



STANFORD
biodesign
ANNUAL REPORT 2012

Biodesign 2012

A Year of Development

We were pleased to witness the incredible output of our Stanford-India Biodesign program this year and to see that the training over the last five years has brought that program to the productive level of our US fellowship. Three devices were launched from SIB, one from our first year (2008), one from the second year and one from 2011. These product launches were a long-time coming as the teams struggled to find ways to commercialize devices in a still-nascent medtech market.

Our SIB fellows remain committed to bringing low-cost devices that are designed and built for the Indian market. We support them in those efforts. In addition, we initiated several research projects to seek answers to the questions of how one commercializes medical devices in resource-constrained settings. These initiatives are detailed below.



The Innovation Fellowship Grows



In 2001 we launched our first fellowship team and our first graduate level course. In 2012 we are excited to announce that as we continue to develop internationally, our own US-based fellowship is also expanding. In 2014, for the first time, we will have three full teams of four fellows each. Thanks to funding from our generous sponsors, we will be able to go from 10 fellows per year to 12 fellows per year. Along with the India and Singapore fellows, we soon will graduate 20 fellows across the globe in coming years.

Our Biodesign Innovation Fellows for 2012-13: Tahel Altman, Rush Bartlett, Emma Essock-Burns, John Paderi, Vijaykumar Rajasekhar, Richard Rink, Kathryn Rosenbluth, Ivan Tzvetanov, Ryan Van Wert and Justin Williams. They're working in the area of Neurology/Neurosurgery.

Stanford-India Biodesign

As mentioned above, the Stanford-India Biodesign (SIB) program is beginning to produce some significant output into the commercial space in India. First, SIB has executed an exclusive worldwide license to commercialize the Fecal Incontinence (FI) technology between BCIL (the Indian government Dept of Biotechnology's technology transfer organization) and Consure Medical Private Limited. The license will serve as a template for future products emanating from the SIB collaboration.

Consure is founded on a device that was invented in the first year of the SIB program. The fellows from that year: Nish Chasmawala, Amit Sharma and Sandeep Singh are moving the company forward. In addition they have raised angel funds



and received two government grants (one from India and one from Canada) which should sustain the business for the next several years.



Hillary Clinton, Secretary of State of the US, visited India in May and was introduced to the Stanford-India Biodesign program and met Balram Bhargava (Executive Director, SIB), Ayesha Chaudhary (pictured), Nish Chasmawala (pictured) and Nitin Sisodia (SIB Fellows).

In December, a Biodesign workshop was held for GE Healthcare in Bangalore. The 2012 SIB Fellows, Siraj Bagwan, Jagdish Chaturvedi, Siddhartha Joshi and Jonathan Pillai along with Ritu Kamal, an SIB fellow from 2010, Rajiv Doshi, the Executive Director for SIB and Christine Kurihara, Associate Director for Global Biodesign, gave the one-day workshop for about 25 GE managers.

In November, a second license was obtained for a device from SIB. HLL of India has licensed the Limb Immobilization (LI) device invented in 2009 by Darshan Nayak, Pulin Raje, Rahul Ribeiro and Asokan Thondiyath, SIB Fellows. HLL Lifecare Limited is a Government of India enterprise under the Ministry of Health & Family Welfare. The LI device will be manufactured and marketed by HLL to government hospitals, ambulances and clinics.



Singapore-Stanford Biodesign

Biodesign received a \$120,000 grant from Singapore to further its textbook work - the money is being used to create additional 'sourcebook' chapters that cover Singapore, India and China plus case studies in those areas. In November we released our first Global Sourcebook Chapters for Singapore. These chapters are addendum to our textbook and cover the healthcare systems, regulatory, reimbursement and IP landscape in our partner countries.

We've now graduated two sets of fellows from our SSB program. The fellows have gone on to continue with their innovations with the hopes of commercializing something within the next few years.

Sponsors

This year we welcomed new sponsors: Knobbe Martens, BD Medical, and Intellectual Ventures who joined our growing list. We also welcomed renewed funding from Boston Scientific.

Research & Policy

A study, first-authored by Jan Pietzsch, was published in the Journal of the American College of Cardiology and suggests that renal denervation may be a cost-effective method of managing resistant hypertension and may result in a reduction in cardiovascular morbidity and mortality in the long term.



The paper *Medical Device Innovators and the 510(k) Regulatory Pathway: Implications of a Survey-Based Assessment of Industry Experience* by Jan Pietzsch, John Linehan and Marta Zanchi was published in the JACC's Journal of Medical Devices.

Biodesign and REAP (the Rural Education Action Project) of Stanford have formed a joint project to study ophthalmological needs in rural China.

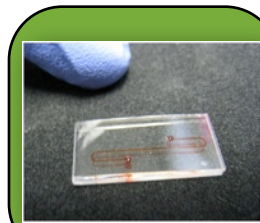
This year we received two grants from the Freeman Spogli Institute - one to support research into barriers to commercialization for Indian medtech; the second to study medical device technology infusion into rural China.

Stanford School of Medicine, Biodesign and the FDA have initiated a Memorandum of Understanding. The agreement lays the groundwork for the FDA and Stanford to collaborate on a number of initiatives, including educational outreach, cross-training of scientific personnel, and the development of new biostatistical methods for more accurately evaluating the safety of emerging medical technologies.



Global Exchange

This past summer Biodesign supported two teams of four students each to travel to India and China to perform needs finding and to experience clinical settings in primary, secondary and tertiary healthcare settings in their respective countries. The India team visited Delhi, Chhattisgarh and Tamil Nadu. The China team traveled to Beijing and beyond. Both teams reported on their findings and the India team is taking a concept forward that they have invented based on their needs finding. This program is sponsored by an NIH award.



In addition to providing student travel opportunities, the NIH grant also provides funding for projects developed by Stanford faculty and students that meet global needs. So far funding has supported the following projects:

- Low-cost infection detection device
- Diabetes Compliance using SMS
- Implantable device for sustained Tuberculosis therapy

We were fortunate to host two visiting global faculty this past year: Dr. PVM Rao from IIT Delhi spent 7 weeks in Biodesign; Dr. Igor Pivovarov from

Moscow State University spent most of winter and spring quarters here. Both professors hope to integrate Biodesign teaching into their curriculum.

Events

Our four 'From the Innovator's Workbench' events for 2012 were a huge success. We featured Alex Gorsky, CEO Johnson & Johnson; Michael Kaschke, President and CEO Carl Zeiss AG; Robert, Tim and Scott Fischell, Father and Son Medtech Innovators and Marty Leon Interventional Cardiologist, Founder, TCT. Audio of the events is available on our website.

Ginger Graham, former CEO of Amylin and former Group Chairman for Guidant, was the featured speaker at our 12th annual Fogarty Lecture. Her talk is available for viewing on our website.



Awards for 2012

Nish Chasmawala and Amit Sharma, founders of Consure Medical, have received an award from the Indo-US Science and Technology Forum Endowment Fund for "A novel way to manage fecal incontinence in non-ambulatory patients." The prize is shared with Lunar.

Jasmine Zia, 2011-12 Fellow, won the Health 2.0 SF HealthE Habits Codeathon for her iPhone app called GutGuru. The prize was \$4000.

Team Calcula (Red Team from 2011-12) took first place in the Tulane Business Plan Competition. The award was \$50,000.

The 2011-12 White Team received an NCIIA award for \$20,000 for their newly formed company Prescient Surgical. The funds will be used to further their CleanCision device.



Dr. Richard Popp was the 2012 recipient of the prestigious Rambam Award honoring "exceptional individuals for their prodigious contributions to science, medicine, and technology, as well as for their leadership and contributions to humanity." Dr. Popp received the honor at the Rambam Summit at Technion University's Rambam Medical Center in Haifa, Israel.

Team DiaLock (SSB Fellows 2012) and Team Calcula (Red Team 11-12) won the first ever Robert Howard Award. The award provides 100 hours of consulting from Lunar, a local design firm.

Interns from SIB this year received a J&J COSAT grant for their product that addresses hand hygiene in clinical settings.

An SIB Project from the 3rd year Fellows received a Center for Innovation in Global Health seed grant. The project, “Newborn hearing screening in the developing world” toward implementation of a novel device and innovative model of service delivery”, has been awarded \$50,000.

Balram Bhargava, Executive Director of SIB in India, received an award of the Indian Science Congress Association at the 98th Indian Science Congress. He was one of 26 persons receiving an award, recipients of which included five Nobel Laureates.

The 2011-12 Red Team also entered and won a number of other competitions this year with their device to treat kidney stones: 1st prize in the Stanford BASES E-Challenge: \$25,000 and 2nd place in the BME Idea competition.



The 2011-12 White Team have been accepted into StartX - an incubator started by Stanford students. The incubator comes with support in terms of mentorship, space and a small amount of funding.

Dr. Paul Yock, Director of Biodesign, Billy Loo, Asst. Prof, Radiation Oncology and Peter Maxim, Asst. Prof Radiation Oncology for their recent Coulter Grant Award for Pluridirectional High-Energy Agile Scanning Electron Radiotherapy.(PHASER.) The grant is for \$50,000.

Tom Fogarty, advising faculty and mentor to the Biodesign program, was inducted into the National Academy of Inventors Fellowship, a newly established Fellow membership category of the NAI. Dr. Fogarty is the first NAI Fellow.

Several of our Advisory faculty also received awards: Scott Delp, the John W. Gardner Visionary Award, Pathways Hospice Foundation; Geoff Gurtner, Award for Outstanding Achievement in Basic and Translational Research, Plastic Surgery Foundation; Michael Longaker, Flance-Karl Award, American Surgical Association.

Ashish Nimgaonkar, Fellow 2010-11, received a \$25,000 Spectrum Award for his project, " A Minimally Invasive Method of Treating Patients with Refractory Ascites."

OneBreath, Matthew Callaghan's ventilator device, took 2nd Place at the Purdue University Life Sciences Business Plan Competition. The prize is \$15,000. Matt was a 2008-09 Fellow who continues to take three of his Biodesign projects forward.

Sponsors

We continue to be honored by the support we receive from our various sponsors in corporate, community, foundation, and venture. In addition we receive funds to support fellows from many individuals. Our in kind sponsors provide goods and services.

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