



BIODESIGN 2015

Expanding our Commitment to Global, Value, and Connected Health

**From the Director,
Paul Yock**

.....

2015 was another busy year for Stanford Biodesign as we worked to increase our momentum and expand our reach and impact in the health technology ecosystem. Reflecting on the year, there were three key themes that dominated our milestones and accomplishments: global programs, value, and connected health.

Global health continues to be a major emphasis for us, and we are proud to announce that after eight successful years the Stanford-India Biodesign (SIB) program has officially become an independent entity. Launched in 2008, SIB was designed to help catalyze a medical technology ecosystem in India by identifying and training a first generation of innovation leaders in the field. Each year, a small group of fellows from India came to Stanford for six months of training in the biodesign innovation process, then returned to India for the second six months of the program to implement this process in the India healthcare setting. Over the program's eight-year duration, we helped train 32 innovators who developed 22 technologies and started seven companies.



2015 Global Fellows and Global Faculty in Training

Two of the many success stories from this program are Consure Medical and HiCARE LIMO. Consure, which was started by SIB fellowship alumni Nish Chasmawala and Amit Sharma, helps bedridden patients and their caregivers manage fecal incontinence, a distressing condition that affects more than 100 million patients worldwide. The Consure team recently received FDA clearance for their low-cost catheter device, and is preparing to launch the product both in the U.S. and internationally.

HiCARE LIMO is an ingenious cardboard splint that allows caregivers to temporarily and cost-effectively immobilize and protect injured limbs in trauma patients before the patient is able to receive definitive care. The technology was licensed by HLL Lifecare Ltd, an Indian healthcare products manufacturing company, and to date has been used to treat nearly 3,000 patients. HiCARE LIMO was developed by SIB fellows Darshan Nayak and Pulin Raje, along with Wenson Chern, Matt Durack, and Rajiv Doshi.

Our goal was always to position SIB to transition to independent status, and it will now go forward as the School of International Biodesign. We wish executive director Dr. Balam Bhargava, his team, and the entire SIB alumni community the best of luck as they continue to lead and inspire affordable, needs-driven medical technology innovation in India.



During his visit to Stanford, Japan Prime Minister Abe highlighted the new Japan Biodesign initiative.

In other news on the global front, we extended our arrangement with the government of Singapore to continue offering the Singapore-Stanford Biodesign (SSB) fellowship beyond the original five-year term. The sixth class of SSB fellows arrived in January 2016 and began working in the clinical area of Physical Medicine & Rehabilitation.

We also entered into an agreement to help launch Japan Biodesign, an exciting new endeavor that was announced during Japanese Prime Minister Abe's visit to Stanford in May of 2015. The new program was established in partnership with University of Tokyo, Osaka University, and Tohoku University and the Japan Federation of Medical Devices, with support from Japan's Ministry of Education. Our role will involve training Japan Biodesign faculty and helping them run their new fellowship program, which was

launched in October 2015. We greatly enjoyed working with new Japan Biodesign fellows, who recently visited Stanford Biodesign for an intensive two-week training experience partway through their fellowship year.



Jan Pietzsch, PhD

Another key theme for our program in 2015 was our focus on value. As concerns about the cost of healthcare in the US and around the world continue to escalate, providers and payers are under increasing pressure to reduce costs and increase efficiency while maintaining the quality of care. As a result, new health technologies must be supported by a strong economic value proposition. To prepare our fellows to meet these challenges, we initiated a series of changes in our fellowship curriculum to make health economics and value an upfront imperative and a pervasive consideration throughout the biodesign innovation process. Under the leadership of consulting associate professor Jan Pietzsch and consultant Cynthia Yock, our fellows are thinking about opportunities to reduce the cost of care much earlier, as they conduct needs finding. They are also learning to understand and develop compelling health-economic analyses in parallel with proving the effectiveness of their clinical solutions.

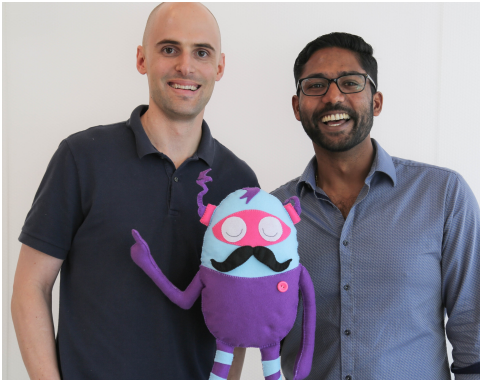


Cynthia Yock, PhD

As a second component of our new value-oriented approach, we established a closer working relationship with Stanford's Clinical Excellence Research Center (CERC), which is dedicated to discovering, designing, and demonstrating new methods of health care delivery to provide better care at a lower cost. To launch this new collaboration, two teams of Biodesign Innovation Fellows and one team of CERC fellows worked in a common clinical area – maternal and fetal medicine – for a year. Through structured interactions, these teams shared ideas and information and helped one another think critically about their projects and enhance their value propositions. Based on the positive feedback we received from the Biodesign and CERC fellows, we look forward to further developing this relationship.

A final area of emphasis this year was connected health. In light of advances in sensors, wearables, mobile phones, and other connected devices, Biodesign has formally expanded its purview from traditional medical devices to include device-based diagnostics, health information technology, and systems that blend products and services to provide connected health solutions. This

change has been driven by changes in the interests of our fellows, as well as growing demand from patients and providers for these types of technologies. It is also enabling us to broaden our focus from strictly interventions and therapies, to prevention and wellness, which dovetails with our interest in innovations that reduce healthcare costs.



The Lully Team, Andy Rink and Varun Boriah, fellows from the 2013-14 Biodesign fellowship year.

Two exciting examples of connected health projects coming out of the fellowship are Lully and Tueo. Lully is a device that prevents night terrors in children by using carefully timed vibrations to partially wake the child just before they occur. The Lully device is linked to a Smartphone app that uses an algorithm to predict the unhealthy part of the child's sleep cycle, and signals parents to activate the device. Tueo Health helps parents take control of their child's asthma by enabling them to measure environmental and other factors that make asthma worse and monitor their child's current asthma status. These accurate, objective indicators of asthma control are delivered via a Smartphone, together with clinical insight and understanding that helps patients and their families achieve the best outcomes.

We anticipate many more exciting changes and accomplishments in 2016 and look forward to sharing them with you soon. As always, thank you for your continued support of Stanford Biodesign.

A handwritten signature in black ink, appearing to read 'Andy Rink'.

2015 At-A-Glance

Check out some of the highlights that helped make 2015 memorable for Stanford Biodesign ...

January 2015

The first group of Biodesign Faculty Fellows (fondly referred to as our “BFFs”) began a five-month pilot training program. The members of this cohort, which included five assistant or associate professors from the School of Medicine and one from the School of Engineering, identified unmet healthcare needs that they found compelling and then advanced them through the biodesign innovation process with coaching from Stanford Biodesign faculty and experts from the medtech field. The initial pilot was so well received that we intend to continue and expand the program in 2016. As one participant described, “The BFF program provides a crash course on concepts a physician or scientist needs to have impact beyond academia. I wish I had the experience years ago. I now have a framework for thinking about solving problems that is completely different from all prior training.” – Shreyas Vasawala, Associate Professor, Radiology

February 2015

Stanford Biodesign proudly announced the release of the second edition of our textbook: *Biodesign: The Process of Innovating Medical Technologies*. The book was significantly rewritten to reflect the many important changes affecting the medtech field, including the industry’s shift to a stronger value orientation and its increasing globalization. As one reviewer explained, “This practical but comprehensive resource is keeping up with the rapid developments affecting medical device innovation. The authors draw on their own extensive experiences and insights, as well as diverse case studies, to present the full range of strategic and operational considerations to bring valuable new therapies to patients in the US and around the world.” –Mark McClellan, Director, Health Care Innovation and Value Initiative, Brookings Institution



The program raffled a few books at the launch party. Here Paul Yock presents a signed copy to Xu Wen Ng, a Singapore fellow.

In parallel, we launched a new version of the ebiodesign.org website that features a video library of more than 300 clips intended to enliven key concepts with the text and reinforce important teaching points. This first-of-its kind video collection, developed with support from the Wallace H. Coulter Foundation, is available at <http://ebiodesign.org/gallery/>.

March 2015

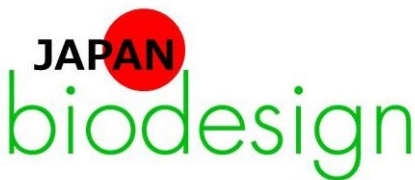
Stanford Biodesign held its third annual Executive Education program, *Managing Innovation*. The program provided corporate leaders with a fresh perspective on how to drive innovation within their organizations. Fifty executives and senior managers from Abbott, BD Medical, Edwards Lifesciences, GE Healthcare, Johnson & Johnson, Stryker, and Terumo attended the event. These anonymous comments from the course evaluation exemplify the favorable feedback we received: “Both informative and inspirational...” “The one-on-one mentoring from program faculty was an invaluable part of the course. Our team received great feedback that reinforced our understanding of the process.” “... relevant content that we could put to use on Monday back at the office.”

May 2015

As noted, Prime Minister Shinzo Abe of Japan visited Stanford University. In a speech he remarked that Japan must transform its economy to mirror the innovation ethos in places like Silicon Valley and Stanford University. As an example of how he will encourage such creativity, Abe announced a new partnership, to be known as Japan Biodesign, which will train the next generation of leaders in biomedical technology innovation. The new program is a collaboration with the Stanford Biodesign program and five higher education and research institutions in Japan. Through the partnership, Stanford leaders will train and mentor their Japanese colleagues and help drive a “fundamental change” in how Japanese society views the process of innovation, from how ideas originate to competition in the marketplace.



Josh Makower and Jay Watkins (seated) present to the Executive attendees at *Managing Innovation 2015*.





Our graduating 2014-15 Biodesign Innovation Fellows.

June 2015

The Biodesign Innovation Fellowship graduated 12 fellows at a ceremony with more than 300 members of the medtech community in attendance. Farzad Azimpour, Michael Feldstein, Viral Gandhi, Bronwyn Harris, William Kethman, Andrew McGibbon, Andrew Mesher, Christian Moyer, Todd Murphy, Theo Tam, and Elisabeth Wynne completed their training and prepared to take new leadership roles in health technology innovation and/or clinical practice. Persis Drell, Dean of the Stanford School of Engineering, made the opening remarks at the event, and Tom Krummel, Co-Director of Stanford Biodesign, shared words of wisdom with the fellows as they embarked on the next stage of their careers. Congratulations to the class of 2015!

August 2015

Twelve new Biodesign Innovation Fellows arrived at Stanford Biodesign to initiate their training experience: Michael Carchia, Elise DeVries, Andrew Ganton, Rachel Gerver, Justin Huelman, Alesandro Larrazabal, Mike Llewellyn, Veronique Peiffer, Shriram Raghunathan, Jonathan Schwartz, Craig Stauffer, and Richard Timm. This group included seven engineers, three physicians, and two physician engineers. Upon arrival they learned that this year's clinical focus would be maternal and fetal medicine. During "boot camp," which spans the month of August, they received a crash course on the biodesign innovation process, had sessions with faculty from Obstetrics & Gynecology, and began interacting with the CERC fellows as part of a new collaboration.

October 2015

Representatives from Stanford Biodesign attended the 10th meeting of the Biomedical Engineering Innovation, Design, and Entrepreneurship Alliance, known as BME-IDEA, in Tampa, Florida. BME-IDEA was started by Paul Yock and a team of bioengineering leaders from universities across the United States in 2003 to facilitate the sharing of information, resources, and best practices. This year's keynote speaker was Stanton Rowe, Corporate Vice President at Edwards Lifesciences, who spoke on the need for greater collaboration between university training programs in biomedical innovation and the medical technology industry.



Ross Venook, Assistant Director for Engineering, works with a group of attendees at BME-IDEA, 2015.

November 2015

Stanford Biodesign said a fond farewell to four key staff members—Mary Gorman, Christine Kurihara, Chris Queen, and Justina Kayastha—who all moved on to other wonderful opportunities within and outside Stanford. While we were sad to see them go, we have been so fortunate to have the continued support of Mary, Christine, and Chris through a transition period in the first half of 2016.



Staff Goodbye Lunch

December 2015

In separate ceremonies held in Singapore and India, our global fellows graduated from their respective programs. Our congratulations go to the Stanford-Singapore Fellows, Ka Mung Chee, Enci Mary Kan, James Mok, and Xu Wen Ng, and the Stanford-India Biodesign fellows, Shashi Ranjan, Debayan Saha, and Harsh Sheth. The India graduation corresponded to the 9th Annual India Medtech Summit, which has grown with Stanford Biodesign's assistance from a meeting of roughly 40 individuals to a major event with more than 200 participants from India's government, academic institutions, and medtech industry, as well as the international community.



2015 SIB Fellows



2015 SSB Fellows

Biodesign by the Numbers

Our trainees go on to pursue many different career pathways related to health technology innovation after completing our program.

Most continue to contribute to the healthcare field through leadership roles in medtech, clinical careers, and by training others in the biodesign process. Although entrepreneurship is just one of the ways that our fellows and students bring better care to patients, here is a tally of the remarkable accomplishments this subset of our graduates have achieved to date.

41 companies launched based on technologies initiated while at Stanford Biodesign.

Those 41 companies have:

- raised \$362.7 million in funding
- treated 489,721 patients
- hired 686 full time employees

92% are active. Six have been acquired or achieved other exits.

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We are exceptionally grateful to the following sponsors who have helped advance the Biodesign mission. Thank you for your continued support!

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Contact Us

Interested in more information about Stanford Biodesign? Please contact Stacey McCutcheon, Manager, Academic Projects and Communications, at staceypm@stanford.edu. We look forward to hearing from you!

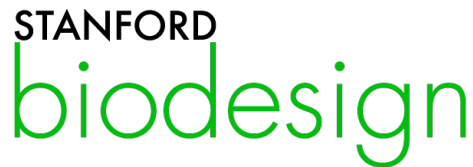
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