

BIOE 273, MED 273 Biodesign for Digital Health

Fall Quarter – Academic Year 2020/2021

Rev. 07.28.2020

Health care 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 does one 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 needs 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 May 28, 2020 and close August 27, 2020. Acceptance decisions are announced on or before September 4, 2020. Up to 32 students will be admitted into the course. Apply online at: https://stanforduniversity.qualtrics.com/jfe/form/SV_4SzA6WGsauESc5

IMPORTANT: Unfortunately, due to university guidelines related to COVID-19, all class sessions and teamwork must take place remotely during fall quarter. However, the teaching team is committed to making this a positive, interactive, and exciting learning experience and has mobilized extra resources to

contribute to your learning experience. We will also be available during weekly office hours to help teams and individual students be successful during this challenging time.

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 16, 2020 and ends on November 18, 2020.

Wednesdays 4:00 – 6:50 pm

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 11:30 am – 12:30 pm

Fridays are for team project work and workshops. There are **five** mandatory, specialty workshops that all students must attend.

September 18, 2020: “Team Kickoff”

Need assignments and team exercise

October 9, 2020: “Intellectual Property in Digital Health”

William Kim, Partner & Owen Allen, Counsel |
Wilmer Hale

October 16, 2020: “Digital Health Regulatory Topics”

Jared Seehafer, Co-founder of Enzyme

November 6, 2020: Design Workshop

Christine Eun, Ryan Brewster | course alum
Ryan and Christine are open to sessions after the workshop to help with your projects.

November 13, 2020: Executive/Investor Presentations

Bob Kocher, MD, Partner Venrock Ventures

The five mandatory workshops will run from 11:30 am -12:30 via Zoom.

Course Materials: No textbook is required. **See the reading list at the end of this syllabus**

for an overview of course reading materials. Access to each reading assignment will be available viaCanvas. Students are expected to complete assigned readings before each class session and will be quizzed on their 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.

Slack: Students will be invited to join a class Slack channel for informal questions and collaboration. We will invite you to the Slack team on the first day of class. If you haven't already downloaded Slack, please do so!

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.

The typical format of a Wednesday afternoon in the classroom is:

- | | |
|----------------|--|
| 4:00 – 4:50 pm | Lecture/Team Activity |
| 4:50 – 5:50 pm | Breakout Session |
| 5:50 – 6:50 pm | Panel Discussion/Case Studies and Networking |

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. All classes will be recorded and made available to students of the class only. 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. |
| 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 (10/16) and at the end of the semester (12/5). |
| 5% | Draft need statement and research plan due on September 29, 2020 at 11:59pm . |
| 15% | Need presentation given Wednesday, October 14, 2020, due in Canvas on Tuesday, October 13 at 11:59pm . |
| 15% | Concept design presentation given Wednesday, November 4, 2020; due in Canvas on Tuesday, November 3 at 11:59pm . |
| 10% | Case Study Quizzes submitted via Canvas: <ul style="list-style-type: none"> ● Glooko, Inc. Case Study Quiz: Due September 29 at 11:59pm ● Sandstone Diagnostics Case Study Quiz: Due October 6 at 11:59pm ● Ginger.io Case Study Quiz: Due October 13 at 11:59pm ● Evidation Health Case Study Quiz: Due October 27 at 11:59pm |

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| | <ul style="list-style-type: none"> Omada Health Case Study Quiz: Due November 3 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 November 18, 2020. 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, November 17 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” that is updated at regular intervals by the team, in addition to three in-class presentations (Google presentations) that should be linked to the team card. The schedule is outlined below:

- **September 29** by 11:59 pm - First draft of need statement and research plan (see templates in Canvas) (submit via team card.)
- **October 13** by 11:59 pm - Need presentation due in Canvas. Team will give the presentation in class on Wednesday, October 14, 2020.
- **November 3** by 11:59 pm - Concept design presentation due in Canvas. Team will give the presentation in class on Wednesday, November 4, 2020.
- **November 17** by 11:59 pm - One-page project summary and final presentation (submit via Canvas); to be presented on the last day of class in presentation format. *Students must also communicate if they are interested in NEXT funding prior to the final presentation.*

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 on November 18 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

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|-------------------|-----------------------|
| Oliver Aalami, MD | aalami@stanford.edu |
| Michelle de Haaff | mdehaaff@stanford.edu |
| Ryan Spitler, PhD | rspitler@stanford.edu |

Teaching Assistant

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| Neha Srivathsa | nehasriv@stanford.edu |
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Course Manager

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| Shiqin Xu | shiqinxu@stanford.edu |
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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/oe>).

WEDNESDAY CLASS CONTENT: A WEEK-BY-WEEK VIEW



Class 1: September 16, 2020

Introduction; Overview of Biodesign Process and Digital Health

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| 4:00PM-4:50pm | LECTURE | Course Overview Digital Health Framework Biodesign Process Overview How Digital Health Can Expand Opportunities in Need-Driven Innovation |
| 4.50PM-5.50PM | KEYNOTE | Digital Health Landscape |
| 5.50PM-6.50PM | PRESENTATIONS | Examples of digital health innovations from past students. |

Lecture

Oliver Aalami, Stanford Byers Center for Biodesign
Michelle de Haaff, Stanford Byers Center for Biodesign

Keynote

Glenn Snyder, Deloitte Medical Technology Practice Leader

Presentations

Alumni Guests (All Biodesign NEXT winners and funding recipients):

- Team Osteotech BIOE273 2020
- Team Autijob BIO273 2020
- Team NuLeaf BIOE273 2016
- Team Surge Therapy BIOE273 2018

This week’s Friday workshop is:

September 18, 2020 at 11:30: Workshop: **“Team Kickoff”**
Needs assignment and working in teams exercise

Class 2: September 23, 2020

Digital Health Needs Finding

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|---------------|------------------|---|
| 4:00PM-4:50pm | LECTURE | Biodesign Process: Needs Finding and Research Plan |
| 4.50PM-5.50PM | BREAKOUT SESSION | Team Activity: Discuss first draft of need statements and develop a research plan |
| 5.50PM-6.50PM | PANEL | Digital Health Needs |

Lecture

James Wall, MD, Faculty, Stanford Byers Center for Biodesign (see if James can add in Research Plan to his lecture)

Panel

MODERATOR:

James Wall, MD, Faculty, Stanford Byers Center for Biodesign

GUEST PANELISTS:

- Scott Barclay, Partner DCVC, Formerly at Surescripts and CVS Health
- Jacqueline Shreibati, MD, MS, FACC, Medical Director, Alivecor (now at Google) - needs finding in a big company
- Julia Hoffman, Psy.D., VP Behavioral Strategy, Livongo
- Pelu Tran, CEO Ferrum Health (Augmetix Founder)

Class 3: September 30, 2020

Designing for the Disadvantaged

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| <p>4:00PM-4:50pm</p> | <p>LECTURE</p> | <p>Socially Conscious Innovation</p> <p>(Need Statement and Research Plan Presentations (2 teams at random))</p> |
| <p>4:50PM-5:50PM</p> | <p>BREAKOUT SESSION</p> | <p>Team Activity: Innovation for the Underserved</p> |
| <p>5:50PM-6:50PM</p> | <p>CASE STUDY</p> | <p>UNO Health Case Study</p> |

Lecture

Narges Baniyadi, PhD, Social Impact Entrepreneur, Designing for the Disadvantaged

Case Study

[Anna de Paula Hanika](#), CEO and Cofounder of UNO Health

Class 4 October 7, 2020

Enabling Technologies

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|---------------|------------------|---|
| 4:00PM-4:50pm | LECTURE | Biodesign Process: Needs Screening and Criteria Selection |
| 4:50PM-5:50PM | BREAKOUT SESSION | Team Activity: Develop first draft of need criteria |
| 5:50PM-6:50PM | PANEL | Enabling Technologies (and how they connect to needs) |

Lecture

Lyn Denend, Director of Academic Programs, Stanford Byers Center for Biodesign

Panel

MODERATOR:

Michelle de Haaff, Stanford Byers Center for Biodesign

GUEST PANELISTS:

- Gloria Lau, Investor DCVC, CEO Alpha Medical
- David Kuraguntla, CEO GraftWorx
- Jiang Li, CEO Vivalink
- Ian Shakil, Founding Chairman, Augmedix, Inc.

This week's workshop is:

October 9, 2020 at 11:30: Workshop **"Intellectual Property in Digital Health"**
William Kim, Partner & Owen Allen, Counsel | Wilmer Hale

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| 4:00PM-4:50pm | LECTURE | Biodesign Process: Concept Generation and Screening |
| 4:50PM-5:50PM | BREAKOUT SESSION | Team Activity: Solution design and storyboarding with the experts! |
| 5:50PM-6:50PM | PANEL | Designing for Health |

Lecture

Varun Boriah, Founder, CEO, Lully Sleep and Pablo Pantaleoni, CEO, Headspace, Present Biodesign NEXT

Panel

MODERATOR:

Pablo Pantaleoni, CEO, Headspace

GUEST PANELISTS:

- Farzad Azimpour, Vice President, Strategic Innovation, Advanced Technology at Edwards Lifesciences, Stanford Biodesign
- Dennis Boyle, Founding Partner at IDEO
- Clare Purvis, Director, Behavioral Science at Headspace
- Silvia Vergani, Head of Research at Flexport and who co-led the Health Portfolio at IDEO

Class 7 October 28, 2020

Business Models / Validation

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|----------------------|------------------|---|
| 4:00PM-4:50pm | LECTURE | Business Model Development and Validation |
| 4:50PM-5:50PM | BREAKOUT SESSION | Team Activity: How are you going to get paid? |
| 5:50PM-6:50PM | PANEL | Business Models and Validation |

Lecture

Oliver Aalami, Stanford Byers Center for Biodesign

Michelle de Haaff, Stanford Byers Center for Biodesign

Panel

MODERATOR:

Ryan Spitler, PhD, PHIND Center and Stanford Byers Center for Biodesign

GUEST PANELISTS:

- Bill Evans, Managing Director, Rock Health
- Peter Hames, CEO Big Health
- Alex Morgan, Principal, Khosla Ventures
- Vineeta Agarwala, Venture Partner, Google Ventures
- Cheryl Cheng, BlueRun Ventures

Class 8 November 4, 2020

Corporate Perspectives

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|---------------|---------------|---|
| 3.50PM-5:50PM | TEAM ACTIVITY | Concept presentations (6 minutes per team, followed by 6 minutes of discussion) |
| 5.50PM-6.50PM | PANEL | Corporate Perspectives |

Panel: Corporate Perspectives

MODERATOR:

Christopher (Topher) Sharp, MD; Chief Medical Information Officer Stanford Hospitals and Clinical Professor of Medicine, Stanford School of Medicine

GUEST PANELISTS:

- Jonathan Wilt, CTO, Innovation, Ochsner, Ochsner Health System, Louisiana
- Steven Denys, Vice President of Strategic Relationships, Glooko
- Alex Gao, Director of Digital Health Lab Samsung
- Vic Tandon, Sr. Manager, Innovation Product Strategy at Blue Shield of California
- Michael Mcconnell, Senior Research Scientist, Google Health and Clinical Prof of Medicine at Stanford (2nd round)
- Don Mordecai, National Leader for Mental and Behavioral Health, Kaiser Permanente

This week’s workshop is:

November 6, 2020 at 11:30am: “Design Workshop”*
 Ryan Brewster, MS3/Former BIOE273 TA/Designer
 Christine Eun, Facebook/Apple

Class 9 November 11, 2020

Incremental Versus Disruptive Solutions

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|----------------------|------------------|---|
| 4.00PM-5:00PM | LECTURE | How to create and deliver a disruptive solution |
| 5.00PM-6.00PM | BREAKOUT SESSION | Team Activity: Thinking out of the box! |
| 6.00PM-6:50PM | CASE STUDY | Grand Rounds Case Study |

Lecture

Robin Goldstein, JD, Former Apple, Sony & DEC Executive, Refining the Need by Going Out of the Box

Case Study

Rusty Hofman, MD Founder, Grand Rounds and Medical Director, Digital Health Care Integration, Stanford Healthcare

This week's Friday workshop is:

November 13, 2020 at 11:30

Workshop: Executive/Investor Presentations

Bob Kocher, MD, Partner Venrock Ventures



Class 10 November 18, 2020

Final Presentations

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|---------------------------|--------------------------------|---|
| 4.00PM- 6.50PM | FINAL PRESENTATIONS | Teams present a full, 10-15 slides presentation of their project to the class and a judging panel. All students must present. Each team will be provided with a 30 minute slot. |
|---------------------------|--------------------------------|---|

Final Presentation Panelists Include:

- Paul Yock, MD, Director, Byers Center for Biodesign
- Rick Altinger, Digital Health Start-up Founder
- Iana Dimkova, Investor GE Healthcare
- Soheil Sadaat, GenieMD/Angel Investor (Healthcare)
- Christina Farr, CNBC Healthcare Reporter

Abbreviated Calendar

Wednesday Class (c)/ Friday Workshop (w)

| | | Lecture, Team Activity, Workshop | Assignment/Reading (due next class) | Panel |
|---------------|----|---|--|------------------------|
| September (c) | 16 | Introduction, Team Formation | Biodesign; The Process of Innovating Medical Technologies: Process Insights pp39.-pp.46 Why do digital health startups keep failing? Paul Yock, Fast Company Magazine; 10.17.18 | Digital Health Keynote |
| September (w) | 18 | Team Kickoff | | NA |
| September (c) | 23 | Needs Finding & Exploration | Glooko Inc., Case Study and Quiz Getting the Need Right Biodesign; The Process of Innovating Medical Technologies: Part I: Identify Section 1.2 Needs Exploration pp. 67-pp. 89 | Digital Health Needs |
| September (c) | 30 | Social and Environmentally Conscious Innovation | Sandstone Diagnostics Case Study and Quiz Need Criteria as a Guiding Light Slow Ideas , The New Yorker Magazine; Atul Gawande, JULY 29, 2013 | UNO Health |
| October (c) | 07 | Needs Criteria Selection | Ginger.IO Case Study and Quiz User-Focused Ideation and Design | Enabling Technologies |
| October (w) | 09 | Intellectual Property in Digital Health | | NA |
| October (c) | 14 | Team Presentation 1: Needs Presentation | | Policy |
| October (w) | 16 | Digital Health Regulatory Topics | FDA Medical Device Classification Overview | NA |

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|--------------|----|---|--|-------------------------|
| | | | Digital Health Software Precertification (Pre-Cert) Program, FDA | |
| October (c) | 21 | Designing for Digital Health | Evidation Health Case Study and Quiz Demonstrating Value | Designing for Health |
| October (c) | 28 | Business Model Development and Validation | Omada Health Case Study and Quiz Establishing Long-Term Business Viability Biodesign; The Process of Innovating Medical Technologies: Part II: Invent Section 3.2 Initial Concept Selection pp. 268-279 | Industry Panel |
| November (c) | 04 | Team Presentation 2: Concept Presentation | | Corporate Perspectives |
| November (w) | 06 | Design Workshop | | |
| November (c) | 11 | How to create and deliver a disruptive solution | | Grand Rounds Case Study |
| November (w) | 13 | Giving the Pitch | | |
| November | 18 | Final Team Presentations | | |

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

A course offered by:



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