

# STANFORD-INDIA BIODESIGN: A LESSON IN ENTREPRENEURIAL HUMILITY

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## ABSTRACT

The Stanford-India Biodesign program, started in 2008, was an attempt to propagate the teaching of the biodesign process to another country. With the help of the Indian Government and faculty at the All India Institute of Medical Sciences and the Indian Institute of Technology Delhi, Stanford launched a fellowship that would bring highly motivated and trained individuals from India to the university for a six-month training program in the biodesign process. This would be followed by a return to India for a second six-month phase where the process taught in the US would be implemented in the India healthcare setting. With our six years of experience with the program, we will discuss lessons learned from the teaching of innovation and working with global partners.

## Introduction

The biodesign innovation process has been taught for thirteen years at Stanford University. In the last six years, we have expanded the training to include international fellows who come to Stanford for six months to learn the process and then return to their home countries to implement it with a focus on healthcare needs in those countries. The first program of this kind was the Stanford-India Biodesign fellowship.

## The Foundation

The Biodesign Program at Stanford University was started in 2001 with the ambitious (some might say audacious) goal of providing robust academic training to the future leaders of the medical device industry. This began as a two-part process: identifying potential leaders and then teaching those individuals a system of needs finding and concept creation that would lead to the successful development of a medical device. The first elements of the program were a year-long fellowship and a graduate level course.

Born out of a desire to mentor, the fellowship program was started by Paul Yock and Josh Makower, each medical technology pioneers in his own right, but also individuals who clearly understood the shoulder-standing aspect of any productive career. According to Dr. Yock, his own mentors shepherded him through the innovation process in a way that helped him succeed, and that it was now necessary to provide such mentorship in a more highly structured way within an academic setting. Dr. Makower, in parallel, had begun a program at Pfizer (called, delightfully, Pfreshtech) that set about to teach innovation within a corporate setting. The two became partners in 2000 at a time when Stanford was beginning to support an upsurge in interdisciplinary initiatives across the campus.

The fellowship and a related course provided the foundation to train a number of individuals in biomedical technology innovation. The first five years were highly productive, training over 200 fellows and students in the biodesign process. Nine companies were formed from products



developed in both the fellowship and course, several of which went on to be commercialized and/or later acquired. Other programs around the country took note of the program's progress and visited or inquired as to how they too could begin such a program.

The program is built around the idea that innovation is teachable. Figure 1 shows the steps of the process as it is taught. Starting with the identification phase, where individuals immerse themselves in a clinical setting for observations, teams of four fellows work together to identify hundreds of needs where medical device solutions may be appropriate. Next, those needs are screened using a host of criteria that dictates which needs are most in need of solutions. These criteria include the obvious such as market size, prevalence, and potential patient impact, but may also include things like the potential to impact an already overextended healthcare system.

## Biodesign Process Overview

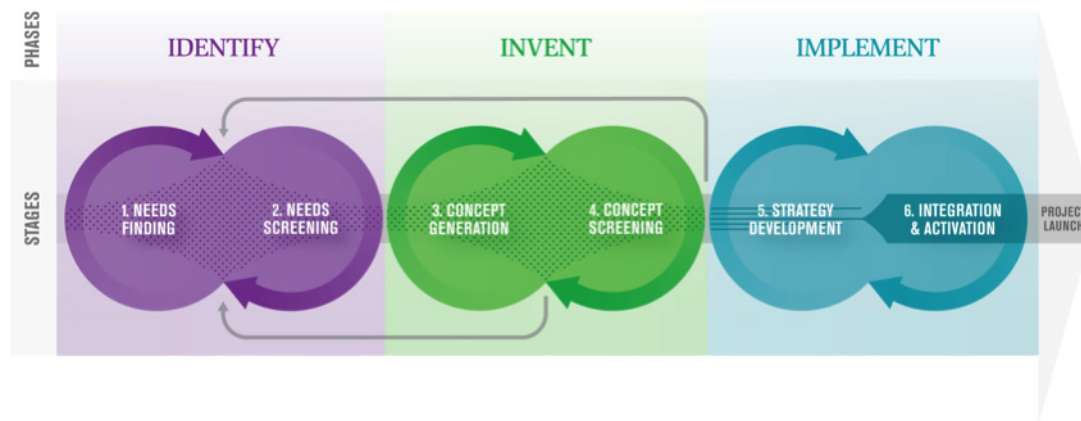


Figure 1. The Biodesign Process

The next phase begins once a handful of needs are determined to hold the strongest potential. Multiple concepts are developed for each need, and those concepts are screened for the most promising. A set of criteria, used as a filter, allows the innovator to find the best of the possible solutions. Finally, in the last phase, the development of a business model and plan comes into play, as in many entrepreneurial course settings.

The successes of the program in those first several years begged the question: was this repeatable in a setting outside Silicon Valley, where the valley's resources are less likely to be available to entrepreneurs?

### The Global Directive

Five years into the Biodesign program, the president of Stanford, John Hennessy, proposed a global mandate for all Stanford faculty: consider broadening your scope of problem-solving to include the world's biggest problems (Hennessy 2005, 2011). Faculty from the Biodesign program took the mandate to heart and started to consider how they might train global leaders in biomedical technology innovation.

At the same time, a discussion was in progress between Stanford School of Medicine's Senior Associate Dean of Research and the Government of India's Secretary of Biotechnology. The subject was how to promote healthcare innovation in India. The Dean pointed the Secretary toward the Biodesign program as an example of how one could teach innovation. Thus began talks on how the program could be directed toward the training of Indian engineers and physicians. Faculty and staff developed a new curriculum based on the existing fellowship; a budget for the program was delineated and Indian government funding was approved in 2007. The Stanford-India Biodesign (SIB) program was launched the following year, with SIB fellows starting in January 2008 (Press Information Bureau 2007).

### The Roll-Out

The Indian government allocated \$4.8 million for the first five years to help fund the Stanford-India Biodesign (SIB) program. The mission of the program, similar to the mission of Stanford Biodesign, is to train the next generation of Indian medical technology innovators. The core of the program is a two-year, team-based fellowship. Following the announcement of applications in the early summer of 2007, over 300 engineers and physicians applied to the program. Screening interviews were conducted in New Delhi in August, and the top eight candidates flew to California for interviews in September. Five candidates were selected for the initial team.

Balram Bhargava, MD, professor of cardiology at the All India Institute of Medical Sciences (AIIMS) in New Delhi, was appointed Executive Director (India) for the Stanford-India Biodesign program. Dr. Bhargava is an internationally known interventional cardiologist who has helped pioneer several procedures and technologies. Dr. Alok Ray, Professor of Biomedical Engineering at Indian Institute of Technology-Delhi (IIT-Delhi), was chosen as the lead for his institution. In

addition, Stanford Biodesign selected Raj Doshi, MD to be Executive Director (Stanford) for the new program. Dr. Doshi is a Stanford-trained physician and entrepreneur.

A new SIB Center was created in Delhi at AIIMS, modeled after Stanford's Biodesign location that includes prototyping facilities, brainstorming spaces, and meeting rooms. Since its opening, it has become a nucleus for medical technology educational programs at AIIMS and IIT-Delhi (Stanford Report 2009). While Stanford's Biodesign program had successfully trained medical innovators for several years, the new partnership took on a decidedly unique perspective where an emphasis on the cost-effectiveness of new technologies was important, with a particular focus on the medically underserved. This would prove to be prescient, as the climate in the United States for new medical technology would change significantly over the succeeding years.

The newly launched Stanford-India Biodesign program welcomed its first set of fellows in January 2008. Through Stanford's Emergency Medicine Department, SIB partnered with the Emergency Management and Research Institute (EMRI), the institute in India responsible for establishing a 911-like service throughout many Indian states. Dr. S. Mahadevan, chair of Emergency Medicine at Stanford, had close ties with EMRI, as he has been responsible for training many of the paramedic staff in India. This partnership allowed training of the fellows in needs finding in emergency medicine the first year of the program both at Stanford and in India.

This first global fellowship had a slightly different profile than the original Biodesign fellowship. The first six months are spent at Stanford, learning the Biodesign process, much like the original Innovation fellowship, but in a condensed format. To get the most of their time, the fellows performed three phases simultaneously: the needs finding (Identify)

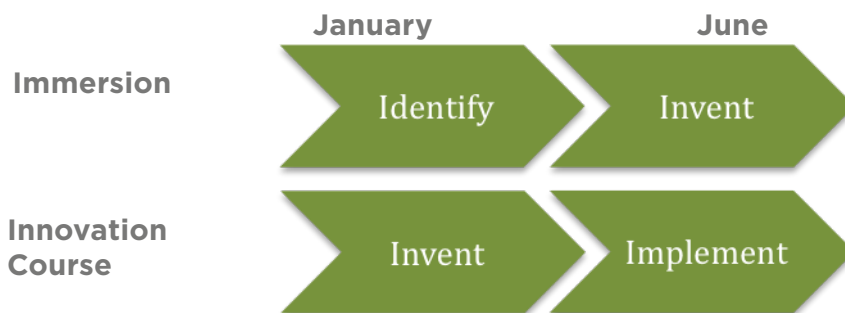


phase was performed with immersion in the Stanford hospital, and the concept development phases (Invent/Implement) were performed as students in the Biodesign Innovation course, which took place during the same period the fellows were at Stanford (January – June).

How the traditional fellowship is taught:



How the SIB fellowship is taught at Stanford:



Having sufficiently grasped the techniques of the process during this period, the SIB fellows return to India to repeat it in their own setting. Clinical immersion takes place at AIIMS in the relevant clinics (although emergency medicine was a focus the first year, that can change from year to year) and operating rooms. Needs are collected and filtered, and the best are chosen for concept development. Development is done at AIIMS in the SIB Centre, with engineering support coming from the Biomedical Engineering department at IIT Delhi.

During the first year of the program, Stanford-India Biodesign hosted the first ever Medical Technology Summit in Delhi, India. Forty professionals participated from many areas of the medical device arena, including education, government industry, and non-government organizations (NGOs). The summit catalyzed the community to address needs in the development of device technology for India. It was clear even from the first meeting that an ecosystem of medical technology professionals needed to be created to support the devices and entrepreneurial careers that would be launching from the program.

### The Working Program

The program structure today is not significantly different from the original model, although the team size is now four. The fellows continue to come to Stanford for the first six months, returning to India for the final six months. An option for a second year has provided the ability for some fellows to carry their projects forward and reach a level of development that allows for funding.

In 2009, the second year of the program, India added an internship to Stanford-India Biodesign

(SIB). This gave the fellows a chance to pass on what they had learned at Stanford and were developing in India. The model of “see one, do one, teach one” was used to reinforce the teaching they were receiving and gave them a chance to have students work on some of the identified needs that they would not be able to develop. The interns became productive members of the community alongside the fellows, and have also produced devices with market potential (see results below).

The Indian Medtech Summit has also continued: in its seventh year, there were over 200 attendees from all aspects of the medtech ecosystem. Featured speakers in the past have included former prime ministers and UN ambassadors, as well as the Director of the US National Institutes of Health. It regularly includes an exhibit of low-cost devices developed for India, both from the fellows and interns, but also from other small companies.

In 2012, SIB launched a Biodesign-for-India curriculum for use by Indian faculty. The offering includes a set of slide decks that can be used to teach biodesign. This may provide an additional method for scaling the approach more broadly.

### The Lessons

Learning to work within a region that is lacking a significant medical technology industry of indigenous players has been humbling, as we have sought to equip our fellows with the skills necessary to be productive innovators. We’ve learned much from the process of introducing this program into India.

First, partnerships with leading institutions and high-profile individuals are half the battle. Having found willing and exemplary partners at the Department of Biotechnology with Dr. Raj Bhan, at AIIMS with Dr. Balram Bhargava, and IIT-Delhi with Dr. Alok Ray (with additional support from the Indo-US Science & Technology Fund) was instrumental

in getting a program started and growing. Since these organizations are government-run or government-funded, the connections to other government resources were more easily made and developed. These connections were critical at several junctures in the development of the program, including securing funding both for the program and for the individual projects, establishing a home base (at AIIMS), and getting licenses developed through Biotech Consortium India Limited (BCIL) – a public company affiliated with DBT.

Second, the way we select fellows is a critical part of the fellowship. It is not sufficient (although necessary!) for a fellow to be highly trained in a particular field. The SIB fellow must also have a high degree of tenacity and creativity. It is important to understand what each candidate might bring to the team in this nascent field. Developing medical devices anywhere in the world is a difficult road, but in India, where many of the resources available to developed world entrepreneurs are not available, one must have the ability to turn a sow’s ear into a silk purse.

Case in point: in the second year of the program, the “winning” need was an inexpensive splint for road accident victims. The scenario was simple but unexpected: when a lower limb is broken, a splint is placed, but as the splint is the only one the ambulance stocks and is very expensive, the splint is removed from the patient at the hospital and returned to the ambulance. Patients are left un-protected for some hours while they await x-ray or other services. The fellows set about to create a less costly splint that could accommodate lower limb injuries but was inexpensive enough that the ambulance personnel could afford to let it go. They found help at a local FedEx box factory. Making the splint from corrugated cardboard resulted in a structurally sound device manufactured at a low cost. And there was an added benefit: the splint could remain on the limb even during x-rays.



Third, medical technology industry know-how is critically needed. Although the SIB fellows have many contacts at AIIMS and in the Delhi community, not many of those contacts have taken a product to market. Fewer have done so in the medical technology arena. Knowing individuals who have successfully gone to market with a medical device is invaluable, even if those individuals did so in the US. Our fellows are mentored on a regular basis by our faculty and staff, even after they have completed their fellowship. The support provided has been critical to these fellows as they launch products in India.

Case 2: Consure Medical, a company that spun out of the first year of the fellowship, ran into difficulties obtaining a license from the Indian government. Since SIB is a government-funded program, all intellectual property developed in India under SIB belongs to the government and innovators who wish to take projects forward must obtain a license for the invention. Although the Department of Biotechnology had issued a number of pharmaceutical licenses, this was a first; never before had a medical technology license been issued by DBT to a company. Fortunately, Stanford had examples of medical device licenses that have been issued in the US and these could be used as a starting point. Our own faculty assisted in the process of getting the first license issued, although it took several months. Once the first license was issued, others came much more quickly.

Fourth, what one might consider “traditional” funding channels are not available in India in the medical technology industry. Approaching non-traditional funding is imperative. First-time funding for many of the projects comes from the government or foundations and not angels and venture capitalists.

Case 3: In year 3, the device developed by the fellowship team in India was a low-cost hearing-screening device for newborns. It was difficult to find interest in funding for

several reasons, but a primary reason was that pediatric devices have a smaller market size and thus are often a neglected area in medical technology from a funding perspective. The team was able to approach an internal Stanford University funding mechanism because of its connection to the faculty. Their first round of funding got them over a technical hurdle that allowed them to get solid data on their device and approach other funding agencies.

## The Results

Much has been learned by following the SIB fellows and their paths to entrepreneurship as they have struggled with doing what many find “easy” in the Silicon Valley: creating and sustaining a startup. But with the right amount of diligence and tenacity, the results of each team’s efforts have been remarkable.

### To date:

- Number of Program Years: 6
- Number of Fellows Trained: 21 + 4 current
- Number of Devices Invented by Fellows and Interns: 22
- Number of Companies Started: 4 (Consure, Sohum, Windmill Health Technologies, Omya Healthcare)
- Number of Licenses Issued: 10
- Number of those Licenses to Fellows: 8
- Number of those Licenses to Others: 2 (LimoCare, Transferlife)
- Number of Interns Trained: 49

## Companies

Consure Medical, the first company to launch from the program, is now four years old and is in a Series A funding round (the first round of funding from a venture capital or angel firm). Their device is a catheter system for fecal incontinence, which represents a \$10B market worldwide. They are currently performing clinical trials in India, manufacturing product in Germany, and are seeking a CE Mark in Europe. They hope to have product on the market in 2015.



*The limb immobilization device, invented in Stanford-India Biodesign in 2009, is now shipping product! Look for HiCareLIMO in your Indian healthcare center today!*

In the second year of the program, the fellows developed a device for splinting lower limbs injured due to trauma. The product was licensed to Hindustan Latex Limited (HLL) and is now in production and in use at government hospitals and ambulances under the name HiCareLIMO.

The third year fellows' device is a hearing-screening monitor for newborns being built by SOHUM, a company started by the fellows from that year. The device has been licensed and is currently in development.

The fourth year fellows produced NeoBreathe, a ventilation device for newborns. The team has formed a company, Windmill Health Technologies, and has obtained a license. They have received funding from the United States - India Science and Technology Endowment Fund and Canada Grand Challenge. The device is under development.

In the fifth year, four devices were developed: Bioscoop, for less-invasive liver biopsy; Noxeno, a simple device to remove posterior impacted foreign bodies from the nasal canal; Parasafe, a device to standardize paracentesis; and Variseal, for the management of upper gastrointestinal, variceal bleeds. A new company has been founded, licenses obtained, and at least two of these devices are moving forward.

## Awards

In addition to licenses, patents, funding and companies, our fellows have also received awards and honors. In 2012, Ayesha Chaudhary, Chinmay Deodhar, Darshan Nayak, and Nitin Sisodia (all SIB Fellows) were named Top 20 Innovators under 35 in India by MIT's Tech Review. 2012 SIB fellows won first prize in the IT Kharagpur Empresario B Plan competition for BioScoop, their liver biopsy device. In 2012, Consure Medical was recognized as one of the Top 75 startups in India to bet on by DARE magazine. In 2010 Nish Chasmawala, 2008 SIB Fellow was chosen as an India TR35 recipient by MIT.

## Other Resources

Additional training opportunities and resources have also been created, including fellows-led workshops, Biodesign India-centric curriculum, India medical technology industry reports, and India medical technology websites (see <http://www.indiabiodesign.org/> and <http://www.stanford.edu/group/biodesign/cgi-bin/indiamedtech/>).

## Conclusion

The Stanford-India Biodesign (SIB) program has been a lesson for everyone involved in how to take the experience of Stanford Biodesign and have it complement training already available at the premier academic centers of India. Stanford has brought the expertise of the medical technology innovation process while our India partners have helped us understand the India context. The partnership has proven to be extremely fruitful and suggests that such programs may be possible in other developing regions of the world.

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