

# Training Innovators at the Stanford *Biodesign* Program and Its Implications

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## Abstract

This article presents an in-depth description of Stanford University's Biodesign, the post-graduate program established in 2001 with a mission to train a new generation of leaders in biomedical innovation. We examined the Biodesign's multidisciplinary curriculum in which the competitively selected fellows undergo an intensive 10.5-month training to identify clinical needs, find innovative solutions and plan business strategies for implementation. The strength of the Stanford Biodesign program lies in its unique selection of the applicants where the committee looks for the following "innovation personalities" (Brinton, et. al, 2013) and put them together as a team: (1) the builder (i.e. engineer), (2) the researcher (i.e. scientist), (3) the organizer (i.e. business expert), and (4) the clinician (i.e. medical doctor). The team members collaborate and learn from each other's expertise as they go through the intensive training. The multidisciplinary nature of Biodesign program enables the participants to acquire critical biomedical thinking, entrepreneurial resource, team-building skills and networking opportunities.

## Introduction

- Design Thinking and diversity is considered as key driving forces to innovate
  - Brown (2008)
  - Belbin (1993)
  - Fleming (2004)

## Stanford University and Silicon Valley -unique eco system -

- Stanford University
  - mainstay of “utilitarian thinking” (Veysey 1965)
  - Terman’s vision and regional advantage of Silicon Valley (Saxenian 1994)
  - high “responsiveness” to the changes and growth in the surrounding environment (Harayama 2001)
- Stanford has created various innovative programs to adapt to the evolving needs in Silicon Valley
- The unique eco system where academia and industry collaborate closely and create synergy gave birth to *Biodesign*

## Biodesign: History

- Dr. Paul Yock created Stanford Medical Device Network (MDN) in 1998 to “stimulate innovation in the field of medical device” within Stanford University and “mentor young inventors and to help them find the right connections.”
- Paul Yock, M.D. (Professor of Medicine at Stanford University + inventor)
  - internationally known for his work in inventing, developing and testing new devices
  - authored fundamental patents for mechanical intravascular ultrasound imaging and helped conduct the initial clinical trials
  - founded Cardiovascular Imaging Systems in 1986, which was acquired by Boston Scientific in 1994.
  - co-founded several other medical technology companies
- Josh Makower, M.D., S.B., MBA
  - until 1995, Founder and Manager of Pfizer’s Strategic Innovation Group
    - launched “Pfresh Tech” Program in 1991 to develop new products by sending a team of Ph.D. students in medical engineering and Pfizer employees to major teaching hospitals who would observe surgeries and find “needs”
  - in 1995, moved to the San Francisco Bay Area and started the medical device incubator, ExploraMed
    - founded several companies through the incubator
- Yock’s vision to create an educational (training) program to medical device industry and Makower’s expertise and talents merged during breakfast meeting in 2000

## Program’s Initial Years

- It started in 2000 as an informal opportunity for three fellows. The participants were granted access to the clinical settings at the Stanford Hospital
  - no curriculum set in stone
  - Fellows received mentoring from experts of medical device developments
  - 4 fellows in the second year
- During the first years, the program involved a series of lectures by local entrepreneur’s. They were gathered through Yock and Macower’s personal network. The speakers shared their personal stories and experiences.
- Todd Brinton (2004-5 Fellow) joined as the program director and developed Biodesign Innovation Fellowship into a more coherent curriculum
  - The only class materials during the initial years were informal print outs that the speakers handed out. These materials were eventually compiled and developed into a cohesive curriculum and were published as a

## Program's Mission, Features

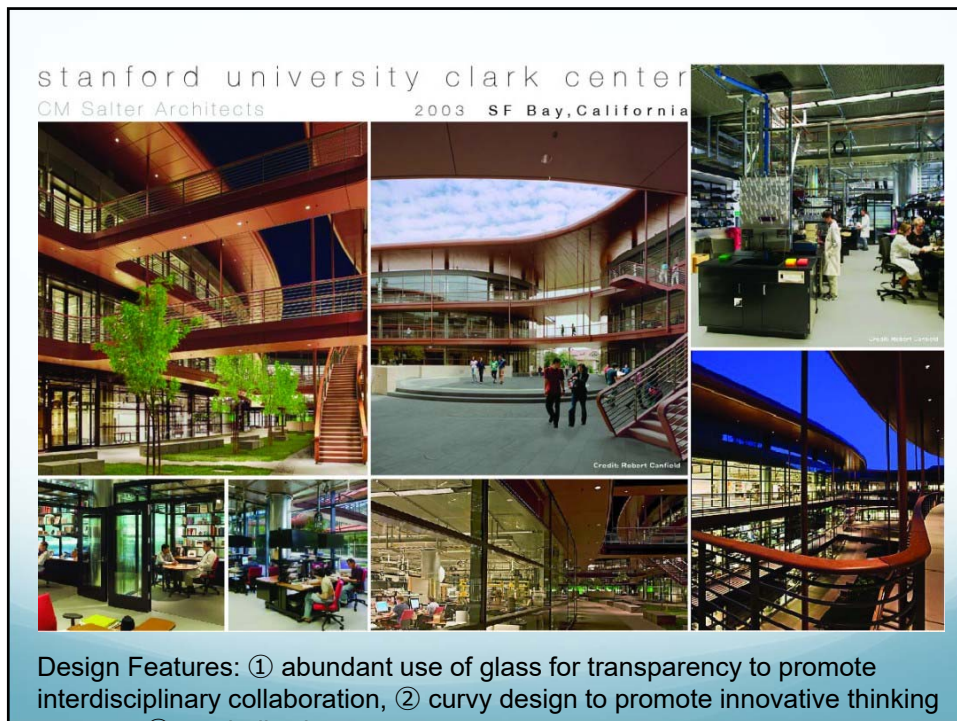
- Biodesign's Mission: to train a new generation of leaders in biomedical technology innovation
- Program Site: inside the Clark Building, Stanford University (located between the School of Engineering and School of Medicine)
- Started in 2000 with 3 fellows; grew into a program to train 12 fellows per year
- Global Programs: India, Singapore, China, Ireland, Japan
- 120 graduates (by 2014); 38 venture firms (by 2016)
- Key Features:
  - 10.5-months, full-time, paid postgraduate training
  - multidisciplinary teams of engineers, scientists, medical doctors and business experts
    - "To our knowledge, [Biodesign] was the first university postgraduate fellowship model of explicitly interdisciplinary, team-based med-tech innovation training." (Brinton, et al. 2012)

## Our Field Work

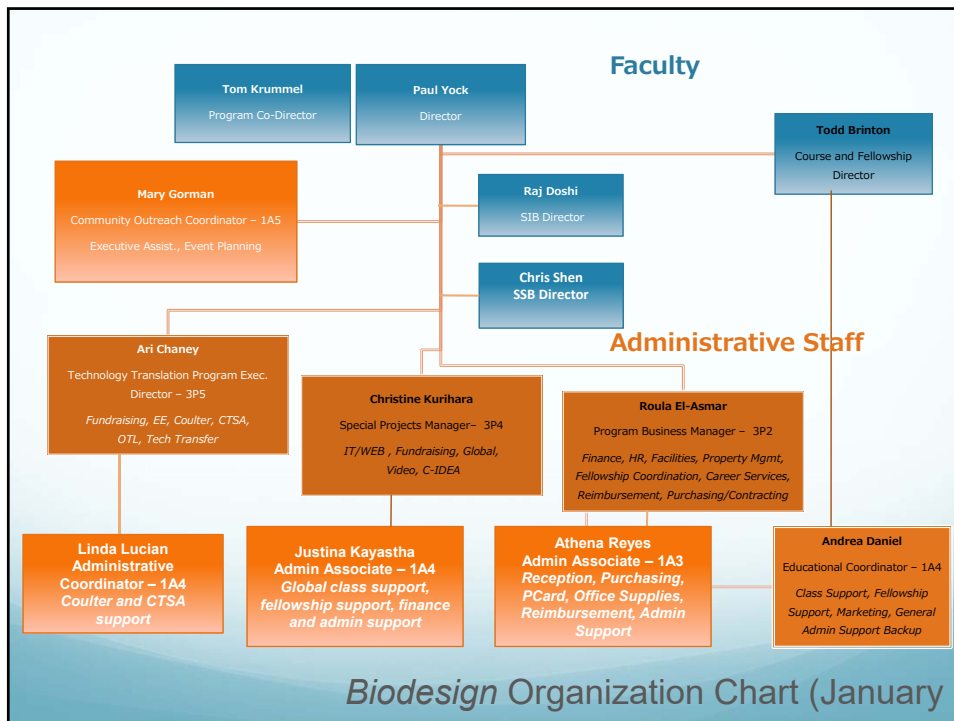
- November 2012 ~ June 2013; April ~ August 2014
- 20 in-depth interviews with 14 individuals

Typology			Faculty	Staff	Fellows
Relationship to Biodesign		Purpose of our interviews			
Stanford Employee/Biodesign Affiliates		To collect in-depth information about the administration of Biodesign	1	3	1
Non-Stanford Employee/Biodesign Affiliates		To solicit objective perspective on Biodesign	1	N/A	N/A
Stanford Employees/ Non-Biodesign Affiliates	School of Medicine	To gather background information on US clinical medicine, medical technology industry and Stanford University	2	2	2
	School of Engineering	To gather background information on US medical technology industry and	1	—	—





# “The Egg”



## 2016 Proceedings of PICMET '16: Technology Management for Social Innovation

Academic Year	Program's Focus			Number of Fellows			
	Biodesign	Stanford-India Biodesign (SIB)	Singapore-Stanford Biodesign (SSB)	Biodesign Innovation Fellow	Pilot Program with Mexico	SIB	SSB
2001-2002	Cardiology			5			
2002-03	Cardiovascular			3			
2003-04	Neurosciences			5			
2004-05	CV Medicine/ Surgery			6			
2005-06	Electrophysiology/General Surgery			9			
2006-07	Orthopedics			11	2		
2007-08	Anesthesia /Critical Care	Emergency Medicine		9		5	
2008-09	Gastrointestinal Diseases /General Surgery	Emergency Medicine		8		4	
2009-10	Cardiology	Pediatrics		8		4	
2010-11	Ophthalmology/Ear, Nose & Throat	Pediatrics	Ophthalmology	9		4	4
2011-12	Transplant, Immunology & Infectious Disease	GI	ENT	10		4	4
2012-13	Neurology/Neurosurgery	Urology	Cardiology	10		4	4
2013-14				9		4	4
2014-15	Radiology	Rheumatic Heart Disease	Dermatology & Plastic Surgery	12		3	4

Created by Authors based on Biodesign's website information

## Program Timeline

Phase	Timeline	Curriculum Content
I	August	"Boot Camp" (Intensive Learning) of the Clinical Area of Focus
II	September-October	Clinical Immersion & Needs Identification
III	November-December	Needs Screening
IV	January - February	Concept Generation & Initial Prototyping
V	March	Externship
VI	April - June	Project Development; Initial Testing; Fundraising

adopted from Brinton, et. al. (2013) and modified by authors based on Biodesign's website information



## Phase I: Boot Camp

One-month intensive learning of the clinical area of focus where the fellows do the followings:

- Attend lectures by medical faculty members and by over 150 experts in Silicon Valley on engineering and business fundamentals of medical technology innovation; begin using the textbook, *Biodesign* (Cambridge University Press, 2010)
- Work on “pilot project” – intensive exercise of characterizing a pre-selected need, inventing solution and selecting a best approach
- Cultivate working relationship with clinicians
- Team building: work with psychologist with extensive group therapy and executive coaching

## Phase II. Clinical Immersion & Needs Identification

Two-months clinical immersion process where the teams do the followings:

- Need Identification:
  - split into pairs and spend time at hospitals
  - come up with 200 (minimum) “needs” by observing physicians, nurses, staff, patients and families in clinical situations
- Need Validation:
  - develop better understanding of the needs through further research and networking with experts
  - test the initial reaction of their clinical advisors to the importance of the needs
  - try summarizing their ideas into a “need statement” that

## Phase III: Needs Screening

- During this two-months phase, the teams do:
- Need Filtering:
  - narrow down the list of needs by identifying a small number of especially promising ideas
    - by exploring clinical context
    - by understanding the market characteristics
- Need Specification:
  - identify the important components of the needs that have to be satisfied by the ultimate product
  - take into consideration of all stakeholders

## Phase IV: Concept Generation & Initial Prototyping

Finally (4 to 5 months into the fellowship), the teams are given go-signs for:

- Concept Generation Phase
  - move forward with top 12-16 needs
  - brainstorm solutions
  - select at least three solutions per need
  - do early prototyping
- Concept Selection Phase (Second Filtering)
  - IP
  - regulatory/reimbursement issues
  - technical feasibility
  - business model

## Phase V: Externship

- In March, fellows work in local medical technology company or venture firm or travel to global Biodesign program affiliates

## Phase VI: Project Development, Early Testing, Fundraising

- During the second half, Fellows also serve as mentors to approximately 50 graduate students from Stanford's business, engineering, and medical schools.
  - These graduate students also form interdisciplinary teams and go through a similar process in an accelerated manner
- Both Biodesign teams and the graduate students create:
  - a business plan for a start-up
  - a detailed licensing plan for invention
  - prototypes to be used for raising seed funding or initiating licensing discussion

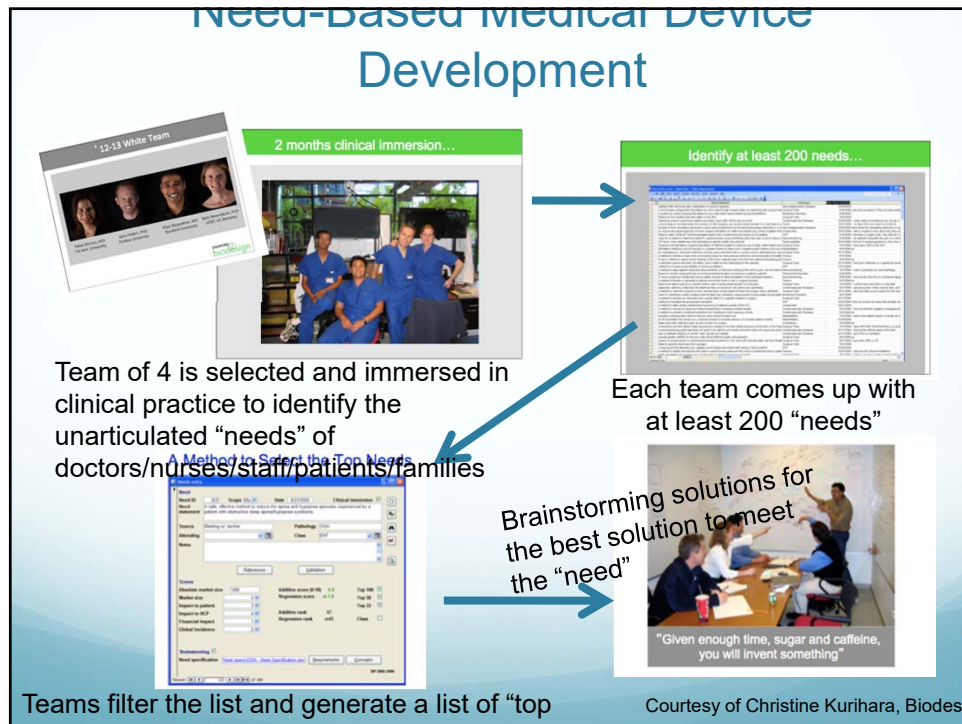
## Interdisciplinary Team

- 2 Teams of Four Fellows
- “Four Innovation Personalities”
  - (1) Builder (engineer?) : who can design and build prototypes  
e.g: MA in Mechanical Engineer
  - (2) Researcher (scientist): who reviews clinical/engineering/business literature  
e.g: Ph.D.
  - (3) Clinician: who understands complexities of bringing technologies into clinical practice  
e.g.: M.D.
  - (4) Organizer: who can manages the team to be on track  
e.g. someone with experiences with managing projects/teams
- Four faculty members play the role of the facilitators/mentors
- to avoid Conflict of Interest, these faculty members do not participate in any of the businesses that emerge out of the *Biodesign*

## “Four Innovative Personalities”

Brinton, et. al. (2013)





## Selection Process

- accept applications online from engineers, scientists, physicians and business people around the world
  - 200 applications for 10 spots (2012)
- Applicants send in CVs, grades, recommendation letters, essays, videos, etc.
- Out of the 100 ~ 200 applicants, 22 to 24 are selected during the first review; finalists are invited for an intensive two-day interviews at Stanford
  - "invention challenge": applicants are asked to respond to a description of a clinical problem by identifying a possible need and brainstorm possible solutions.
  - By the end of the 1<sup>st</sup> day, faculty sort the applicants into "Definitely In" "Definitely Out" and "Others" categories
  - On the 2<sup>nd</sup> day, faculty focus on those in the "Others" category.
- Candidates are evaluated for their creative thinking, technical depth, teamwork, etc.
  - not only technical skill sets and knowledge, but also inter-personal skills and leadership quality are important.
  - Biodesign looks for people who can collaborate effectively with others and

## Globalization of Biodesign

- Stanford-India Biodesign (SIB): 2008-2015
  - Launched in collaboration with the All-India Institute of Medical Sciences + the Indian Institute of Technology in Delhi
  - Sponsorship by the Department of Biotechnology
  - Very similar interdisciplinary team of four fellows from India
  - 6 month at Stanford + 1.5 year in India
- Singapore-Stanford Biodesign (SSB): 2011-Present
  - Launched as a collaboration between Stanford and the Agency for Science and Technology and Research + the Economic Development Board of Singapore, partnering with the National University of Singapore + the Nanyang Technical University
- SIB and SSB have their own evaluation criteria. However, Stanford Biodesign faculty participate in the final round of review and decision making.

## Challenges and Lessons Learned

- The program started with a vision to develop the next generation of leaders in the medical device innovation; it evolved through trials and errors.
- The key feature of the program is its focus on “interdisciplinarity.” The unique team formation of “four innovation personalities” – builder, organizer, researcher and clinician – not only brings different skill sets and expertise but also diverse perspectives to the teams and ultimately generates innovative ideas.
- Bringing the top talents with multidisciplinary background can also produce challenges with communication and team dynamics. Biodesign teams work with psychologist on regular basis (shared personnel with Stanford Design School) who facilitates communications among the members and prevent potential conflicts.
- Globalization of the Biodesign program brings fellows from around the world. This might bring even more diverse perspectives and challenges. It is important to come up with an effective way to generate productive interactions amongst all members

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