



2019 ANNUAL REPORT

A Message from Paul Yock

As Stanford Biodesign wraps up 2019, our commitment to identifying and solving compelling unmet health-related needs continues to generate meaningful outcomes in terms of innovators trained, novel technologies developed, and patients helped. This past year, however, we discovered an important need right here at Biodesign. The catalyst was an alumni survey that brought into focus the fact that women made up only 28% of all fellowship graduates, that the faculty members who train them have been primarily white and male, and that some women have experienced gender bias during their time in our programs.

To see these findings underscored in such stark terms was a wake-up call. To address these critical shortcomings, we formed several committees, including the ongoing D&I working group, to help us strengthen diversity and inclusion at Stanford Biodesign. Their efforts include recruiting diverse participants into all of our programs, diversifying our faculty and staff, establishing policies that ensure a learning environment where people feel respected by and connected to each other, and monitoring our progress. You can learn more about these efforts on the [diversity page](#) of our website.

This effort also prompted us to learn more about the gender landscape in the broader health technology industry. Together with our innovation partner, The Fogarty Institute for Innovation, and Maria Sainz, a medtech CEO and longtime Stanford Biodesign mentor, we sent out a survey that garnered 403 responses.

Among the key findings: women are significantly underrepresented in senior leadership, and men and women experience the workplace differently. For example, men are more likely to believe that promotion criteria are equitable and the major barrier to leadership roles for women is work/family balance. Women perceive a less meritocratic workplace in which their ability to rise is

hindered by exclusion from influential communication networks and stereotyping/bias.

To share some of this data and raise awareness, we organized a small-group working summit in March 2019, in which participants used our biodesign methodology to develop a deeper understanding of some of the problems around gender and inclusion in our industry. We also asked participants think about solutions from the perspective of “small wins,” a model developed by Stanford sociologist Shelley Correll, PhD, that asserts that small changes, especially at the institutional level, add up and lead to bigger ones.

As a next step, a steering committee of summit attendees developed and launched an Annual Diversity Challenge, focused in 2020 on mentorship, as a way for individuals in health technology to take action to address these workplace inequalities. You can join this challenge at any time. Please visit bit.ly/AnnualDiversityChallenge to learn more.

These initiatives to improve gender equality are just the first steps in a larger goal of addressing diversity more broadly at Stanford Biodesign and across our industry. Not only does a diverse mix of people enable more creativity, but in order to address the full spectrum of patient populations, we need innovators who bring unique and important perspectives to the framing of healthcare needs. We believe that these efforts, plus those of other groups in our industry, will amplify each other and stimulate change. Our commitment is strong. We look forward to keeping you informed about our progress.

Paul Yock, MD

Founder and Director, Stanford Byers Center for Biodesign

2019 Highlights

January

Welcome GFIT! Masaomi Saeki, a clinical fellow at Nagoya University Hospital department of hand surgery, Hirotada Masuda a cardiovascular surgeon and project researcher at Osaka University, and Hiroshi Noguchi, a physician scientist in orthopedics at University of Tsukuba Hospital, joined us at Biodesign as our sixth class of Global Faculty in Training (GFIT). The GFIT spend five months at Stanford training intensively on the biodesign innovation process and how we teach it with the goal of helping to launch similar programs at their own universities. During their first month, they also got to interact with the Japan Biodesign Fellows who come to Stanford Biodesign for a week as part of their training experience.



Masaomi Saeki, Hirotada Masuda, and Hiroshi Noguchi

by an FDA grant, is led on the Stanford side by Biodesign Innovation fellowship co-director and pediatric surgeon James Wall.

Also in February, another grant program, Neuroscience: Translate, announced its first round of recipients. Stanford Biodesign is partnering with Wu Tsai Neuroscience Institute to manage the program, which provides funding and guidance for teams developing devices, diagnostics, biopharmaceuticals or digital health therapies that address clinical needs in neuroscience with the goal of bringing these solutions to the patients.

Other major translational grant programs that Stanford Biodesign helps administer include the Stanford-Coulter translational research grants (in partnership with Stanford Bioengineering) and the NIH-funded Spectrum Medtech Grants.

innovation process and then practiced applying it, first through an exercises and then to real-world project from their own companies. Robert Sutton, an organizational psychologist and professor of management science and engineering at Stanford University, joined the speaker line-up this year to shared ideas with participants on “Scaling Excellence.”



Paul Yock and Lyn Denend

March

Managing Innovation, our three-day Executive Education program, drew 90 executives from Abbott, BD, Edwards Lifesciences, Johnson & Johnson, Stryker, and WL Gore & Associates. Participants learned the fundamentals of the biodesign



Josh Makower and Annette Ewanich

February

Each year, far fewer medical devices are approved by the US FDA for children than adults. To help address this shortfall, the UCSF-Stanford Pediatric Device Consortium was formed to help innovators develop promising ideas into patient-ready products. The first round of proposals for the consortium’s direct funding program were due in February; innovators submitted concepts for consideration to win up to \$50k in seed funding, prototyping support, and advising. The partnership, which is funded



Participants at Executive Education

April

We welcomed Jason Field, President and CEO of diversified material science company WL Gore & Associates as our featured speaker at our From the Innovator's Workbench event in April. Best known by consumers for its Gore-Tex fabric, Gore creates products for a variety of markets, from expedition clothing to therapeutic solutions and medical devices. It is also known for its award-winning corporate culture. "The company embodies all the ideals we foster at the Fogarty Institute and at Stanford Biodesign, from entrepreneurship to teamwork," said Andrew Cleeland, CEO of The Fogarty Institute for Innovation, which co-sponsored the event.

Also in April we were thrilled to announce the release of the newest translation of the Biodesign textbook, which is now available in Korean (as well as in Chinese and Japanese).

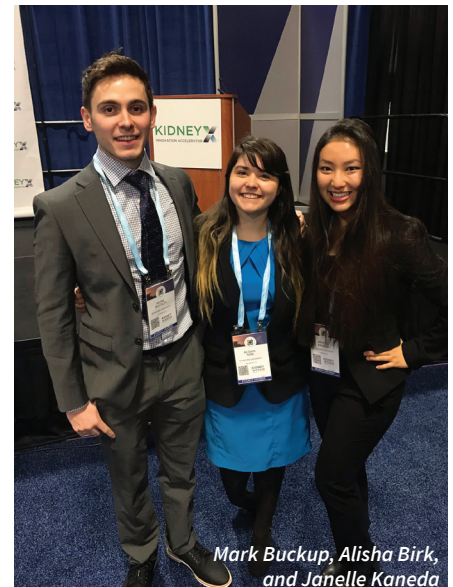
May

The seven winners of this year's Stanford-Coulter Translational Research Grants were announced and included four Stanford Biodesign-originated projects.



Zeit Medical's Synaptis seeks to improve stroke detection for patients with atrial fibrillation (2017-18 Innovation Fellows Urs Naber and Orestis Vardoulis); Pulmera is a visualization system for early stage detection of lung cancer (2017-18 Innovation Fellow Bryan Hartley with Harmeet Bedi); Earbuddy is a non-invasive solution for children with a common ear infection (2018 GFIT Matt Oldakowski and Josef Bartunek with Peter Santa Maria); and CatWatch, a neonatal catheter positioning monitoring device (Innovation Fellowship co-director James Wall with Ban Tsui.) Each team will receive \$100,000 plus mentorship to help them advance

their projects towards patient care. Also in May, two Stanford teams won \$75,000 at KidneyX Redesign Dialysis competition. Janelle Kaneda, Mark Backup, and Alisha Birk, an undergraduate team from the Bioengineering Capstone Design course led by Biodesign's own Ross Venook, were recognized for their project, OpticLine, which enables early detection of infection in patients undergoing peritoneal dialysis. And 2017-18 Innovation Fellows Dimitri Augustin and Racquel Redwood, won for their project Fluo Medical which seeks to reduce the failure of fistulas, a specific type of venous access used for hemodialysis.



June

Graduation is always a momentous event at Stanford Biodesign as we officially launch the newest class of innovators, thank our mentors and coaches, and share other accomplishments. One of the highlights is learning the winner of the Robert Howard Next Step Award, created by LUNAR Design (now McKinsey Design) in memory of a beloved colleague. The award conveys complimentary consulting hours to a team addressing an important health-related need that can benefit from the firm's expertise in product design.

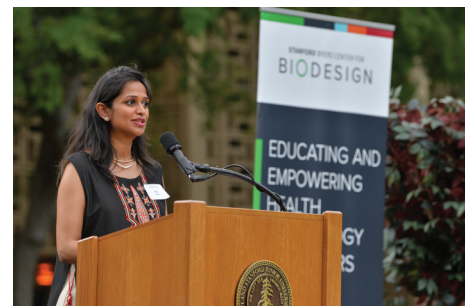
The winners this year were Amanda Calabrese and Greta Meyer, two graduating product design engineers and former high-level athletes who used their experience and training to invent Tempo, a tampon re-engineered to eliminate leakage. The award will help the pair refine their prototype, improve brand identity, and hone their FDA strategy for a US launch, planned to follow an initial product launch in Europe.

July

Part of Stanford Biodesign's effort to support innovation education is its participation in the Biomedical Engineering Innovation, Design & Entrepreneurship Alliance (BME-IDEA). The program brings together representatives of innovation education programs to share best practices and plan collaborations that will help trainees successfully address healthcare needs. In addition to an annual US meeting, Stanford Biodesign also supports BME-IDEA meetings in Europe, Asia Pacific, and most recently, Africa. In July we convened in Japan for the 4th Annual BME-APAC meeting.

Also in July we offered our third Needs Finding in Healthcare program. This experience gives undergraduate students a unique opportunity to shadow physicians and other care providers and observe real-world unmet health needs. Participant feedback indicates that the class is eye-opening and inspirational, with students reporting that it motivates them to persevere through demanding engineering and pre-med coursework.

Scenes from Graduation



McKinsey partner John Edson with Greta Meyer and Amanda Calabrese



L to R: Dan Azagury, Kate Garrett, Vic McCray, Sandra Waugh Ruggles, and James Wall

August

The arriving class of Innovation Fellows was not the only thing new at Stanford Biodesign this August. After 14 years as the director of the Innovation Fellowship program, Todd Brinton departed to take a senior level position at Edwards Lifesciences. While we miss him, the change provided an opportunity to re-imagine our teaching approach. Five Innovation Fellowship alumni were appointed as the new leadership team: director for education Dan Azagury, director of program development James Wall, and assistant directors Kate Garrett, Victor McCray, and Sandra Waugh Ruggles.

Stanford Biodesign's Founders Forum events in India help medtech start-ups scale their products and services to meet the unique needs of the Indian population by bringing together stakeholders to help identify problems and develop solutions. Evidencing the growing impact of these gatherings, a large and influential group of representatives from the Indian government joined in for the first time at

the most recent Founders Forum event, held in August in New Delhi, to discuss government support of new medical technologies.

September

Many groups within the Stanford medical school have promising digital health ideas that are ripe for development but lack the software engineering and healthcare compliance know-how to take them forward. To meet this need, Stanford Biodesign introduced Building for Digital Health, a new course sponsored by the Stanford School of Medicine (SoM) and Stanford's Computer Science (CS) department. The course provides CS students with the opportunity to apply their skills to real-world health technology development projects, while enabling SoM faculty to leverage these talented individuals to help advance their technology concepts. Both audiences learned a repeatable approach for developing new digital health technologies and preparing to launch them into patient care.

Where Are They Now?

An update on the 2018-19 Innovation Fellows

Start-up Life: Adam Gold, Ashley Seehusen, and Shira Koss founded Nasus Medical out of the Biodesign Fellowship to continue working on a better solution for treating chronic sinusitis.

Back to Clinical Practice:

Abubaker Khalifa returned to McMaster University as an assistant clinical professor of medicine and a critical care physician. He is also consulting at NXT Biomedical. Melissa Morgan Medvedev is an assistant professor of pediatrics at UCSF and a clinical consultant for Roam Analytics. Jonathan Toma has returned to practice as an interventional cardiologist at Southlake Regional Health Centre in Toronto.

On to Industry: Delphine Huang is working as a medical director at IDEO San Francisco, and is also an advisor for QB3/Rosenman Institute's start-ups and D-REF. Vlad Levering is a consultant at the Fogarty Institute for Innovation and The Foundry. Manasi (Ramachandran) Reardon is the head of advanced development, neuromodulation at Abbott. Chris Stivers is working as a health technology consultant. Heather Underwood is a vice president of strategic marketing at Triple Endoscopy, Inc., and a biodesign consultant at SparkMed Advisors. Amanda White is an associate project architect at ExploraMed Development, LLC.

We also welcomed a new instructor to our digital health team. Michelle de Haaff, former vice president at diabetes management platform Glooko, Inc, and a health technology and software advisor, joined Oliver Aalami as the co-director of the Biodesign for Digital Health course.

October

The 21st Annual Fogarty Lecture featured Biodesign co-director Tom Krummel in a one-on-one conversation with Brook Byers, founding member and partner at Kleiner Perkins Caufield and Byers. Addressing a well-over-capacity audience, Brook shared insights from 40 years of working with scientists, physicians, engineers, and patients to create new products and build companies. The event was co-sponsored by The Fogarty Institute for Innovation and Stanford Department of Surgery.

Also in October our newest class of Biodesign Faculty Fellows got started on their eight-month journey. Designed to help motivated faculty from the

Stanford schools of medicine and engineering gain an understanding of technology translation challenges and opportunities, the BFF program trains participants to identify important innovation opportunities within or outside their departments, invent cost-effective solutions, and prepare to implement those inventions to help patients.

November

In November, all of team Biodesign, including staff, faculty, industry mentors, and current Innovation Fellows, mobilized for two days of candidate interviews for the 2020-21 Biodesign Innovation Fellowship. The jam-packed 48 hours of individual and group activities is designed to help us get to know the candidates and help them get a sense of our program so that we can assemble high potential, high functioning fellowship teams. We love meeting these talented and accomplished individuals and wish that we could accommodate all of them in our programs. The new class of fellows will be announced in spring 2020.



Group activities at candidate interviews

December

We celebrated the holidays with multiple events, including the annual Biodesign party hosted by Tom and Susie Krummel, a staff celebration, and a holiday extravaganza and with our innovation partner, The Fogarty Institute for Innovation. We also collected toys and donations for several worthy causes. It was a wonderful way to wrap up the year and spend time with colleagues, family members, and friends.



The 2019-20 Innovation Fellows with Brook Byers



Fellows and Friends at the Biodesign Holiday Party



Our Impact

Stanford Biodesign is proud to have helped educate and empower...

173 Innovation Fellows since 2001

2,000+ Stanford students since 2002

553 corporate executives since 2013

140 global fellows and faculty since 2015

62 Stanford faculty since 2015

People

Departures:

Todd Brinton, director of the Biodesign Innovation Fellowship, accepted a new position as corporate vice president, advanced technology, and chief scientific officer at Edwards Lifesciences.

Cece Torres, our program assistant/temporary course manager/graphic designer extraordinaire has departed for a year of travel and adventure. She promises to come back to Stanford Biodesign and we look forward to her return.



Awards:

Biodesign assistant director Ross Venook was recognized with the Tau Beta Pi Teaching Award – “The highest teaching honor a faculty member can achieve.” The student engineering honors society selects only a handful of faculty across the Stanford School of Engineering each year to receive this award for excellence in teaching.



Biodesign director Paul Yock was one of five innovators chosen to receive the National Academy of Engineering's 2019 Russ Prize. Yock was honored for two of his inventions that advance the minimally-invasive treatment of advanced coronary artery disease.



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

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For more information on how you can support Stanford Biodesign, please contact Allie Gregorian at (650) 724-9910 or Robert Busch at (650) 223-9121.

For other information about Stanford Biodesign, email Stacey McCutcheon at staceypm@stanford.edu or visit us [online](#).

