International Initiatives of Stanford University's Biodesign Program

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Abstract

The President of Stanford recently challenged the university community to explore global partnerships in order to help meet the world's problems. In response, Stanford Biodesign has two initiatives to train biomedical technology innovation leaders. The partnerships have recently been finalized, both with potentially powerful outcomes. In Mexico we are partnering with faculty at ITESM, training them in the Biodesign process so that they may start a similar program there as a gateway to Latin America. Already, through a pilot, we have brought one faculty member and one medical student to Biodesign for six months. In India, working with the government, we are establishing an international fellowship that will bring four fellows to Stanford for half of a two-year fellowship. In both instances the goal is to train young engineers and physicians to identify major health needs and develop solutions that are cost-effective and widely deployable across a broad socio-economic spectrum.

Introduction

> "The world's problems—international peace and security, global health, poverty—present themselves in the form of challenges that defy traditional rubrics. By unifying and strengthening our efforts in the area of international affairs, we affirm that Stanford has a special role to play in addressing these issues and providing real-world solutions." -John Hennessy, PhD, President, Stanford University

In 2006, President Hennessy challenged Stanford University to expand its commitment to addressing global issues including health and poverty. In response to this challenge, the Stanford Biodesign Program is partnering with educational institutions around the globe to establish new training programs in order to help create the next generation of biomedical technology innovators.

The Stanford Biodesign international outreach program seeks to train young engineers and physicians to identify major health needs in developing countries and develop solutions that are cost-effective and widely deployable across a broad socio-economic spectrum.

Background

Initiated in 2001, the Biodesign Program at Stanford is dedicated to training tomorrow's leaders in medical technology using an experiential approach to technology innovation. Program elements include: (1) interdisciplinary, team-based learning combining engineering, clinical, and business trainees; (2) intensive exposure to medical needs-finding and characterization; (3) "hands-on" process of invention, prototyping, and early stage testing; (4) practical instruction in regulatory, reimbursement, patenting, and technology transfer; and (5) mentoring by highly experienced technology innovators, including Stanford faculty as well as a wide range of "real world" industry experts.

The focus of the Biodesign Program has been to train the next generation of biomedical technology innovators, taking advantage of the wealth of experience of Biodesign faculty and affiliated industry advisors. Biodesign has bridged the gap between academia and industry by partnering with the local and national biomedical technology industry. The program has established teaching methods that provide innovation tools to engineers, physicians, and business people, allowing them to create and develop innovative healthcare solutions.

The core of the Biodesign Program is a multidisciplinary, team-based fellowship. The current fellowship is one year long, with an optional second year to further develop a technology invented during the first year. Fellows are selected from an international pool of applicants who come from engineering, medical, or business

backgrounds. The engineering fellows have typically completed PhD or MS degrees; the clinical fellows typically have received their MD degrees and are completing their residencies or fellowships; the business fellows have typically had several years of relevant work experience in addition to having received their MBAs. Fellows are selected based on a track record of innovation (patents, inventive research projects, and occasionally a licensed product or a start-up company).

Fellows initially spend three months immersed in the hospital and clinics setting, spending their time observing within a specialty area. Their goal is to identify at least 200 clinical needs – that is, clinical problems potentially addressable by a technology solution. During the next two months, the team filters the list down to the top 15-20 needs, with heavy advising from faculty and "real world" mentors, such as CEOs of local med tech startups or serial entrepreneurs who have founded dozens of medical device companies. Over the next several months, the fellows select and further explore their top 3-5 needs through a process of inventing, prototyping, and product development.

Fellows and students have invented a number of compelling new technologies during their time at Stanford. To date, seven venture capital-backed companies have been founded from these inventions. Four of these companies have developed devices that have been cleared for marketing by the FDA and are in substantial clinical use. Two of the companies have been acquired by larger publicly traded companies.

Mexico

Our first outreach initiative entailed a collaboration with Tecnologico de Monterrey (ITESM) School of Medicine. This pilot project had four aims:

- Establish a collaborative relationship with the Tecnologico de Monterrey (ITESM) School of Medicine.
- Train a physician (from the residency program at ITESM) and a biomedical engineer (junior faculty member at ITESM) in the medical device innovation process.
- Develop new affordable devices to address clinical needs in an underserved community in Mexico.
- Develop an international presence for Stanford Biodesign as a pilot study to determine the feasibility of transferring our process.

Mexico was chosen to be our pilot host country as we were motivated by the opportunity to build a collaboration with a strong academic institution, the Tecnologico de Monterrey, with which we had contacts.

The Tecnologico de Monterrey is a non-for-profit private university based in Monterrey, Mexico, the third largest city in the country. The university, one of the most recognized universities in Latin America, has thirty-three campuses throughout the country and hosts approximately 96,000 high school (30%), undergraduate (59%), and graduate (11%) students. Its School of Medicine was created in 1978 and has approximately 600 students in the areas of Medicine, Nursing, Nutrition, and Biomedical Engineering. Even though the university is well known for its training in both engineering and medicine[1], the Department of Biomedical Engineering has only recently been formed.

The School of Medicine has facilities in two of the thirty-three campuses: Monterrey and Mexico City, including a referral hospital in Monterrey. The school has also recently created the Center for Innovation and Translation in Healthcare (CITES) to promote research and innovation in medicine and bioengineering. The school created a three-year "Medical Quality" residency program for physicians interested in improving the quality of healthcare through innovation in information technology, healthcare systems, and medical technology.

Mexico Fellow Training at Stanford

The Mexico fellow training period at Stanford ran from January through June, coinciding with the winter and spring quarters at Stanford. Prior to arriving at Stanford in January, the fellows participated in clinical needs finding in Mexico. The validated needs formed the basis of course projects developed at Stanford during the winter and spring quarters. Two courses were involved.

The course Entrepreneurial Design for Extreme Affordability (EDEA) is jointly offered during the winter and spring quarters by the School of Engineering and the Graduate School of Business (GSB) at Stanford University, and co-taught by James Patel from the GSB, David Kelly from the Hasso Plattner Institute of Design, and David Beach from the Department of Mechanical Engineering. See http://extreme.stanford.edu/.

The class focuses on teaching graduate students to apply engineering and business skills in the design of comprehensive solutions to challenges in developing countries. The course also includes lectures throughout both quarters on topics appropriate to the course theme. Students work in small teams to research, brainstorm, design, build, and field-test affordable products that solve specific needs. A particular emphasis of the course is affordability. A project addressing clinical need(s) was viewed as an attractive enhancement to the class.

The Stanford students in the EDEA class are selected by the co-instructors after a detailed application process that includes filling out a questionnaire and writing personal statements. The co-instructors for the course, in collaboration with Biodesign faculty, selected the six Stanford students (engineering, business, and/or medical) to form a team with the Mexico fellows to work on a medical device project.

Prior to starting the winter quarter, the Stanford students traveled to Monterrey, Mexico for two weeks and worked with the Mexico fellows on observation and needs finding. ITESM arranged additional field visits through different clinical settings inside and around the city (e.g., tertiary private and public hospitals, public primary care centers and clinics, rural health facilities). This allowed the team not only to identify possible needs for their project, but also allowed for full immersion into the socioeconomic structure of the country and the forging of relationships with clinicians in Mexico for future validation and iteration. After the observation and initial validation phase, the team (including the two members from ITESM) came back to Stanford.

After needs validation, the teams selected a specific need to address in their project throughout the winter and spring quarters of the EDEA class. Biodesign faculty and existing fellows served as mentors for the EDEA teams.

The Mexico fellows also enrolled in the Biodesign Innovation course offered during the winter and spring quarters by Biodesign faculty members Drs Paul Yock, Josh Makower, and Stefanos Zenios. This project-oriented class focuses on the medical device innovation process. Lectures are provided on clinical needs finding, validation, and specification through prototyping to business planning.

Again, the fellows formed teams with other Stanford students and worked on a clinical need identified during needs finding in Mexico (different from the EDEA course).

Fellows Return to Mexico

At the conclusion of the spring quarter in June, the fellows took both projects back to ITESM in Mexico and continued working on the projects in the setting of an innovation class designed by the fellows for ITESM biomedical engineering, medical, and business students. This provided continuity for the project while also allowing further training of students in Mexico in the Biodesign process.

Results

The pilot fellowship had several successful outcomes. Both teams were able to create new processes or technologies that are moving forward. One team also became a finalist in an international design contest. ITESM, impressed by the outcome of the pilot project, has since decided to open a Biodesign Center in their facilities and to initiate a program similar to ours. A second team invented, not a device, but a better process for training local paramedic women who might form diabetes support groups for women in their respective villages.

Stanford-India Biodesign

Due to the success of our pilot program with Mexico, Biodesign decided to launch a more ambitious international collaboration with the government of India. The emerging Indian biomedical technology industry is uniquely positioned to become a model for a new, globally relevant approach to affordable technologies for health and we hoped to capitalize on this opportunity.[2]

The Stanford-India Biodesign (SIB) Program has been established as a partnership with the Department of Biotechnology in the government of India. Through this partnership we will select and train a cadre of young biomedical technology innovators, who will help seed the emerging medical technology academic and industry sectors in India while training subsequent fellows and students. The core of the proposed SIB Program is a two-year, multidisciplinary, team-based fellowship program housed both at Stanford and in India. Fellows will

commit to remain in India at the completion of the program, with the intent of returning to academia, creating entrepreneurial ventures, or joining medical technology companies.

Stanford-India Biodesign will sequentially create two SIB training centers that will become the home bases for the Fellows and an educational hub for the region. Beginning in 2008, Stanford, in collaboration with the All India Institute of Medical Sciences (AIIMS) and the Indian Institute of Technology (IIT) Delhi, will launch the first SIB Center in New Delhi. By 2010, a second SIB Center will be created in a different Indian city. The two SIB Centers will then help to build other centers and programs in sites of academic excellence across India. By 2013, Stanford will transition oversight of these two SIB Centers to its Indian counterparts, who will continue to grow the centers. The two SIB Centers and numerous satellite centers across India will help enable the growth of the biomedical technology industry in India.

The Opportunity in India

The Indian biomedical technology industry is still nascent compared to other Indian corporate sectors and compared to the biomedical technology industry in the United States and Europe. Given the very favorable demographics, the rapidly expanding technology base, and increasing venture capital flow into India, it is anticipated that a major biomedical technology industry will develop in India over the next twenty years.[3] An ever-increasing number of Indian and foreign venture capital firms are raising sizable India-focused funds with fund allocation to biomedical technology and biotech ventures located within India. In short, the Indian biomedical technology industry is poised to grow dramatically.

Health care trends in India have dramatically shifted in the last twenty years and are becoming important financial drivers in the biomedical technology industry. There has been a radical shift from infections to "lifestyle-related diseases" (cardiac, GI) where average inpatient cost is radically different (Rs. 4k vs. Rs. 29k).[4] Decreasing Length-of-Stay (LOS) is becoming an important issue for private hospitals; ambulatory surgical growth is becoming more highly desired (requiring the use of minimally invasive devices). It should be noted that relatively few Indians have health insurance.[5] Additionally, there is much greater diversity of health care settings (smaller hospitals, rural clinics) compared to the US. Importantly, the reasons for hospitalization are substantially different compared to the United States. As the biomedical technology industry develops, an important part of the social and business opportunity will be to address the hundreds of millions of citizens who are poor and medically underserved (the "bottom of the pyramid"). David Green, Director of Project Impact, MacArthur Foundation Fellow, and advisor to Stanford-India Biodesign, has had extraordinary success in guiding the development of low-cost intraocular lenses and hearing aids that are manufactured inexpensively and delivered to hundreds of thousands of Indian patients.[6] With the right understanding of the marketplace, there is a major opportunity to develop cost-appropriate technologies for the underserved as well as the burgeoning middle class.

The educational infrastructure in both engineering and medicine is extraordinarily strong in India. In the past few years, several elite engineering universities have developed new programs in biomedical technology, following the international trend of promoting collaboration in training between engineers and clinicians.[7] However, in these new interdisciplinary programs there has been little explicit effort to teach the process of innovation or to transfer the results of academic research to clinical use. As the Stanford Biodesign Program has demonstrated, much of the process of innovation in the biomedical technology domain lends itself to a systematic, experiential training program—the goal of which is to get new products to market that improve patient care.

Program Details

The mission of Stanford-India Biodesign (SIB) is to develop leaders in biomedical technology innovation in India. To accomplish this goal, SIB is developing a two-year, interdisciplinary, team-based fellowship conducted both at Stanford and in India. Graduates of the program will help direct the future development of biomedical technology innovation in India from both academic and industry platforms, with particular attention to creating solutions for the needs of the medically underserved. The program will create two SIB training centers in India that will serve as regional centers of excellence to inspire and educate future leaders in the field. Furthermore, through the SIB Centers, courses and other academic offerings will serve to inspire and educate dozens of undergraduate and graduate level students each year, preparing them to join the emerging medical device industry in India. Our

expectation is that our model will be transferable to many other academic training sites across India, further broadening the impact of the program.

Fellow Selection

Candidates for SIB will be recruited both from India and from Indian citizens in the United States and elsewhere seeking to re-patriate to India. Interestingly, in our planning process, we have already spoken with substantial numbers of highly trained medical device specialists in this latter category (engineers and physicians in Silicon Valley area who are seeking opportunities to return to India and who have expressed interest in SIB). These individuals are committed to moving back to India permanently and view the SIB training as the stepping-stone to do so.

Fellowship Timeline

During Phase I (seven months), Fellows will receive an intensive introduction to clinical medicine through lectures by clinical faculty and exposure to two courses: one focusing on needs finding and innovation and the second on affordable design. In these courses, the Fellows will learn the fundamentals of product development, legal strategies, and entrepreneurship in a classroom setting, thus preparing them for the "on the ground" experiences in the months ahead.

During Phase II (five months), the Fellows will transition to India for a period of in-depth clinical immersion and medical needs identification and exploration. This will involve spending time in large urban hospitals to rural clinics. This phase will leverage what has been learned during the Phase I didactic coursework. This experience in needs finding, validation, and specification is the heart of the Biodesign process. This clinical immersion in the Indian healthcare setting (as opposed to the United States setting) will ensure the needs to be solved are relevant for and tailored to the Indian market.

Specifically, the Fellows will search for difficulties that patients and health care providers are encountering—that is, specific obstacles or problems that could potentially be addressed with medical technology solutions. Representative medical areas of interest may include diabetes, heart disease, and pregnancy/neonatal issues, though many other areas are possible. The Fellows will be charged with identifying at least 300 clinical needs during this period.

In Phase III (two months), the Fellows will return to Stanford for intensive training designed to revalidate and prioritize needs under the direct guidance of Stanford Biodesign faculty, other physician inventors, and experienced technology innovators from Silicon Valley. We anticipate that 8-10 well-characterized needs will emerge from this process. Fellows will also pursue their top 4-5 needs on their own (as a team) and will be mentored through a process of brainstorming and invention. The resulting concepts will be evaluated with particular attention to technical feasibility, practicality, cost, manufacturability, and distribution. Each solution will be prototyped in a rapid, iterative fashion as the concepts are refined, using Stanford facilities.

During Phase IV (ten months), the Fellows will return to India where they will develop and refine solutions to 2-3 needs by continuing the hands-on process of invention, prototyping, and early stage testing. The goal will be to develop projects that can be advanced in India, both from the standpoint of further engineering/testing and ultimate business creation and clinical implementation. Mentoring from venture capitalists and industry experts from both India and the Silicon Valley will be essential in making these assessments. The Fellows will attempt to launch one or two of their concepts into an actual business, either through licensing or by means of a new start-up company. The Fellows will continue to be mentored in this process by Biodesign faculty and advisors, venture capitalists, and industry leaders.

The New Stanford-India Biodesign (SIB) Center

Home base for the program in India will be a new, state of the art, Stanford-India Biodesign "twin" Center (SIB Center) to be located at the All India Institute of Medical Sciences (AIIMS) in close collaboration with IIT Delhi. The SIB Center will be housed in a physical space that encourages clinicians, engineers and "real-world" experts in medical technology and finance to interact with and mentor young innovators. Modeled after Stanford Biodesign, the Center will facilitate the meeting of industry leaders, faculty, and students, all united by common

interests. The interior design of the Center (meeting spaces, brainstorming rooms, prototyping laboratory) will be informed by the Biodesign spaces at Stanford. We also anticipate that the SIB Center will develop into an educational home for new courses and seminars for engineering and medical students, and others who are interested in learning the Biodesign process. The Fellows and alumni of the SIB program, along with their faculty and industry colleagues in the program, will serve as effective teachers and mentors for these extended educational initiatives.

In year three of the program, a second SIB Center (in a different Indian city) will be created. In general, the two SIB training centers will be developed in locations selected on the basis of key "natural resources"—including the presence of world-class medical and engineering universities and the infrastructure to support a blossoming biomedical technology industry. We believe that these SIB Centers will help catalyze the expansion of the industry in India, which we hope will parallel the extraordinary growth of the biomedical technology industry in the Silicon Valley over the past twenty-five years.

Proposed Outcomes

With the SIB Centers as the base, the fellowship, related courses, and ancillary offerings will help create a broad academia-to-industry partnership for biomedical technology innovation in India.

Training of SIB Fellows

Based on our experiences over the past six years with US Biodesign Fellows, we expect the SIB Fellows to pursue one of three pathways upon graduation:

1. Join the faculty in an academic medical center or engineering university, with a focus on translational bioengineering research and teaching of the Biodesign process.
2. Launch a new venture in India based on an invention from the program.
3. Join an existing biomedical technology company in India as an emerging leader.

Further, we anticipate that SIB alumni will form a close-knit network to help each other in their early career development, as well as provide connections between their universities and companies.

Development of SIB Centers

A careful and stepwise development of the first SIB Centers is essential for the successful expansion of this approach in India. The centers will become an important catalyst for biomedical technology innovation in the region, becoming a networking hub for industry and academic connections. These centers will provide the incentive and focus to develop courses and other teaching programs that bring together medical and engineering students in new ways.

New Courses and Curriculum

A series of new courses will be created in association with the SIB program, similar to what has occurred at Stanford. Through working with the Fellows, faculty in medicine and engineering will become motivated to help teach the Biodesign innovation process to their students. The Fellows themselves will become excellent teachers and mentors. Similar to Stanford Biodesign, industry experts will provide guest lectures in their areas of expertise.

Many aspects of the written and video curriculum developed by Stanford Biodesign will be relevant for the students in India. Stanford will expect to make these materials web-accessible. There will be significant new curricular areas to pioneer. These may include needs finding for rural patients and patients at the "bottom of the (economic) pyramid," intellectual property and regulatory pathways in India, and approaches to cost-effective manufacturing, supply chain, and distribution in the Indian setting.

Global Student and Faculty Exchange

From Stanford's perspective, an important motivation for the development of the SIB Centers will be to offer an opportunity to selected Stanford students and faculty to learn about biomedical technology in India. We also see the opportunity for a reverse exchange of Indian students and faculty spending time at Stanford. Specifically, we look forward to SIB Center faculty from India spending time at Stanford to learn and practice our training process (training the trainers).

Biodesign Expansion in India

The two SIB Centers will promote Biodesign training in their respective regions and will be open to visits and training sabbaticals for faculty from other Indian universities and medical centers. An open "blueprint" for the program will be available to help promote additional sites across India, though Stanford's direct priority will remain the two SIB Centers. Faculty at the SIB Centers, however, are expected to be involved in the expansion of the program to these other sites across India. In other words, Stanford aims to have the two SIB centers train future centers in its proven methodologies, allowing for many programs across India to participate as the industry grows.

It is important to recognize that the SIB Centers will represent only one approach to training in biomedical innovation. Other types of educational programs are already under development at various centers in India, and these will grow and flourish in parallel with the SIB Centers. It will be highly valuable to develop a national forum to share best practices in this space. An example of this is the annual Biomedical Engineering Innovation, Design and Entrepreneurship Alliance (BME-IDEA) Educational Workshop that occurs annually in the United States. See http://www.bme-idea.org/. Stanford will actively collaborate with Indian institutions that share the common vision of providing biomedical technology solutions to the medically underserved.

Program Sponsorship

The Indian Government's Department of Biotechnology has funded a portion of the costs of the five-year initiative. Funds for the remainder of the program costs are being sought from other sources including foundations, institutions, corporate sponsors, and individuals.

Conclusions

Stanford Biodesign has developed ways to meet President Hennessy's challenge as he proposed them in 2006. By initiating a pilot Mexico program to test the waters of international collaboration, we were able to confidently move to the next project: Stanford-India Biodesign. The new initiative has been launched and is moving forward as planned. Currently five fellows have been selected to come to Stanford in January 2008 to start the fellowship. The SIB Center at AIIMS is under construction and will be completed in time for the Fellows return to India in August 2008. We look toward the future with anticipation as we build a medical technology leadership training program in conjunction with AIIMS and IIT Delhi.

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