

BIOE 273, MED 273 Biodesign for Digital Health

Fall Quarter – Academic Year 2022/2023

Rev. 09.21.2022

Healthcare is facing significant cross-industry challenges and opportunities created by a number of factors including: the increasing need for improved access to affordable, high-quality care; growing demand from consumers for greater control of their health and health data; the shift in focus from “sick care” to prevention and health optimization; aging demographics and the increased burden of chronic conditions; and new emphasis on real-world, measurable health outcomes for individuals and populations. Moreover, the delivery of health information and services is no longer tied to traditional “brick and mortar” hospitals and clinics: it has increasingly become “digital,” enabled by apps, sensors, wearables, and the cloud; simultaneously, it has been augmented and often revolutionized by emerging digital and information technologies, as well as by the data that these technologies generate. Government initiatives to implement electronic health records (HITECH Act, 2009), firm rules to dramatically expand data interoperability via APIs (21st Century Cures Act Information Blocking Final Rule, 2020), and increased reimbursement for remote monitoring and telemedicine particularly spurred by the needs during the COVID-19 pandemic have all heightened the relevance of digital health solutions. This multifactorial transformation presents opportunities for innovation across the entire cycle of care, from wellness, to acute and chronic diseases, to care at the end of life.

But how can you approach innovation in digital health to address these health care challenges while ensuring the greatest chance of success? At Stanford Biodesign, we believe that innovation is a process that can be learned, practiced, and perfected; and, it starts with a well defined need. In Biodesign for Digital Health, students will learn about digital health and the Biodesign needs-driven innovation process from over 30 industry experts. Over the course of ten weeks, these speakers join the teaching team in a dynamic classroom environment that includes lectures, panel discussions, case studies, and breakout sessions. These experts represent startups, corporations, venture capital firms, accelerators, research labs, health systems, and more. Student teams will take actual digital health challenges and learn how to apply Biodesign innovation principles to research and evaluate needs, ideate solutions, objectively assess them against key criteria for satisfying the needs, and ensure all stakeholders in the ecosystem are addressed. Teams take a hands-on approach with the support of need coaches and mentors from industry. On the final day of class, teams present to a panel of digital health experts and compete for project extension funding.

Enrollment by application only. Applications open Thursday, June 2, 2022 and close Wednesday, September 7, 2022. Acceptance decisions are announced the week of September 16, 2022. Up to 32 students will be admitted into the course. Apply online via [this link](#).

Please reach out to us about how you’re doing and how the class is going at any time, by email or during virtual office hours. We also encourage you to engage with the support Stanford offers through Counseling and Psychological Services (CAPS), available 24 hours a day at (650) 723-3785.

Units: 3 units

Day/Time/Location: The class starts on September 28, 2022 and ends on December 7, 2022. In person sessions will be held at Li Ka Shing Center Room 101/102.

Wednesdays 3:30 – 6:20 pm - In Person

Wednesdays will include a combination of lectures, panels, and breakout sessions. We will use a variety of interactive tools to create an engaging and exciting journey through healthcare technology innovation.

Fridays 12:30-1:30pm via Zoom

Fridays are for team project work and workshops. There are **six** mandatory, specialty workshops that all students must attend. These are held via Zoom to provide the utmost flexibility. Enjoy lunch while learning and engaging with experts.

September 30, 2022: “Team Kickoff”

Need assignments and team exercise with class instructor: Michelle de Haaff

October 7, 2022: “Intellectual Property in Digital Health”

Jennifer Mikulina and Jed Gordon, Partners, McDermott Will & Emery LLP

October 14, 2022: “Digital Health Regulatory Topics”

Stephen W. Bernstein, Partner, McDermott Will & Emery LLP

November 4, 2022 Robin Diane Goldstein

Disruptive Innovation
former Apple, Zoox, and Sony Executive

November 11, 2022: Design Workshop

Christine Eun, Ryan Brewster, Valory Banishek
Design health tech design leaders and experts

November 18, 2022: Executive/Investor Presentations

Bob Kocher, MD, Partner Venrock Ventures

Course Materials: No textbook is required. **See the reading list next to each session in the class calendar table below.** Access to each reading assignment will be available via Canvas. Students are expected to complete assigned readings before each class session and will be quizzed on the content.

Additional course materials on Canvas include information on guest speakers and templates/worksheets for completing class assignments. Presentation slides from the speakers who give consent will also be posted.

Course Communications: **Canvas:** Canvas will be used for all formal class communications and the submission of assignments.

GOALS FOR THE COURSE

At the end of this course, students will:

- be able to ask informed questions and apply critical thinking to understand the evolving digital health industry sector;
- be able to recognize, describe and apply the needs-driven Biodesign approach to the creation of innovative concept solutions in digital health;
- have developed the start of a real concept that might merit additional work towards the creation of a solution;
- identify the interests and alignment with all the key stakeholders;
- have developed or refined the soft skills required to work in teams and with the support of external advisers and mentors towards achieving and presenting digital health projects outcomes.

INSTRUCTIONAL METHOD

The Biodesign for Digital Health course is taught by faculty from Stanford University and other organizations, as well as invited speakers from the digital health industry and entrepreneurial community. Students will devote significant time and effort working in teams, with the guidance of need coaches/mentors. The course provides a unique chance to gain real-world insights; to acquire or refine the soft-skills necessary to work in multidisciplinary teams and interact with outside experts; to build a relevant network of digital health enthusiasts and professionals; and to learn about career paths in health innovation.

STUDENTS RESPONSIBILITIES

Absences

No more than one unexcused absence is permitted. A second absence may be permitted with written justification by the student and make-up work negotiated with his/her team members on the course project. If you become ill and cannot attend classes live, please inform the instructors so that other accommodations can be made. Please communicate absences to the TA in advance. **More than two absences will reduce the student's final grade by one full letter grade, unless you have a note from a physician.**

GRADING

3 Units – CR/No CR or Letter Grade

Students may elect to attend the course for CR/No CR or for a Letter Grade. In addition to attending classes, completing readings, and participating actively in the classroom environment, students are required to complete a class project exploring a need in digital health. See the Class Projects section below for more information.

Grading will be based on:

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| 10% | Attendance in class; no more than 2 absences are allowed (see attendance policy above). |
| 10% | Class participation and teaching team assessment ; based on preparedness, engagement, and participation in class discussions & breakout sessions; as well as your completion of the CATME surveys. |
| 10% | Peer evaluations : via a confidential survey tool, students will be asked to evaluate their teammates for dependability, effort, quality of work, attitude, and initiative. Students will be sent a CATME link to the survey halfway through the semester (10/28) to do this. We encourage students to communicate with each other to work through issues. If teams face challenges that they cannot overcome, in addition to this survey, please attend office hours to discuss with the course instructors. |
| 5% | Chosen vignette due to teaching team by Tuesday, October 4, 2022 at 11:59pm Draft need statement and research plan due on October 11, 2022 at 11:59pm. |
| 15% | Need presentation given October 26, 2022 , due in Canvas on October 25, 2022 at 11:59pm. |
| 15% | Concept design presentation given November 16, 2022 ; due in Canvas on November 15, 2022 at 11:59pm. |

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| 10% | <p>Case Study Quizzes submitted via Canvas:</p> <ul style="list-style-type: none"> ● Glooko, Inc. Case Study Quiz: Due October 4 at 11:59pm ● Ginger.io Case Study Quiz: Due October 11 at 11:59pm ● Evidation Health Case Study Quiz: Due October 18 at 11:59pm ● Omada Health Case Study Quiz: Due November 1 at 11:59pm ● Alivacor Case Study Quiz: Due November 29 at 11:59pm |
| 25% | <p>One-page project summary and culminating presentation discussed with the faculty and special guests from industry and Biodesign NEXT on December 7, 2022. The faculty and industry experts will provide live feedback during the session. Project teams should share presentation responsibilities. The slide deck (Google Slides) must be submitted in advance and no later than Tuesday, December 6, 2022 at 11:59pm.</p> |

CLASS PROJECTS

Prior to the first day of class, students will be matched into cross disciplinary teams of approximately four to six members based on the information they provided on the course application. As a group, the team will choose a project from the need areas that have been sourced by the teaching team. The team will then outline a research plan to evaluate the chosen need area, draft and refine a focused need statement based on primary and secondary research, ideate solution concepts, and objectively assess them against key criteria for satisfying the needs.

Project progress will be tracked via a Google doc “team card” which is your initial breakout group worksheet. This should be updated at regular intervals by the team, in addition to three in-class presentations (Google presentations) that should be uploaded to Canvas.

The key criteria we are looking for in the project deliverables are **(1) understanding of the need** and **(2) representation of the biodesign innovation process** from need finding to concept generation and screening. The first is paramount and involves a clearly formulated and well-researched need statement. The second involves a strong process towards solution generation and selection (**originality** and **potential for impact** will be praised), with attention to opportunities for technical development (**feasibility**) and delivering strategies (**sustainability**, as can be achieved after thorough understanding of the competitive and stakeholder landscape and the market viability).

By focusing on the need and how students have applied the innovation process to address it, teams will demonstrate that their solution has a reasonable likelihood of being accepted by all stakeholders. In evaluating the projects, we will place greater emphasis on evaluating the caliber of the research performed and what students have learned. High quality of content and deliverables is most important, and is always preferred over quantity with limited insight. Additional information on the final presentations and past examples of project papers and slides will be distributed in November.

BIODESIGN NEXT PROGRAM

The top teams chosen by the final presentation panelists are eligible to continue working on their projects through the **Biodesign NEXT** extension funding program. Students who participate in Biodesign NEXT can register for additional credit and receive ongoing mentorship, as well as extension funding for 1-2 additional quarters. More information about this opportunity will be provided in class.

INTELLECTUAL PROPERTY / OWNERSHIP

As part of this project-based course, you and your teammates will potentially generate an invention that may be patented or copyrighted. As a general rule, all potentially patentable inventions conceived or first reduced to practice in whole or in part by Stanford's community in the course of their University responsibilities or with more than incidental use of University resources are owned by the University regardless of the source of funding, if any. Similarly, Stanford holds the copyright for materials developed with the significant use of University resources or personnel. If you and your teammates wish to take your invention forward beyond your time at Stanford, please contact the teaching team and we will help facilitate an introduction to Stanford's Office of Technology Licensing, which will work with the team to understand your options. Stanford has a long, successful history in technology licensing marked by collaborative relationships with inventors and by flexibility in negotiations. The OTL is committed to helping faculty, staff, and student teams navigate the processes of patenting and licensing with the goal of transferring their research to industry in order to benefit society.

CONTACT INFORMATION

Course Directors

Oliver Aalami, MD

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COURSE CULTURE

We are committed to affirming the identities, realities, and voices of all students, especially those from historically marginalized or underrepresented backgrounds. This course values the use of person-centered language and preferred gender pronouns, and respect for the experiences of others.

STUDENTS WITH DOCUMENTED DISABILITIES

Students who may need an academic accommodation based on the impact of a disability must initiate the request with the Office of Accessible Education (OAE). Professional staff will evaluate the request with required documentation, recommend reasonable accommodations, and prepare an

Accommodation Letter for faculty dated in the current quarter in which the request is made. Students should contact the OAE as soon as possible since timely notice is needed to coordinate accommodations. The OAE is located at 563 Salvatierra Walk (phone: 723-1066, URL: <http://studentaffairs.stanford.edu/oae>).

WEEKLY SESSION DETAILS

Wednesday Class (c)/ Friday Workshop (w)

| Date | Lecture, Team Activity, Workshop | Assignment (indicates assignment & due date) |
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| Week 1 | | |
| September 28 (c) Lecture | What is Biodesign? Digital Health Introduction <ul style="list-style-type: none"> • Oliver Aalami, Stanford Byers Center for Biodesign • Michelle de Haaff, Stanford Byers Center for Biodesign | Pre-read: Why do digital health startups keep failing? Paul Yock, Fast Company Magazine; 10.17.18 Reading due 9/30: INTENTIONAL TEAMWORK https://biodesignguide.stanford.edu/toolkit/intentional-teamwork/ |
| Keynote | Digital Health Technology Innovation Landscape Pedro Arboleda, Managing Director of Healthcare Strategy, Deloitte | |
| Presentations | Alumni Guests (All Biodesign NEXT winners and funding recipients): <ul style="list-style-type: none"> • Team Malama BIOE273 2021 • Team TrueTone BIOE273 2021 | |
| September 30 (w) | Team Kickoff Workshop and Exercise | Team assignment: Chosen vignette due 10/4 at 11:59pm on Canvas. Individual assignment: Glooko Inc., Case Study and Quiz Getting the Need Right due on 10/4 1at 11:59pm on Canvas. |

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| | | <p>Readings due 10/4: CHOOSING A NEED AREA AND DRAFTING YOUR FIRST NEED STATEMENT https://biodesignguide.stanford.edu/toolkit/choosing-a-need-area-and-drafting-your-first-need-statement/</p> <p>BECOMING AN EXPERT IN YOUR NEED THROUGH RESEARCH https://biodesignguide.stanford.edu/toolkit/becoming-an-expert-in-your-need-through-research/</p> |
| Week 2 | | |
| <p>October 5 (c) Lecture</p> | <p>Biodesign Process: Needs Finding and Research Plan</p> <p>James Wall, MD, Faculty, Stanford Byers Center for Biodesign</p> | <p>Reading due on 10/7: IP BASICS: https://biodesignguide.stanford.edu/toolkit/ip-basics/</p> |
| <p>Breakout Session</p> | <p>Team Activity: Discuss first draft of need statements and create your research plan</p> <p>Biodesign Fellows facilitate breakout sessions</p> | |
| <p>Panel</p> | <p>Digital Health Needs Moderator: Sunny Kumar, GSR Ventures</p> <ul style="list-style-type: none"> ● Erin Palm, Suki Health, Head of Product ● Julia Hoffman, Psy.D., VP Behavioral Strategy, Livongo ● Pelu Tran, CEO Ferrum Health ● Jon Bloom, CEO Podimetrics | |
| <p>October 7 (w)</p> | <p>Intellectual Property in Digital Health</p> <p>Jennifer Mikulina and Jed Gordon, Partners, McDermott Will & Emery LLP</p> | <p>Team assignment: Draft need statement and research plan due on 10/11 at 11:59pm on Canvas.</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div> <p>Readings due 10/11: The New England Journal of Medicine: We</p> |

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| | | <p>Can Do Better — Improving the Health of the American People, September 2007</p> <p>The New York Times: The U.S. Is Lagging Behind Many Rich Countries. These Charts Show Why.</p> <p>Startup innovation for underserved groups: 2021 digital health consumer adoption insights</p> <p>Individual Assignment: Ginger.IO Case Study and Quiz User-Focused Ideation and Design due on 10/11 at 11:59pm on Canvas.</p> |
| Week 3 | | |
| October 12 (c) | Socially Conscious Innovation | <p>Readings due on 10/14:</p> <p>FDA Medical Device Classification Overview</p> <p>Digital Health Software Precertification (Pre-Cert) Program, FDA</p> |
| Lecture | Narges Baniasadi, PhD, Social Impact Entrepreneur, Designing for the Disadvantaged | |
| Case Study | UNO Health Anna de Paula Hanika, CEO and Co-founder of UNO Health | |
| Breakout Session | Team Activity: Innovation for the Underserved | |
| October 14 (w) | Digital Health Regulatory Workshop Stephen W. Bernstein, Partner, McDermott Will & Emery LLP | <p>Reading due on 10/18:</p> <p>MAKING YOUR RESEARCH ACTIONABLE VIA NEED CRITERIA https://biodesignguide.stanford.edu/toolkit/making-your-research-actionable-via-need-criteria/</p> <p>Individual Assignment: Evidation Health Case Study and Quiz Demonstrating Value due at 10/18 at 11:59pm on Canvas.</p> |

| Week 4 | | |
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| October 19 (c) Case Study | Transforming Healthcare Delivery Through Digital ONE MEDICAL Case Study Amir Rubin, CEO One Medical (now part of Amazon) | Team assignment: Need statement and criteria presentation given on 10/26, due on Tuesday, 10/25 at 11:59pm on Canvas. |
| Lecture | Biodesign Process: Needs Screening and Criteria Selection <ul style="list-style-type: none"> • Lyn Denend, Director of Academic Programs, Stanford Byers Center for Biodesign • Uday Kumar, MD, Founder/Former CEO iRhythm, Adjunct Professor Stanford BioE | |
| Breakout Session | Team Activity: Develop first draft of need criteria Biodesign Fellows facilitate breakout sessions | |
| Week 5 | | |
| October 26 (c) Presentations 3:40-5:20 | Team Presentations: Need Statement and Need Criteria Team Presentations Each team will be given 15 minutes to present and have 3 minutes for Q&A/comments | Reading due 11/01: Slow Ideas , The New Yorker Magazine; Atul Gawande, JULY 29, 2013 |
| Panel 5:30-6:20pm | Policy Rap Session <u>Digital Health Policy Expert Rap Session</u> <ul style="list-style-type: none"> • Lucia Savage, Head of Policy at Omada • Deven McGraw, Lead Data Stewardship and Sharing, Citizen Platform at Invitae • David Amor, Director Global Regulatory Affairs, Apple Inc. | |
| Week 6 | | |
| November 2 (c) | Concept Generation and Screening - Designing for Digital Health | |

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| <p>Lecture</p> | <ul style="list-style-type: none"> • Uday Kumar, MD, Founder/Former CEO iRhythm, Adjunct Professor Stanford BioE • Pablo Pantaleoni, Chief Digital Officer, Lifestance Health Present Biodesign NEXT | |
| <p>Panel</p> | <p>Designing for Health</p> <ul style="list-style-type: none"> • Pablo Pantaleoni, Chief Digital Officer, Lifestance Health • Trina Histon, Senior Principal Consultant Prevention, Wellness & Digital Health, Kaiser Permanente. trina.histon@kp.org • Clare Purvis, Senior Director, Behavioral Science at Headspace. clarekpurvis@gmail.com • Toi Valentine, Head of Service Design, LifeStance Health and ex-IDEO. toivalentine@gmail.com • Dennis Boyle, Founding Partner, IDEO. dboyle@ideo.com | |
| <p>Breakout Session</p> | <p>Solution design and storyboarding with the panel</p> | |
| <p>November 4 (w)</p> | <p>Disruption in Healthcare Workshop Robin Diane Goldstein, Executive Advisor & Strategic Consultant, Former Executive at Apple, Zoox, & Sony</p> | <p>Readings due 11/08: BRAINSTORMING https://biodesignguide.stanford.edu/toolkit/brainstorming/</p> <p>CONCEPT SCREEN AND SELECTION: https://biodesignguide.stanford.edu/toolkit/concept-screening-and-selection/</p> <p>Individual assignment: Omada Health Case Study and Quiz Establishing Long-Term Business Viability due on 11/8 at 11:59pm on Canvas.</p> |

| Week 7 | | |
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| November 9 (c) Case Study | Digital Health Start-ups to Verily Jacqueline Shreibati, MD c | |
| Lecture | <p>Concept Generation - Brainstorming</p> <ul style="list-style-type: none"> Farzad Azimpour, MD, VP, Innovation & Advanced Technology at Edwards Lifesciences, AD Stanford Biodesign Shiqin Xu, Biodesign Course Manager | |
| Breakout Session | Concept Brainstorming | |
| November 11 (w) | <p>Design workshop</p> <ul style="list-style-type: none"> Ryan Brewster, MD, MS3/Former BIOE273 TA/Designer Christine Eun, Facebook/Apple/Facebook Valory Margaret Rubio Banashek/Product Designer | Team assignment: Concept presentation given on 11/16, due on Tuesday, 11/15 at 11:59pm on Canvas. |
| Week 8 | | |
| November 16 (c) Presentations | <p>Team Presentations: Team Concept Presentations</p> <p>Each team will be given 15 minutes to present and have 3 minutes for Q&A/comments</p> | Individual assignment: Alivacor Case Study and Quiz; Iterating The Business Model In A Nascent Market : Alivacor due 11/29 at 11:59pm on Canvas. |
| Panel | <p>Corporate Perspectives</p> <ul style="list-style-type: none"> Christopher (Topher) Sharp, MD; Chief Medical Information Officer Stanford Hospitals and Clinical Professor of Medicine, Stanford School of Medicine Jonathan Wilt, CTO, Innovation, Ochsner, Ochsner Health System, Louisiana | |

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| | <ul style="list-style-type: none"> • Vic Tandon, Director, Health Innovation Product Strategy at Blue Shield of California • Efreem Castillo, Senior VP Optum Care | |
| November 18 (w) | <p>Giving the Pitch Workshop Bob Kocher, MD, Partner Venrock Ventures <i>Note: This session will not be recorded - sensitive information will be shared!</i></p> | |
| Week 9 | | |
| <p>November 30 (c)</p> <p>Lecture 3:40-4:20 pm PST</p> | <p>Digital Health Business Models</p> <p>Michelle de Haaff, Stanford Byers Center for Biodesign</p> | <p>Team assignment: One-page project summary and culminating presentation. The slide deck (Google Slides) and one page project summary must be submitted in advance and no later than 12/6 at 11:59pm presentations to be given on 12/7 during class.</p> |
| <p>Breakout Session 4:30-5:10 pm PST</p> | <p>How will you get paid?</p> | |
| <p>Panel 5:20-6:20 pm PST</p> | <ul style="list-style-type: none"> • Bill Evans, Managing Director, Rock Health • Alex Morgan, Partner, Khosla Ventures • Vineeta Agarwala, General Partner, Andreessen Horowitz (a16z) • Bronwyn Harris (Carbon Health, Former Apple) | |
| Week 10 | | |
| <p>December 7</p> <p>Week 10</p> | <p>Final Team Presentations</p> <p>Each team will be given 20 minutes to present and have 5 minutes for Q&A/comments. All students must present.</p> <p>There will be a small reception at the end of class and we will announce the NEXT winners!</p> <ul style="list-style-type: none"> • Chris O'Dell, Executive Director, Digital Health Stanford Healthcare • Soheil Sadaat, GenieMD/Angel Investor | |

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| | <ul style="list-style-type: none">• Josh Makover, Biodesign Center• Jessica DaMassa, WTF• Angela McIntyre, Executive Director of the Stanford Wearable Electronics (eWEAR) Initiative• Stephen Bernstein, Partner McDermott, Will, & Emery• Pablo Pantaleoni, Chief Digital Officer LifeStance Health (NEXT Awards)• Linda Lucian, Biodesign Department (NEXT Awards) |
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Additional Recommended, but Optional Reading

- Reinventing American Health Care: How the Affordable Care Act Will Improve Our Terribly Complex, Blatantly Unjust, Outrageously Expensive, Grossly Inefficient, Error Prone System. March 4, 2014. By: Ezekiel J. Emanuel
- OECD: [Health for Everyone? Social Inequalities of Health and the Health System](#)
- The New Yorker: [Costa Ricans Live Longer Than We Do, What's the Secret?](#)

A course offered by:



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