



## A Message from Josh Makower

The Stanford Byers Center for Biodesign achieved a major milestone this year, celebrating our 20th anniversary. We're proud of many accomplishments over the last two decades, but none more than the over 4 million patients so far who have been helped by technologies invented by our students and fellows in the program.

As Stanford Biodesign's new director, I am deeply grateful to Paul Yock for his leadership and vision, and to the entire Biodesign community for the support and contributions that have made these achievements possible. With your help, Stanford Biodesign has grown from a small group of fellows into a global leader in need-driven health technology innovation training. Our portfolio of educational and translational programs, strong industry and academic partnerships, and track record of results have inspired and guided the development of similar training programs worldwide.

With this robust foundation, we are now setting our sights on the next 20 years of Stanford Biodesign. While we are still early in this process, I am excited to share three focus areas that will underpin our new endeavors.

- **Health Technology Innovation Policy:** While our innovation education mission remains central to our activities, we believe we owe it to the innovators we support to play an active role in facilitating their ability to improve patient care by engaging in policy research, education, and training. To this end, we are launching a new Health Technology Innovation Policy Program within Biodesign. Our research effort will deliver timely and valuable insights and published data to help inform local, state, and federal policy-makers on topics impacting health technology innovation such as regulatory, reimbursement, patent, tax, and fiscal policies. On the education front, we are designing an immersive policy fellowship program with the goal of training future policy leaders whom, we hope, will ultimately seek roles in government and throughout the ecosystem.
- **Lifesciences Expansion:** A second new direction will be to expand the scope of our training to support innovation across all life

science disciplines. While our roots remain firmly in medtech and digital health, today's solutions often require innovators to call on technologies used in biotechnology, diagnostics, services, consumer tech, artificial intelligence, and many others. To empower our trainees to utilize this expanded tool set in their efforts to improve health, we are evolving our program to include training and access to other life science disciplines, with deeper technology expertise, partnerships, and other expanded resources as needed.

- **Mission-Driven Global/Health Equity:** Our third new direction will be to explore new partnerships intended to improve health equity and outcomes for traditionally underserved populations both here in the US and Internationally. The goals of this new effort will be to bring our methodology to economically developing regions, train and support local health technology innovators, and foster the development of the overall health technology innovation ecosystem necessary to bring important new solutions to patients and providers.

I am very excited to begin working with you to develop and establish these new programs in the years ahead. Stanford Biodesign thrives because of the support of the many people who donate their time, talent, and financial support towards the advancement of the next generation of innovators. In this way, Biodesign is truly a community effort, with a central purpose to advance health outcomes and equity for patients. Working together, we can do even more to improve lives everywhere in the next 20 years and I look forward to taking this important journey with you.

Sincerely,

Josh Makower, MD  
Director and Co-Founder, Stanford Byers Center for Biodesign

# 2021 Highlights

## January

We started the year with former FDA commissioner Scott Gottlieb on the virtual stage as our guest in the “From the Innovator’s Workbench” series. In an interview conducted by David Cassak of MedTech Strategist, Gottlieb shared insights into the FDA, pointing out that the



Scott Gottlieb

organization’s commitment to advancing public health includes both protecting consumers from unsafe products and introducing new technologies that improve medical outcomes. He also asserted that device makers have a more challenging regulatory path than pharmaceuticals because part of their efficacy depends on the physicians who deploy them. “Medical devices are tools in the hands of physicians. You can’t evaluate devices apart from how they are going to be used,” he said.

On the global front, our Japan Biodesign program took an important step towards permanent integration into the Japanese health technology ecosystem when one of our three educational partners, the University of Tokyo, promoted Tokyo Biodesign from a program to an official department of the university hospital. Yujiro Maeda, a 2014 Global Faculty Trainee and co-director of Japan Biodesign was appointed as director. Fumiaki Ikeno, the US-based Japan Biodesign program director, will continue in his role as advisor to the department.

January also included the 2021 start of the Global Faculty Training (GFIT) program, which is a five-month experience that teaches participants the biodesign innovation process and how we teach it with the goal of catalyzing similar programs at institutions around the world. This year’s cohort included trainees from China, Israel, and Taiwan. Due to COVID



Global faculty trainees in China



Global faculty trainees in Israel

restrictions, the program was taught entirely remotely for the first time ever. Special thanks go to David Hao, Shashank Ravi, and Alexei Wagner, who acted as virtual clinical coaches as the GFITs performed their clinical immersion in local emergency medicine departments.

## February

In February, the UCSF-Stanford Pediatric Device Consortium, which is led on behalf of Stanford Biodesign by our

Innovation Fellowship director for program development, James Wall, completed a project that demonstrated the potential of real world evidence to make more technologies available to pediatric patients. Real world evidence is an approach to regulatory decision-making that uses information about how a medical device has performed in patients who are not in a clinical trial to evaluate their safety and effectiveness. The project was an important step in the effort to increase medtech innovation for kids, which is hampered in part by companies’ reluctance to conduct clinical trials with pediatric patients.

Also in February, Biodesign for Digital Health instructor Oliver Aalami and his team participated in MIT Hacking Medicine to grow the awareness and use of CardinalKit, an open source framework for digital health innovators and institutions designed to accelerate rapid prototyping of digital health applications and reduce costs. Introduced last year, the extensible, scalable platform uses Apple iOS as the frontend and Google Cloud as the backend.

## March

Our second Innovator’s Workbench event featured three high-powered health technology leaders with interconnected stories. Erica Rogers, CEO of Silk Road Medical, and Leslie Trigg, CEO of Outset Medical, were both recruited for their leadership roles by Bess Weatherman, a special limited partner at Warburg Pincus. Weatherman led investments in both companies because she believed they addressed major unmet clinical needs, and recruited leaders who were able to overcome significant obstacles. Both companies completed IPOs to fund continued growth and development. Special thanks to interviewer David Cassak.



## April

Women represent 70% of the global health workforce but hold only 25% of executive positions and 5% of CEO-level positions. To bring more talented women to the table to solve global health challenges, WomenLift Health launched a Leadership Journey program to help mid-to senior-level women in health practice, policy, and research expand their power and influence. Ritu Kamal, Biodesign's associate director of global programs, was chosen to participate in the 2021 US cohort and launched her journey in April. We look forward to sharing more information about her experience, which included mentorship, coaching, and a self-directed leadership project, after she completes the program.

## May

Education advocate Ingrid Ellerbe became the first executive director of Diversity by Doing Healthtech (DxD), the industry-wide initiative founded and supported by Stanford Biodesign and Fogarty Innovation. Created to improve diversity, inclusion, and equity in the health technology innovation ecosystem within early and mid-stage companies, DxD focused initially on gender inequity before expanding to target racially and culturally diverse and underrepresented groups. "Health technology innovation can reach its greatest potential when the



people involved – from entry level all the way up to leadership – look like the people they serve," said Ellerbe. Ellerbe has spent the last 30 years helping members of underserved communities succeed in technology and education.

## June

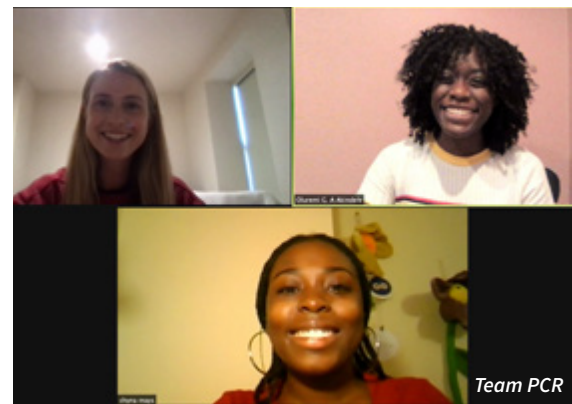
While we were sad that we were unable to hold a large graduation event with the extended Stanford Biodesign community,

Another June tradition is our annual Health Technology Showcase, which gives Stanford student teams the opportunity to present the compelling early-stage solutions they have developed to address important unmet health needs. This year, the "best need" award went to Team CoVer. These students helped develop an affordable way to prevent COVID-19 through their work on a prophylactic, intranasal drop made from an egg yolk-derived antibody. The "most promising



we did have a small gathering for the 2020-21 Innovation Fellows with members of the immediate fellowship team. The graduating fellows provided a humorous look back at the year, and program leaders offered reflections and best wishes. To find out what our 2020-21 Innovation Fellows are up to currently, see the side bar entitled "Where are they now?"

solution" award went to Team PCR, which addressed bladder pain syndrome by developing a tool that guides injection placement for increased accuracy. This team went on to receive the "design excellence" prize at the 2021 National Institutes of Health DEBUT Challenge. Special thanks to keynote speaker Sid Satish, founder and CEO of Gauss Surgical, and an alum of the graduate-level Biodesign Innovation course.



## July

Each year, the Innovation Fellows have the opportunity to compete for summer extension funding in order to advance projects that address needs identified during their training. Winning teams

*Keith Hansen works on a prototype*



this year were Keith Hansen and Victoria Wu, who are working on a temperature regulation device to improve transplanted organ function and survival, and Alexander Sackeim and Nishant Doctor, who are developing a less painful way to treat kidney stones in an office setting. The teams received mentoring from Stanford Biodesign faculty and Fogarty Innovation.

## August

On August 1, Josh Makower took over as our new director. Makower was the lead architect of the biodesign innovation process and director of the Innovation

Fellowship for Biodesign's first four years. He then returned to the private sector to focus on entrepreneurship and technology development, but maintained close ties to the program as a mentor and advisor. As part of his new role, Makower was appointed to an endowed professorship as the Boston Scientific Applied Biomedical Engineering Professor of Medicine and Bioengineering. Founder and director emeritus Paul Yock is remaining closely associated with the program in a new, more limited role.

And just a day later on August 2, the 2021-22 Innovation Fellows arrived for an in-person start to the new fellowship year. Their clinical focus is cardiology.

*2021-22 Innovation Fellows scavenger hunt*



Another major accomplishment in August was the launch of new set of multimedia teaching materials called the [Student Guide to Biodesign](#). Director of academic programs Lyn Denend led the

design and development of the guide, which she describes as an “on ramp” to the biodesign innovation process for undergraduates and other introductory learners. “This modular collection of multimedia toolkits gives early-stage classes and project-based teams just enough information to get started and get excited about innovating in health technology,” she said. The Student Guide is freely available online in order to make the biodesign innovation process widely accessible.

## September

September marked a major milestone – Stanford Biodesign's 20th anniversary! To celebrate, we produced a [short video](#) and gathered leaders from across the university to reflect on the accomplishments and impact of this pioneering innovation training program. “Stanford Biodesign has led the way in making sure that work done within the walls of the university transcends them,” said Stanford's president, Marc Tessier-Lavigne. “Creative solutions developed there have saved lives and improved health around the world. This model of translation was a prelude for the way we are working across the university today.”

September also saw one of the first offerings from our new Health Technology Innovation Policy Program. More than 300 physicians, innovators, and others attended [CPT Codes and Innovation](#), an American Medical Association webinar co-sponsored by AdvaMed, Wilson Sonsini Goodrich & Rosati, MedTech Strategist, Silicon Valley Bank, and the Medical Device Manufacturers Association. The webinar was designed to help attendees understand how the CPT codes used by physicians, qualified healthcare professionals, health plans, health technology companies, and others to describe care also support innovation.



*Founder and director emeritus Paul Yock and director and co-founder Josh Makower*



Another first in September was Needs Finding in Healthcare, a new intersession course developed by Paul Yock, Lyn Denend, Ross Venook, and a team of

## October

In October, our newest cohort of 12 Biodesign Faculty Fellows from Stanford Medicine and Stanford Engineering launched their educational journey. The program equips participants to identify innovation opportunities within or outside their departments, invent cost-effective solutions, and prepare to implement those inventions to help patients.

Later in the month, with 20 years under our belts and a new director on board, the time seemed right to revisit our purpose and values as a center. With creative help from Paulo Simas from Real Chemistry, the extended Stanford Biodesign team gathered to consider the problems we

## Where Are They Now? Updates from the 2020-21 Innovation Fellows

- Ashwin Amurthur - Finishing his final year of medical school at University of Pennsylvania and consulting for his externship sponsor, Tulavi Therapeutics.
- Nishant Doctor - Consulting for multiple medical device companies, working on a neuromodulation project with Stanford Urology and on a different device with teammate Alexander Sackeim and Stanford Immunology.
- Sarah Greasley - Working as an entrepreneur-in-residence as a member of the Stanford Pediatric Device Consortium.
- Keith Hansen - Continuing to work on the his team project Kidney Keeper, an organ cooling jacket that improves transplant outcomes and increase organ longevity. Keith is also a UCSF Innovations Research Fellow.
- George Korir - Working as a health technology consultant in Palo Alto.
- Susana Lopes - Working as a senior associate at transatlantic VC fund Glide, focusing on medtech, digital, and life sciences tools.
- John Lindsey - Finishing his chief residency year at UCSF before starting a fellowship at Baylor College of Medicine.
- Alexander Sackeim - Working in the Stanford Emergency Department and partnering with Nishant and Stanford Immunology on a medical device.
- Victoria Wu - Leading the clinical and engineering development of a robotic assistant for laparoscopic surgery at Moon Surgical, a seed-funded start-up based in Paris and San Carlos, CA.

*Sophomore college students*



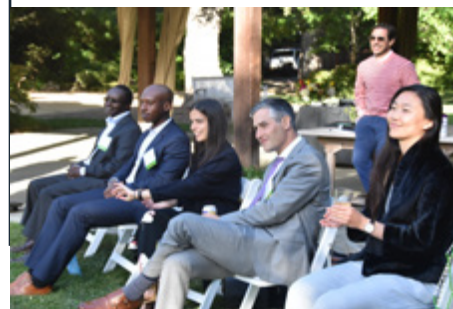
others. The 3-week, immersive residential program had two objectives: to give the students an intensive deep-dive into needs finding in healthcare, and to connect students and faculty on a deeper, more personal level than what is typically possible during the school year.

Wrapping up the month, we celebrated Tom Krummel as he stepped down as the co-director of Stanford Biodesign with a small gathering on the beautiful Fogarty Innovation rooftop. The theme was storytelling, and Tom shared some of his [best stories](#) alongside Paul Yock, Andrew Cleeland, Josh Makower, and Carla Pugh.

*Assistant faculty fellowship director Partha Ray at the offsite*



*Senior advisor Tom Krummel and director of academic programs Lyn Denend*



*Graduating 2020-21 Innovation Fellows*

are trying to solve, the things we do to achieve those goals, and how we define our relevance, reach, and results.

*Assistant innovation fellowship director Kate Garrett at the offsite*



Another October highlight was the 23rd Annual [Fogarty Lecture](#), featuring Lisa Earnhardt, executive vice president of medical devices at Abbott. Earnhardt shared her vision for innovation and driving value in the healthcare system by focusing on access and affordability.

“While the health tech industry is adept at creating new technologies that address clinical problems, that’s only part of the solution,” she said. “We also need to address health-related social challenges, which means making sure that the patients who need these treatments receive them.”



*2021-22 Innovation Fellows with Lisa Earnhardt and Deb Kilpatrick at the Fogarty Lecture*

## November

November saw the annual convening of the Biomedical Engineering Innovation, Design & Entrepreneurship Alliance, Asia Pacific (BME-IDEA APAC). This summit allows representatives of innovation education programs to share common challenges, best practices to start or sustain programs, and new opportunities post-COVID. This year, the gathering was a one-day virtual event followed by a two-day international medical innovation conference. Special thanks to Taipei Medical University and Perth Biodesign, who led the planning.

Also in November, we completed Innovation Fellowship interviews – once again via Zoom. Thanks to the detailed preparations of team members, faculty, and mentors, and the patience and stamina of the candidates, the entire three-day program was a huge success. We look forward to announcing the 2022-23 Innovation Fellows in early 2022.

## December

We wrapped the year with Paul Yock being named to the National Academy of Inventors, the highest professional distinction awarded to academic

inventors. Recipients were selected based on their “innovation in creating or facilitating outstanding inventions that have made a tangible impact on quality of life, economic development, and welfare of society.”

## People

Welcome! Meghan Stawitcke joined Stanford Biodesign as our fellowships manager, Laura Rodriguez-Borrayo joined us as an administrative and communications assistant, and Jill Hanneman came on board to be Josh Makower’s chief of staff.



*Meghan Stawitcke*



*Laura Borrayo-Rodriguez*



*Jill Hannemann*



# Our Impact

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

**195** Innovation Fellows since 2001

**2,400+** Stanford students since 2002

**192** global fellows and faculty since 2015

**86** Stanford faculty since 2015

## Snapshots



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## Get Involved!

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](mailto:staceypm@stanford.edu) or visit us [online](#).



Innovation fellow John Mascari



Assistant innovation fellowship director Vic McCray and associate director of engineering Ross Venook



Executive assistant Annette Ewanich after the offsite