



2022



PURPOSE

ADVANCING HEALTH OUTCOMES
AND EQUITY THROUGH INNOVATION
EDUCATION, TRANSLATION, AND POLICY

A Message from Josh Makower

The Stanford Biodesign community continues to inspire me, and our combined efforts to advance the state of healthcare by training the next generation of health tech innovators gives me great hope for the future. This year, we reached the amazing milestone that technologies developed by our alumni during their training have cumulatively touched the lives of over 7.6 million people. As I reflect on 2022, I am so grateful for your engagement and support, and I am deeply proud of what we have accomplished together.

When I became Director of Stanford Biodesign in August 2021, after listening to all of the valuable input on where Stanford Biodesign should go next, we set a number of ambitious goals that included playing an active role in health technology innovation policy, expanding the Biodesign approach to include broader support for all life science technologies, and focusing our mission-driven programs on health equity and global health – all while continuing to excel in our primary goal to educate and empower the next generation of leaders in health technology innovation. Over the last 12 months, we have made great progress against our new objectives and I am thrilled to share some of our key accomplishments.

Health Technology Innovation Policy

We recruited Dr. Kavita Patel and are actively working towards her appointment as the incoming director of the new Stanford Biodesign Policy Program. A practicing physician and nationally recognized health policy expert, she brings a wealth of experience from the White House, Capitol Hill, and the Brookings Institution, where she worked extensively on healthcare reform. With Kavita's guidance, we have assembled a strong team of core faculty, including Lyn Denend, director for academic programs, James Wall, policy fellowship director, and Sandra Ruggles, policy research director, who collectively will lead the new policy fellowship and other programming. In addition, we have engaged an outstanding network of external advisors with deep expertise in six core focus areas, who will help guide our research and educational efforts, including our own Jan Pietzsch (health economics and value), Eb Bright, Esq. (intellectual property policy), Nancy Isaac, Esq. (regulatory policy), Dr. Stella Safo (health equity), Jay Khosla, Esq. (legislative affairs), and Piper Su, Esq. (healthcare finance and payment). We also have recruited our first class of four policy fellows. These individuals will begin their two-year training program with us in August 2023. For more information about the new Policy Program, visit <https://biodesign.stanford.edu/programs/policy-program.html>.

Broader Lifesciences

In expanding our approach, we decided initially to focus on how we can adapt the Biodesign process to support unmet needs that might be addressed through biotechnology solutions. Early in 2022, Innovation Fellowship alumnus Michael Ackermann, who has used the process to launch

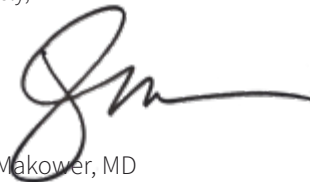
successful device and biotech companies, joined us as our director of biotechnology. Since then, Michael has been collaborating with the Innovation Fellowship teaching team to develop curriculum enhancements focused on biotech and biopharma solutions and is actively helping the 2022-23 Innovation Fellows apply new solution sets to their projects. At the end of this academic year, we will reflect on this experience, optimize our approach, and use key learnings to expand into other areas, with digital-enabled services next on our list of technology domains to address.

Mission-Driven Global/Health Equity

Given the importance of intentional, thoughtful action in this space, we took 2022 as a year of exploration regarding the best way to play a role in mission-driven global and health equity. While plans are still taking shape, we are excited to announce two emerging partnership opportunities. The first will be a program development partnership, like the one we initiated with Japan Biodesign, initially involving the University of Rwanda and the University of Global Health Equity. We will begin training two faculty members from Rwanda in January 2023, and will actively work with those individuals and the East-African leadership team to develop a fellowship program that is tentatively scheduled to launch in early 2024. The second partnership will be with a historically Black college and medical school based in the United States. We are currently in discussions with multiple institutions and formulating the best way to engage with these groups to train future leaders in innovation from their communities. Please stay tuned for more information about these exciting programs.

I want to thank the entire Stanford Biodesign team for the hard work and dedication that has made this progress possible, all while we continue to deliver our existing portfolio of courses, fellowships, grants, and other programs at the highest level of quality. My deep appreciation also goes out to the sponsors, mentors, and other community members who enable us to sustain what we do in so many different ways. As I look into the future, I know that we collectively will advance health outcomes and equity through innovation education, translation, and policy as we continue to work together.

Sincerely,



Josh Makower, MD

Director and Co-Founder, Stanford Byers Center for Biodesign
The Yock Family Professor, Professor of Medicine and of Bioengineering,
Stanford University Schools of Medicine and Engineering

2022 HIGHLIGHTS

January

We started the year with some exciting publications. First, in *The Bridge*, a peer-reviewed journal of the National Academy of Engineering, we published, “Are We Making a Difference? A Case Study of Assessment in Innovation Training.” In this article, we shared results from our latest outcomes tracking efforts of our Innovation Fellowship alumni. Data gathered from public sources showed that our trainees choose careers in the health technology field in greater numbers than candidates who interviewed for the fellowship but were not selected. Our alumni also hold leadership positions at a higher rate than this comparison group. Survey data revealed that 94 percent of alumni respondents said they found the fellowship beneficial to their career development, and 91 percent reported that the fellowship was influential on their chosen career trajectory.



The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem

[Sandra Waugh Ruggles](#), [Juliana R. Peri](#), and [Zachary Sexton](#), Stanford Byers Center for Biodesign; [Kevin Schulman](#), School of Medicine, Graduate School of Business, Stanford University; and [Josh Makower](#), Stanford Byers Center for Biodesign, School of Medicine, School of Engineering, Stanford University

In *Health Management Policy & Innovation*, we published “The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem,” in which we reported survey results from innovators and investors familiar with reimbursement

processes through the Centers for Medicare and Medicaid Services (CMS). The data showed that for important breakthrough therapeutic technologies, it takes 4.7 years (+/- 2.8 years) to establish nationwide coverage, a devastatingly long time for patients, as well as for small, venture-backed companies without deep financial resources to sustain their operations through this period.



GFIT trainees, alumni, and faculty

In January, we also launched the ninth year of our Global Faculty In-Training (GFIT) program with a cohort of nine university and medical center educators from Brazil, China, Israel, and Taiwan. This five-month intensive training experience prepares participants to launch Biodesign-like programs at institutions around the world.

February

In February, Diversity by Doing Healthtech (DxD), the industry-wide initiative founded and supported by Stanford Biodesign and Fogarty Innovation, began promoting an interactive seminar series on diversity, equity, inclusion, and belonging (DEIB). The purpose of the sessions was to help small and mid-sized health technology companies make DEIB a priority in their organization in terms of workforce management, company culture, talent acquisition, and more. The series was well-attended and received widespread praise from its participants.



Our first graduate course reunion

March

March opened with our first-ever graduate course reunion! On the day of the event, a dozen alumni of the two-quarter Biodesign Innovation course, with backgrounds in medicine, engineering, and business, shared their diverse career paths in health technology innovation with our 35 current students. Then, the students, teaching team, and more alumni enjoyed a networking reception. In total, 84 graduate course alumni, representing all

20 years that the course has been offered, joined the fun. Many recounted how their exposure to health technology innovation in the Biodesign Innovation class was transformational to their careers. We were so touched by the turnout, delighted to see friends and teammates reunite, and inspired by the new connections that were forged.

Panel Discussion



Dirksen Lehman
Edwards Lifesciences



Josh Makower
Stanford Byers Center for
Biodesign



Parashar Patel
ViewRay



Steven Schuman
Stanford Graduate School of
Business

- What are the key elements of an expedited pathway to ensure both quicker access and safe, appropriate use of breakthrough devices?
- What are some of the features in the current national and local coverage processes that work well and can be applied to an expedited coverage pathway for breakthrough devices? What are some features that could be reevaluated?

BIODESIGN INNOVATION PROGRAM

Duke MARGOLIS CENTER for Health Policy

Later in the month, we partnered with Duke University's Margolis Center for Health Policy for a virtual event focused on "The Need for Transitional Coverage for Emerging Technologies." The webinar, which was an extension of the policy research we published in January, explored research findings, stakeholder perspectives, and potential policy solutions to inform CMS in their coverage reform efforts for safe and effective breakthrough technologies. The session was led by Josh Makower and Dr. Mark McClellan from Duke. The nearly two-hour discussion featured Dr. Lee Fleisher, the chief medical officer for CMS, as well as a host of other university and health technology industry leaders.

2022 HIGHLIGHTS

April

The annual three-day Stanford Biodesign Executive Education program included more than 120 representatives from eight companies – Abbott, Baxter/Hillrom, BD, Edwards Lifesciences, Johnson & Johnson, Stryker, Teleflex and Zimmer Biomet. Through didactic learning and hands-on workshops, participants learned the fundamentals of the Biodesign process and how they can use it to drive increased innovation within their organizations. Additionally, with coaching from Stanford Biodesign faculty, they applied need-driven innovation principles to a project centered on an unmet need of interest to their company. We are grateful to all who attended, as well as the dozens of faculty and staff who made the event a success.



Working hard at Exec Ed 2022

May

Representatives from the two cohorts of GFITs that weren't able to come to campus during the pandemic finally made it to Stanford! During their visit, they met with their clinical coaches from the Stanford Emergency Medicine department,

as well as the various coaches and mentors who guided them through their training experience. They also attended the final presentation event for the 2022 global faculty. In that session the 2022 GFITs shared their technology innovation projects, along with their plans for building or expanding Biodesign programs at their home institutions.



Three years of Innovation Fellows, plus faculty and staff

June

Fellowship Graduation! After two years of COVID-restricted gatherings, we celebrated three classes of Innovation Fellows. Dr. Eldrin Lewis, chief of the Stanford's division of cardiovascular medicine, who hosted the 2021-22 fellows for their clinical immersion, gave the keynote speech to an audience of nearly 300 people. Other highlights included remarks from speakers representing the 2021-22, 2020-21, and 2019-20 fellowship classes, as along with a musical salute to Stanford Biodesign's founder and director emeritus, Paul Yock (whose last name conveniently rhymes with "rock"!).



Students presenting their project at the Health Tech Showcase

The 2022 Health Technology Showcase convened students from across campus with an interest in health technology innovation. Eight teams from the Biodesign Fundamentals, Biodesign for Digital Health, and Bioengineering Senior Capstone Design courses presented their early-stage innovations, with the audience voting on the top projects. Team TrueTone, which created a next-generation sunscreen solution for all skin tones, won the award for most compelling need. Anxieteam, which designed an oral retainer to alleviate the need for an extensive hospital stay to diagnosis epilepsy, won the award for the most compelling solution. As always, this was a great community-building event.

At Stanford Medicine Grand Rounds, Josh Makower presented “Health Technology Innovation: From Phenomenon to Proven Process.” During this session, he shared the origin story of the Biodesign process and examples of how and why it works, as well as plans for the future of Stanford Biodesign.

Did You Know?

Translational Grant Programs

Stanford Biodesign manages multiple seed grant programs to help early-stage innovators translate their health technology innovation projects from the university into commercial development. These funds are awarded on a competitive basis to researchers and innovators within the Stanford University community. The three most significant programs are:

Spectrum Health Tech Grants

Funded by the National Center for Advancing Translational Sciences at the NIH to support translational research involving medical devices, diagnostics, and digital health solutions to diagnose and treat human disease.

Stanford-Coulter Translational Research Grants

Funded by the Wallace H. Coulter Foundation to enable multidisciplinary teams of biomedical engineers and clinical scientists to advance projects focused on device, diagnostics, and therapeutics.

Neuroscience: Translate Grants

Funded by Stanford’s Wu Tsai Neurosciences Institute to support collaborative research teams working on devices, diagnostic procedures, software, and pharmaceutical therapies in any area of neuroscience or brain health.

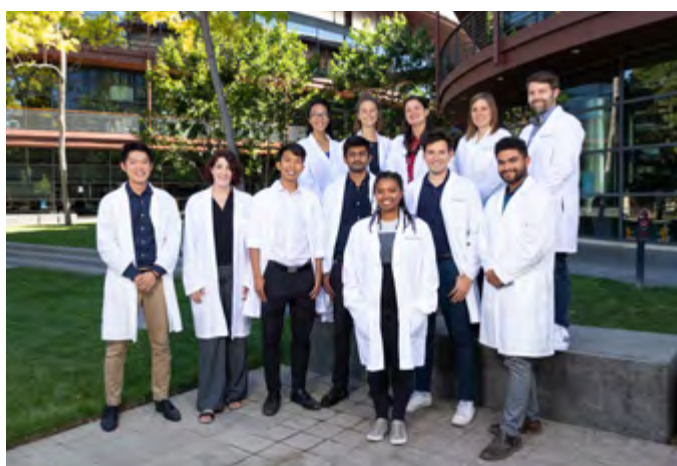
In 2022, across all three programs, Stanford Biodesign supported 19 projects addressing a wide variety of clinical indications. Examples of the technologies in development range from a diagnostic for type 2 diabetes, to a neurostimulation device to restore hearing, to oral inhibitors for the treatment of drug-resistant coronavirus variants. This year’s awardees received a total of \$1.45 million in funding, as well as intensive, hands-on mentorship and practical guidance to more efficiently and effectively advance their technologies toward patient care.

We are proud of our translational grant programs, which collectively have supported hundreds of projects, dispersed more than \$15 million in funds, and helped catalyze the launch of 54 companies over the years. For more information, contact Linda Lucian (llucian@stanford.edu).

2022 HIGHLIGHTS

July

With recruiting for the new, two-year Stanford Biodesign Policy Fellowship well underway, our Policy Program leaders hosted a webinar for potential candidates. During the session, the team provided details on the fellowship structure, explained how it could serve as a launch pad for a variety of careers in policy-making organizations, and encouraged participants to apply for the inaugural year of the program.



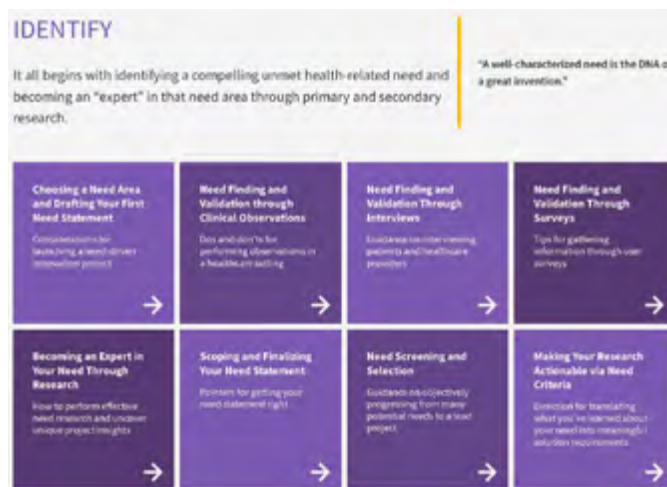
The 2022-23 Innovation Fellows on their way to the hospital

August

The 2022-23 Innovation Fellows arrived on campus and kicked off their training year with their month-long bootcamp experience. This year's class included six men and six women, from medicine, engineering, and business backgrounds, representing Africa, Canada, Germany, India, Spain, and locations across the US. As always, the bootcamp line-up included an overview of steps in the Biodesign process and a fast-paced mini-project to practice the approach, along with team building activities

and clinical lectures to prepare the fellows for clinical immersion. The 2022-23 clinical focus was Emergency Medicine, with fantastic support from Dr. Andra Blomkalns, who chairs the department at Stanford.

Additionally, three 2021-22 Innovation Fellows remained on campus to help us pilot a collaboration with the Wu Tsai Human Performance Alliance. This unique opportunity provided these second-year fellows with the opportunity to implement the Biodesign process to identify and address important unmet clinical needs related to thriving at all stages of life. The plan is for the most compelling needs to be taken forward as technology innovation projects or handed-off to researchers who are part of the alliance for further exploration.



In August, we also released six new "toolkits" as part of the Student Guide to Biodesign, a collection of online multimedia learning materials targeted at introductory learners (visit <https://biodesignguide.stanford.edu/>). Originally launched in 2021, the Student Guide provides a

“quick start” on health technology innovation projects, with more comprehensive information available in the Biodesign textbook. The Student Guide has been well received at Stanford, and a feedback initiative conducted over the summer confirmed that nearly 1,300 students and instructors around the world consider it a valuable resource too!



Networking at MedtechVision

September

For the tenth anniversary of the MedtechVision conference, Stanford Biodesign was delighted to join forces with MedtechWomen and co-host the event on campus. This annual event provides a forum for business leaders, inventors, investors, physicians, and policymakers to discuss real-world solutions to the most challenges issues facing the health technology industry. The all-star line-up of speakers featured numerous Stanford Biodesign contributors, including Kavita Patel, Kate Rosenbluth, Kate Garrett, Lisa Earnhardt, and many more. We're grateful to MedtechWomen, MedTechColor, and the other conference supporters for the opportunity to be involved.

People

During 2022, we welcomed multiple people to the fulltime Stanford Biodesign team:



Jody Berger
Communications manager



Lauren Brown
Translational program coordinator



Jill Hannemann
Chief of staff



Juliana Perl
Pediatrics and health technology
policy researcher



Susie Spielman
Senior manager for curriculum and
assessment



Peng Yuan
Financial analyst

We're delighted to have these individuals contributing to our work!

2022 HIGHLIGHTS

October

The ninth class of Stanford Biodesign Faculty Fellows began their training with a kick-off session at the d.school. The 12 fellows come from a diverse range of clinical specialties, including anesthesia, cardiothoracic surgery, emergency medicine, neurosurgery, otolaryngology, pain medicine, psychiatry and behavioral sciences, radiology, and sleep medicine. We also have one faculty members from the department of electrical engineering. The part-time “BFF” program runs from October until June, offering the fellows didactic training on the Biodesign process and hands-on coaching on their individual innovation projects. Following their training, our BFFs have used the Biodesign approach to infuse a need-orientation into their research, run innovation projects in their labs, and launch start-up companies.



The 2022-23 Biodesign Faculty Fellows and teaching team

November

Representatives from seven historically black colleges and universities (HBCUs) – Bowie State University, Dillard University, Charles Drew

Medical School, Howard Medical School, Meharry Medical School, Morehouse College, and Southern University and A&M College – visited Stanford Biodesign to learn more about our training programs and explore potential partnership opportunities. During their time with us, they toured the Clark Center, met with faculty and alumni, and participated in a hands-on workshop on the Biodesign process.



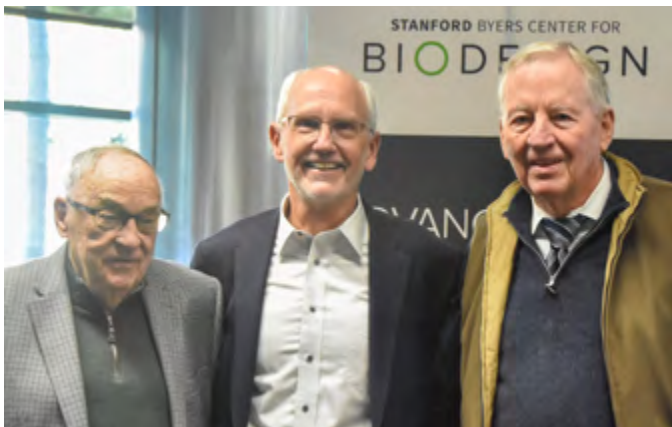
Visitors from US-based HBCUs

We also held a working session with our extended team of faculty and staff to review progress against our strategic goals, discuss ongoing improvement opportunities, and align around plans for 2023. That same day, we devoted time to a teamwork activity led that involved a holiday bike-building challenge for children in need!

December

Paul Yock presented at Stanford Medicine Grand Rounds and was honored with the Albion Walter Hewlett Award, which is given annually to an exceptional physician who combines a scientific approach to medicine with a strong commitment to patients. Afterwards, friends, family, and

colleagues gather at Stanford Biodesign to celebrate his accomplishments and mark his retirement, which became official at the end of 2022. Among the guests were two of Paul's formative mentors -- health technology legends Drs. Tom Fogarty and John Simpson.



Fogarty, Yock, and Simpson



McGlynn, Cassak, McEvoy, and Makower



Makower, Eshoo, Yock, and Patel

Speakers

January

Claude Steele, an American psychologist and author of *Whistling Vivaldi and Other Clues to How Stereotypes Affect Us*, discussed the ways negative stereotypes affect social groups and alter their performance in school and at work.

April

Physician **Kavita Patel** shared how policy impacts innovation, along with learnings from her work driving health policy reform with Senator Ted Kennedy and in the Obama Administration.

Anne Wojcicki, co-founder and CEO of 23andMe talked about how following her curiosity about DNA enabled her to build the company into a 12 million-person community that is mining valuable lessons from our genetic code.

June

Ashley McEvoy, executive vice president and worldwide chairman for medtech with Johnson & Johnson, discussed challenges and opportunities associated with transforming health care from inside a global corporation.

October

US Congresswoman **Anna Eshoo** told stories from her long career on Capitol Hill, and stressed the importance of policy and regulation in enabling healthcare innovation.

Mir Imran, CEO and chairman of InCube Labs, reflected on his 40-year career in technology innovation and the many breakthrough technologies he created.

Our thanks go to Wilson Sonsini and Fogarty Innovation for partnering on many of the events listed above.

SPONSORS MAKE IT POSSIBLE

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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VentureWell
Wallace H. Coulter Foundation
Wu Tsai Neurosciences Institute

We also appreciate all of our individual donors, along with all those who are supporting our named fellowships:

The Cottrell Biodesign Innovation Fellow
The Duerig Family Innovation Fellow
The Khosravi Innovation Fellow
The Lu Family Innovation Fellow
The Stanford Biodesign Alumni Association Fellowship Fund
The Biodesign Innovation Fellowship Support Fund in honor of Paul Yock

Get Involved!

For more information on how you can support Stanford Biodesign, please contact Gordon Saul (650) 725-4291. For other information about Stanford Biodesign visit us at <https://biodesign.stanford.edu>.



Students from the graduate Biodesign Innovation course



Innovators at work!



Anne Wojcicki and the 2021-22 Innovation Fellows

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

- 207 Innovation Fellows since 2001
- 2,500+ Stanford students since 2002
- 201 global fellows and faculty since 2015
- 98 Stanford faculty since 2015



Fellows and friends at the annual tailgate party



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