FEATURE

Educating from Bench to Bedside:

Stanford's Biodesign Program

by VINCA CHOW and RAY GUO

What sparks ignite when students from medicine, engineering, and business are brought together? How does Stanford train the next generation of biomedical device innovators?

SIX YEARS AGO, CARDIOLOGISTS struggled for hours to insert a pace-making lead in the coronary sinus in order to resynchronize the heart from both sides. Implant failures were as high as 14%. Now, with the use of an endocardial visualization catheter, clinical trials report a staggering success rate of 98%.

The innovators behind the transformation of this clinical procedure were Nicholas Mourlas and Christian Eversull. They developed the enabling visualization system during their fellowship in the first year of the Biodesign Innovation Program at Stanford University. Biodesign emerged in 2001 under the vision of Paul Yock, an interventional cardiologist and professor at Stanford Medical School, and Joshua Makower, an entrepreneurial inventor who founded a similar program at Pfizer earlier. This partnership between academia and industry epitomizes the program's structural backbone. By knitting together the academic and industrial communities, Biodesign trains the next generation of biomedical device inventors to construct and launch revolutionary clinical tools.

Through this educational program in innovation, Mourlas and Eversull began a career to enhance the delivery of heart therapy by founding Acumen Medical Inc. Within a space of six years, they expanded the market from an experiment at a single Stanford hospital to a routine procedure at multiple hospitals across the world. Strategic partnerships with companies like Medtronics to ensure compatibility reflect the device's acceptance into the mainstream market.

Acumen Medical Inc. was only the first of many success stories from Biodesign. Alumni have launched other startups, including Kerberos Proximal Solution and NeoGuide Medical Systems, or have been recruited to biotech firms to engineer technologies, advance concepts through to clinical implementation, and nurture novel ventures.

How does Biodesign spur its fellows on to brilliant careers in biomedical device development? It does so by exposing budding biotech innovators to each step of the process of invention, from identifying the problem to devising the solution, to patenting and attracting venture capital.

There are two branches to the Biodesign program, both of which bring students or professionals in medicine, engineering, and business together into a stimulating and collaborative process. The first is a rigorous one-year fellowship that begins with a "boot camp," where the fellows are mentored by Stanford faculty members as well as "real world" experts in the whole spectrum of innovation, from design to patenting and financing. Equipped with this robust foundation, the fellows then immerse themselves in the hospital for two months where they assess clinical needs with keen eyes and questioning minds. They closely observe each procedure and ask difficult questions—why did the cardiologist use that catheter, why did the surgeon incise in the midline? The process enables the multidisciplinary team to understand the precise details of the shortcomings they observe.

"By building relationships with the clinical faculty, [the fellows] come to understand not just the clinical problem, but also who the stakeholders are, and how it impacts the nurses and the financial system. They understand the entire backbone of why there is a problem and why it has not been met yet," Todd Brinton, MD, co-director of the Biodesign Innovation Program, explains. Only after gaining a thorough understanding of the problem does the team of clinicians, engineers, and business professionals go to the drawing board.

Illustration by Cheng Qu; colouring by Julie Ma

Following the same model of multidisciplinary collaboration, the second component of Biodesign offers courses that take graduate or postdoctoral students through the entire process of innovation from needs assessment to concept development and implementation. For example, the two-quarter Biodesign Innovation elective course combines lectures from faculty, industrial experts, and venture capitalists on the development of patent strategies and assessment of clinical and market potential.

While the medical students gravitate toward understanding the clinical problem, the engineers contribute their technical expertise and the business students offer their entrepreneurial insights. "These are the three key components that you need to be successful in an entrepreneurial way," Brinton points out.

Brinton himself had gone through the fellowship program before serving as its co-director. Prior to entering medical school, Brinton was trained as a biomedical engineer at the University of California, San Diego, and worked in R&D at a company focused on non-invasive hemodynamic monitoring. His passion for developing medical devices prompted him to work with Paul Yock and eventually join the Biodesign fellowship program while serving as the chief fellow in cardiology at Stanford.

"I had been exposed to a lot of engineering and to the clinic, but I had not had the opportunity to integrate the two. And certainly I did not have the tools to understand a business," Brinton reflected. Under the guidance of academic and industrial experts, venture capitalists and mentors from law firms specialized in biotech start-ups, he learned how the different components fit together. "This is the best opportunity for real world experience in an academic setting."

This outstanding bench-to-bedside training is gathering momentum in other academic institutions as well. At least 20 other programs from colleges such as Johns Hopkins and Washington University at St. Louis have visited Stanford, and the faculty at Biodesign has shown them the organizational framework of the program.

Furthermore, committed to training the next generation of biotech inventors, Biodesign is globalizing its methods of "teaching innovation." In partnership with the government of India, the Stanford-India Biodesign (SIB) Fellowship was launched in May of this year. The goal is to stimulate innovation in medical technology in India, where the industry is poised for explosive growth. In particular, the SIB program emphasizes the development of cost-effective solutions so as to better meet the health needs of those in the bottom rungs of India's socio-economic ladder.

Fellows from India receive hands-on training at Stanford that would enable them to return to India to examine the existing health needs, identify opportunities, and develop biotechnological solutions. "By sharing our teaching methods with our Indian partners, we expect similar Biodesign training programs to spring up around India, fueling the development of exciting new technologies within the next decade," said Paul Yock, the current director of Biodesign.

The fellows graduating from Stanford Biodesign are key agents for disseminating this strategy of uniting scientific innovation and entrepreneurial ventures. Whichever corner of the globe they work in, these innovators will be leaders in devising medical technologies that are not only more successful as commercial enterprises, but more importantly, that are more successful for patients.