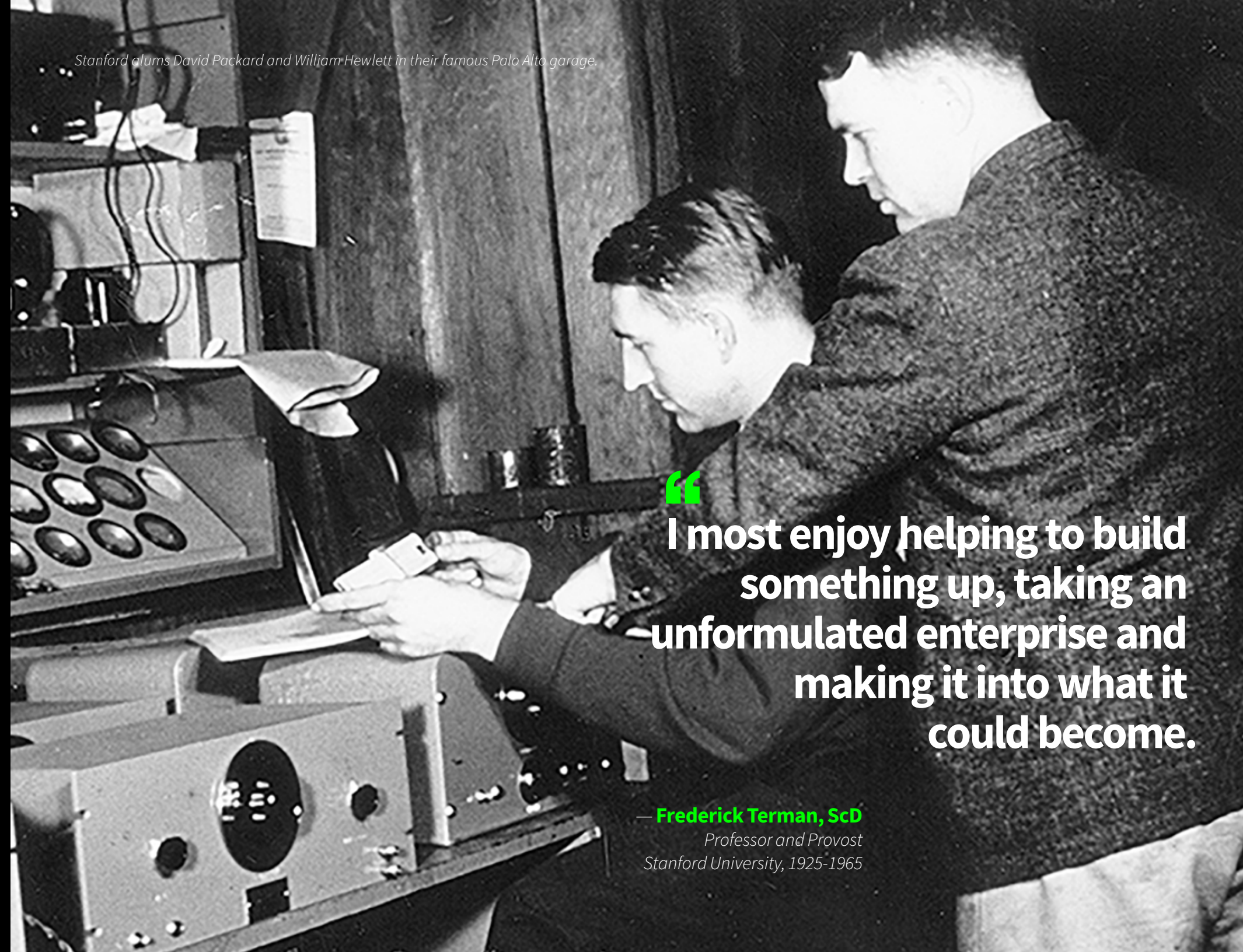
it was born in the valley

It couldn’t have happened anywhere else. When Stanford professor Fred Terman had the vision to help his students Bill Hewlett and Dave Packard take their idea and turn it into a company, they started a revolution that would become Silicon Valley. Terman knew that if he could create an environment where students and industry leaders could teach each other, it would change the world. Half a century later, we decided to apply the same idea to biomedical technology innovation.

Bio-X, Stanford’s university-wide biosciences initiative, laid the foundation for Biodesign—a program to foster innovation at the intersection of technology and basic science. For us, the “X” in Bio-X stands for design, and we owe both our name and our culture to this extraordinary multidisciplinary endeavor. Backed by the academic clout of Bio-X, all we needed to succeed was the expertise of Silicon Valley’s best. Josh Makower, a prominent inventor and serial entrepreneur, became a co-founder of Biodesign, developing and leading our training program, and cemented our connection to industry.

Over the past 15 years, this collaboration has grown into the most successful partnership between academia and the health tech industry anywhere. We’ve created a community that couldn’t exist anywhere else. The world’s most successful tech leaders generously give their time to teach classes and advise Biodesign fellows, faculty, and leadership. They also provide connections that fellows wouldn’t have otherwise and that last for their entire careers. At any time, fellows can pick up their phones and bounce ideas off the best. And that can mean the difference between success and failure.

Stanford alums David Packard and William Hewlett in their famous Palo Alto garage.



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I most enjoy helping to build something up, taking an unformulated enterprise and making it into what it could become.

— **Frederick Terman, ScD**

*Professor and Provost
Stanford University, 1925-1965*

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You'd be surprised at some of the ways health care is delivered in different parts of the world. Biodesign has taught me how to design and innovate anywhere. It's equipped me with the right set of tools and skills to meet the needs of any market, especially emerging ones.

— Dorothea Koh, MSzv



Motorcycle in Anhui Province, China, with make-shift IV drip.

it works in every setting

In China, scalability is key to successful innovation. In Japan, everything depends on building relationships. In Africa and India, funding and business models require as much innovation as the technologies themselves. No matter where health care is delivered, vital insights like these are revealed by the Biodesign process.

The traditional approach to medtech innovation is upside down. It usually starts with a solution in search of a need. But the Biodesign process *starts* with the need. And for a solution to truly meet a need, it has to work in the setting where that need exists.

The three-step process is ruthlessly pragmatic. When it's rigorously applied, it automatically takes setting into account. When you're identifying needs, whether you're in a hospital in Palo Alto or an infusion clinic in rural China, you have to immerse yourself in the physical and cultural environment and consider the perspectives of all stakeholders.

When you're inventing a solution, the process forces you to carefully consider exactly how and where it will be used. And when you're implementing a solution, the process again requires you to examine everything from traditions to economics to infrastructure so you can successfully get it to patients.

The very nature of the process shuts ideas down early if they don't take setting into account. That's why it works everywhere.

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When I first moved to Shanghai, I visited an outpatient infusion center. It was the first time in my life I saw so many people getting IV drips all at once—it looked like a dialysis center, but instead of machines, it had row after row of IV poles.

China is the world's largest infusion market with about 10 billion infusions given annually. That's 8-10 bags per person—five times more than the world average! You see people hooked to infusion bags everywhere, even young kids.

How do you think about delivering care in a setting like this? You can't take solutions that were created for developed markets and bring them into an emerging one like China and expect them to work the same way. Bringing health care to millions and millions of people requires you to change your paradigm.

Every day, I use the Biodesign process to create and commercialize disruptive business models tailored to the Chinese market. We identify unmet needs, prototype in market, and pilot until we feel the model is ready for scale. Then we plug it back into the core business. This has allowed us to create a center of excellence to innovate for China that is unique.

— Dorothea Koh, MS, '08

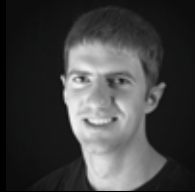
Director of Business Model Innovation
Baxter China



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We noticed that ICU patients with breathing tubes were almost always sedated to the point of being in a coma. This is the current standard of care to manage the extreme discomfort of being intubated, which is like having a snorkel shoved down your throat. That's why we invented the Wyshbone catheter. It continuously delivers Lidocaine to numb the throats of intubated patients.

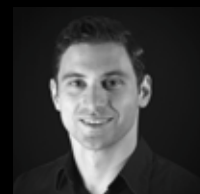
— **Rush Bartlett II, PhD, '13**
Co-Founder, AWAIR



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Sedatives for these patients cost up to \$800/day. More than half of heavily sedated ICU patients develop delirium, which costs \$30 billion annually to treat. We believe Wyshbone could cut drug costs by half, reduce hospital-acquired complications, and help people get well faster. That generates enormous value.

— **Ryan Van Wert, MD, '13**
Co-Founder, AWAIR



it's driven by value

The rising cost of health care is one of the most pressing economic and political issues of our time. The way we used to innovate—“progress at any price”—doesn't cut it in a health care landscape that's increasingly concerned with better outcomes at lower cost. Especially in resource-challenged settings, both here at home and around the world, there's an urgent demand for health tech that's more affordable and more effective.

The Biodesign process has value in its DNA. It inherently reduces cost, just as it inherently works in every setting. The process is all about getting the need right. So, in a world that's desperate for more affordable health care solutions, value automatically becomes part of the need. For a solution to be worth pursuing, the cost/benefit equation must be compelling enough to get providers and/or patients to change their behavior. The solution has to be better than other solutions. And it has to make financial sense to whomever's paying for it.

In a new era of accountable care, cost effectiveness is one of the top criteria used to screen potential needs. And as the solution to a promising need begins to take shape, fellows think about value in more concrete, concept-specific terms. If the added cost of an innovation doesn't lead to an increased net value, it doesn't make the cut. For the right concept, the cost savings to the system is a source of competitive advantage for the product and differentiates it in the marketplace.

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The cost of ICU care creates a tremendous burden for hospitals, insurance companies, and patients alike. Wyshbone represents a simple change in practice that has the potential to improve the patient experience while dramatically reducing costs and complications.

I.C.U. — **Stephen Ruoss, MD**
Clinical Chief, Pulmonary and Critical Care Medicine Division
Stanford Medicine



Clinton at a U.S.-India innovation event organized by the U.S. State Department at Taj Palace, New Delhi

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These cutting-age innovations cost a fraction of other medical devices that address these same problems and make life-saving health care available to people who may not otherwise be able to afford it.

— **Hillary Clinton**
Former U.S. Secretary of State

Stanford - India Biodesign

it's gone global

The Biodesign process is spreading everywhere. Since 2001, we've trained more than 1,000 people to use it. If you count all the people they've trained, its practitioners number many times that. We've written a textbook, which is now in its 2nd edition and has become the standard in the field. We've created an extensive video library as a free and public resource. And we've inspired dozens of health tech innovation programs across the United States and in 18 countries, many started or managed by Biodesign fellows and trainees.

But it's not enough to spread the process. Like Nish (*at right*), we have to become thought leaders who inspire change in our own country and around the globe. We have to foster an environment that's conducive to getting innovative new technologies into patient care. We have to find new, more approachable ways to teach health care economics to innovators. And we have to give them the knowledge and flexibility to stay relevant in an environment that's increasingly competitive and constantly changing.

It's time for us to become a leading voice in the national health care conversation. By researching everything from regulation to reimbursement, and sharing what we learn, we'll influence the decision makers who are shaping the legal and political landscape.

The world of tomorrow will demand technology that delivers better health outcomes at a lower cost. And the next generation of Biodesign innovators will invent it.

They are the future of health care.

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I was in the first class of Stanford-India Biodesign fellows. We quickly learned how important frugal innovation is in India. Almost everybody pays for health care out-of-pocket, so you have to get the same clinical outcome for a tenth of the cost.

Our team created a device that would help thousands. But we couldn't test it because India had no system for licensing. So we helped the Indian government create a licensing process based on U.S. protocols. Now you can license a new device in India within two weeks.

But we didn't stop there. We established the Stanford-India Biodesign Center and helped unite a fragmented health tech ecosystem. We established a new tech transfer process, grantmaking facilities, and even started an annual health tech summit.

I'm still passionate about inventing devices that help patients. But what really excites me is finding new ways to deliver devices in the most cost effective way to the most people. I think that's a much bigger contribution.

— **Nish Chasmawala, '08**
Director & Co-Founder
Consure Medical



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I'm one of the many volunteers who have worked with Biodesign at Stanford. For nearly 15 years, I've mentored, coached, and supported fellows and the program. I've had the pleasure and honor to get to know Paul Yock and the very talented leadership team very well.

I'm thrilled that Biodesign has earned the designation of a formal "Center" at Stanford. This program is uniquely positioned to improve human health around the world. Their fellows and medical innovations change health care and have already directly benefited hundreds of thousands of patients. And they're inspiring and empowering others by sharing best practices globally.

and you can be a part of it.

Thanks to our many supporters and friends, we've launched a new generation of health tech innovators while spreading our three-step process around the globe. These amazing Biodesign trainees have invented more than 100 devices, started more than 40 companies, raised hundreds of millions of dollars to support those companies, taught hundreds of others the process, and helped many hundreds of thousands of patients.

Biodesign is completely reliant on the generous annual support of our corporate, foundation, and individual donors. We are very grateful to them. But yearly funding is unpredictable. We need long-term funding we can depend on to secure the future of Biodesign. With your philanthropic partnership, we'll build an endowment so we can expand our horizons—beyond each new class of fellows.

Help us unleash the power of innovation. With your support, we can teach and spread the Biodesign process for generations to come. We can create hubs of innovation around the world so everyone can benefit from the Biodesign process. And we can focus on eliminating threats to health tech innovation so our trainees can keep delivering solutions to the world's biggest health care challenges.

For us to have a real impact on the future, we have to ensure our own. **Please join us.**

For more information on how you can support Biodesign, please contact Melanie Erasmus at 650.723.9948 or via email at merasmus@stanford.edu.

—**Brook Byers**

Partner
Kleiner Perkins Caufield & Byers



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This program is uniquely positioned to improve human health around the world.

—**Brook Byers**

Uday Kumar, MD, '06

Founder, President, CEO
Element Science



entrepreneur

400,000 patients treated and growing
 >\$110M raised in disclosed funding
 >100 people trained in the Biodesign process
 13 patents (9 as lead inventor)
 4 companies founded/co-founded

corporate leader

guides global business strategies across Intel
 leads healthcare investments and clinical projects
 >350 people trained in the Biodesign process
 11 patents (9 licensed)

professor

\$57M raised in disclosed funding
 >700 people trained in the Biodesign process
 3 companies founded
 2 patents

Asha Nayak, MD, PhD, '02

Chief Medical Officer, Intel Corporation

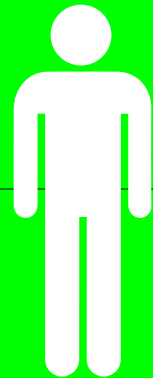


Todd Brinton, MD, '05

Fellowship Director, Stanford Biodesign
Clinical Associate Professor
Cardiovascular Medicine, Stanford Medicine



**Every
path our
fellows
follow
leads**



**to better
care for
patients
around
the world.**

That's why we're creating hubs of innovation everywhere.

