

Biodesign - Course Sketch and Syllabus -2020-21

Introduction

“Biodesign *Innovation*” course is a need driven health-Tec innovation program, that is Design Thinking based. The course was developed at the “Stanford Bayer Center for Biodesign” and has been running for over 20 years.

The Biodesign course is based on the following pillars:

1. Clinical need driven challenges
2. Multidisciplinary approach combining Medical, Technological and Business students and faculty.
3. Value based solutions implemented in a project-based process.

The Biodesign course set to run as of October 2020 in the Rambam-Technion realm, is an identical duplication of the Stanford Biodesign course that runs yearly in Palo Alto, with only minor adaptation to meet Technion’s semesters length, the Technion’s students and the Israeli ecosystem. The program will be closely monitored by Stanford faculty, and scrutinized to meet guiding principles set by Stanford as condition for the Israeli branch to be fully accredited within a 3-year time.

The course will be given by the “Biodesign Israel”, particularly by 4 Stanford Biodesign alumni.

The Biodesign methodology is based on tree main phases:

1. **Identify** –
each team is assigned with a different clinical vignette, a need area. In the first phase of the program the participants immerse in this clinical world, guided by their clinical mentor, interviewing physicians, nurses, patients, patient family members etc. Teams map a large number of unmet medical needs based on their own observations. Afterwards and launch a process of screening the list down to the promising few, based on clinical impact, current relevant technological landscape, and competitive market analysis. The output is a well characterized unmet need with carefully formulated need specifications. This frame is presented as a need statement which is formulated by defining the problem, the population and the measurable outcome.
2. **Invent** –
During the second phase, participants will brainstorm and come up with a number of solution concepts. Define the must have and nice to have criteria, they will devise solutions to the defined need, implementing design thinking methodologies, creative ideation techniques, prototyping and testing principles and a filtering process based on objective risk criteria. The output is a final concept with well recognized risks and a basic prototype.

3. **Implement** –

Creating multi-year plan for developing said concept into a real product. Developing and integrating core strategies for technical, regulatory, reimbursement and a valid business model. The output is a well-defined roadmap for execution.

Guidelines

1. A two-semester course with biweekly 2-hour mandatory meeting.
2. Lectures:
 - a. Basic skills and methodologies
 - b. Learning through cases – Industry
 - c. Workshops:
 - i. Design thinking
 - ii. Prototyping
 - iii. IP, Regulatory and Business models strategies developing
 - iv. Pitch and presentation skills
 - v. Team dynamic coaching
 - d. Mid-term and end of semester presentations
3. Self-work
 - a. Clinical immersion
 - b. Weekly quizzes
 - c. Weekly assignment
 - d. Prototyping
 - e. Semester Final report assignment
4. Lecturers:
 - a. Dr Yona Vaisbuch
 - b. Dr Tahel Altman
 - c. Dr Lior Lev Tov
 - d. Dr Nitai Klein
 - e. Guests lecturers (will be approved by Biomedical engineering faculty)
 - i. Stanford Biodesign center Faculty
 - ii. Leaders from industry
 - iii. Entrepreneurs from academia
 - f. Tutor (Biomedical engineer)
 - i. Weekly assignments
 - ii. Tutorials (cases based)
 - iii. Biomedical Technology Lab mentoring
5. Grades:
 - a. Biodesign 70%
 - i. Weekly quizzes (individual) = 15%
 - ii. Final Presentation (group) = 20%
 - iii. Mentors (individual) = 10%
 - iv. Final report (individual) = 25%
 - b. Mother Faculty mentors = 30%
6. Material:

- a. Book: “BIODESIGN- The process of innovating medical technologies” 2nd edition, Yock, Zenios, Makower
 - b. Lectures & Moodle
 - c. Stanford Biodesign video library and YouTube (Free access)
7. Venue:
- a. Rambam Yeda (Rambam health care campus)
 - b. Biomedical engineering faculty (several times per semester)
 - c. Biomedical engineering Tec-Lab and other sites by demand.

Syllabus (Summary)

First semester will deal with the identification phase and the concept generation – going through clinical immersions and need finding along with clinical mentoring, need filtering technics – technology and business potential analysis. Then students will be introduced with the design thinking philosophy, brainstorming and prototyping workshops. The final presentation will deal with the need statement evaluation, need criteria and 3 optional concepts.

The second semester will begin with the 2nd part of the ideation (concept screening) by deep analysis of the technical feasibility using prototyping, regulatory and reimbursement approach analysis along with relevant business models. Then continue with the implementation phase developing plan for initiation by advanced prototyping, timeline and strategic approach for the different aspects, along with risk analysis. The final presentation will deal with the leading concept, prototyping presentation, other achievement as provisional patent application and future plan/collaboration for licensing.

Syllabus (by weeks)

1st semester (Winter 2020)

Week #	1 st class	2 nd Class
1	Need statement development	Validation interview
2	Med-Tec environment & ecosystem	Need Fair
3	Validation interview exercise	Disease state & Existing solutions
4	Clinical immersion	Clinical immersion
5	Need statements validation	Stakeholders and Market analysis
6	Need criteria	Need criteria exercise
7	Need driven from Industry	Team dynamic workshop
8	Brainstorming (introduction)	Progress validation
9	Design thinking workshop	Mid-Term presentation
10	Initial concept selection	Brain-map and concept clustering
11	Learning from failure	Team dynamic workshop
12	Industry case study	Introduction to Prototyping
13	Prototyping workshop	Progress validation
14	1 st semester Final Presentation	1 st semester Final Presentation

2nd semester (Spring 2021)

Week #	1 st class	2 nd Class
1	Final concept selection	IP basics
2	IP workshop	Brainstorming
3	Regulatory basics	Progress validation
4	Regulatory workshop	Prototyping workshop
5	Reimbursement basics	Reimbursement approaches
6	2 nd level prototyping	2 nd level prototyping
7	Business models and Value proposition	Team dynamic workshop
8	Progress validation	Mid-Term presentation
9	Reimbursement workshop	Development planning
10	Commercialization & Business coaching	Pitch workshop
11	Operative plan and financial model workshop	Funding approaches
12	Presentation workshop	Industry giant panel
13	Progress validation	Teamwork
14	Final Presentation	Final Presentation