JACC: BASIC TO TRANSLATIONAL SCIENCE
PUBLISHED BY ELSEVIER ON BEHALF OF THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION.

VOL. 1, NO. 6, 2016
ISSN 2452-302X
http://dx.doi.org/10.1016/j.jacbts.2016.06.011

TRANSLATIONAL PERSPECTIVES

Needs-Based Innovation in Cardiovascular Medicine

The Stanford Biodesign Process

Jonathan G. Schwartz, MD,[a,b] Uday N. Kumar, MD,[a] Dan E. Azagury, MD,[a,c] Todd J. Brinton, MD,[a,b] Paul G. Yock, MD[a,b]

SUMMARY

More than a decade ago, a formalized fellowship training program in medical device innovation, the first of its kind, was created at Stanford University. Now in its 15th year, the Stanford Biodesign Fellowship Program is a 10-month program whereby postgraduate students with a prior background in medicine, engineering, and/or business form interdisciplinary teams for an experiential process of identifying unmet clinical needs, inventing new solutions, and implementing these ideas (the 3 "I's"). A key component of this structured process is focused attention on needs finding and characterization, which differs from the traditional "tech-push" model (i.e., technologies looking for problems to solve). Although the Stanford Biodesign process can be applied to a wide variety of clinical areas, cardiovascular medicine is particularly well suited, given the breadth of clinical presentations it touches and its history of innovation to solve important clinical problems. Physicians play a vital role in the process, especially for needs identification and characterization. This paper outlines the Stanford Biodesign process and presents an argument for its repeat applicability, discusses its relevance to physicians and to cardiologists in particular, and provides a case study of the process that resulted in a currently available cardiovascular medical technology that came directly from the Fellowship Program. (J Am Coll Cardiol Basic Trans Science 2016;1:541–7) Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Innovation and entrepreneurship have been widely celebrated in recent years, reaching as far as mainstream television with multiple current on-air shows (e.g., Silicon Valley, Shark Tank, etc.). In parallel with this increased cultural awareness, universities across the country have developed entrepreneurship training programs, initially focusing on engineering, but more recently expanding to the life sciences. One of the oldest life science programs is Stanford Biodesign, which focuses on training young innovators of biomedical technologies (particularly medical devices) (1). A primary distinction between the Stanford Biodesign process and more traditional approaches to innovation is an upfront focus on identifying and characterizing the clinical need, rather than beginning with a promising technology. The central dogma of the Stanford Biodesign process is that "a well-characterized need is the DNA of a great invention" (2). This needs-based approach to innovation begins in the clinical environment, where practicing clinicians are ideally placed to spearhead the process. Although many companies have germinated from the fellowship program, the true goal is to teach a repeatable approach to health technology innovation, which can then lead to a "multiplier effect," where graduates can

From the [a]Stanford Byers Center for Biodesign, Stanford, California; [b]Division of Cardiovascular Medicine, Department of Medicine, Stanford University School of Medicine, Stanford, California; and the [c]Department of Surgery, Stanford University School of Medicine, Stanford, California. Dr. Kumar is the founder, a current consultant, and major stockholder of iRhythm Technologies, Inc.; the founder, president, CEO, and major stockholder of Element Science, Inc.; and a board member of G-Tech Medical, Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received June 16, 2016; accepted June 17, 2016.

ABBREVIATIONS AND ACRONYMS

EP = electrophysiologist/electrophysiology

IP = intellectual property

apply this process serially to solve unmet clinical needs.

The program is both field- and technology-agnostic but has deep roots in cardiovascular medicine; the Stanford Byers Center for Biodesign is directed by Dr. Paul Yock, an interventional-trained cardiologist and serial entrepreneur who invented the Rapid Exchange balloon angioplasty/stenting system and intravascular ultrasound (3,4). In just 15 years of existence, more than 180 engineers, physicians, and business professionals have completed the fellowship training, and nearly a thousand students have taken undergraduate or graduate courses in Biodesign. To date, 41 companies have been launched by these first-time innovators directly from Stanford Biodesign, and many other technologies have been invented by alums of the program after graduation.

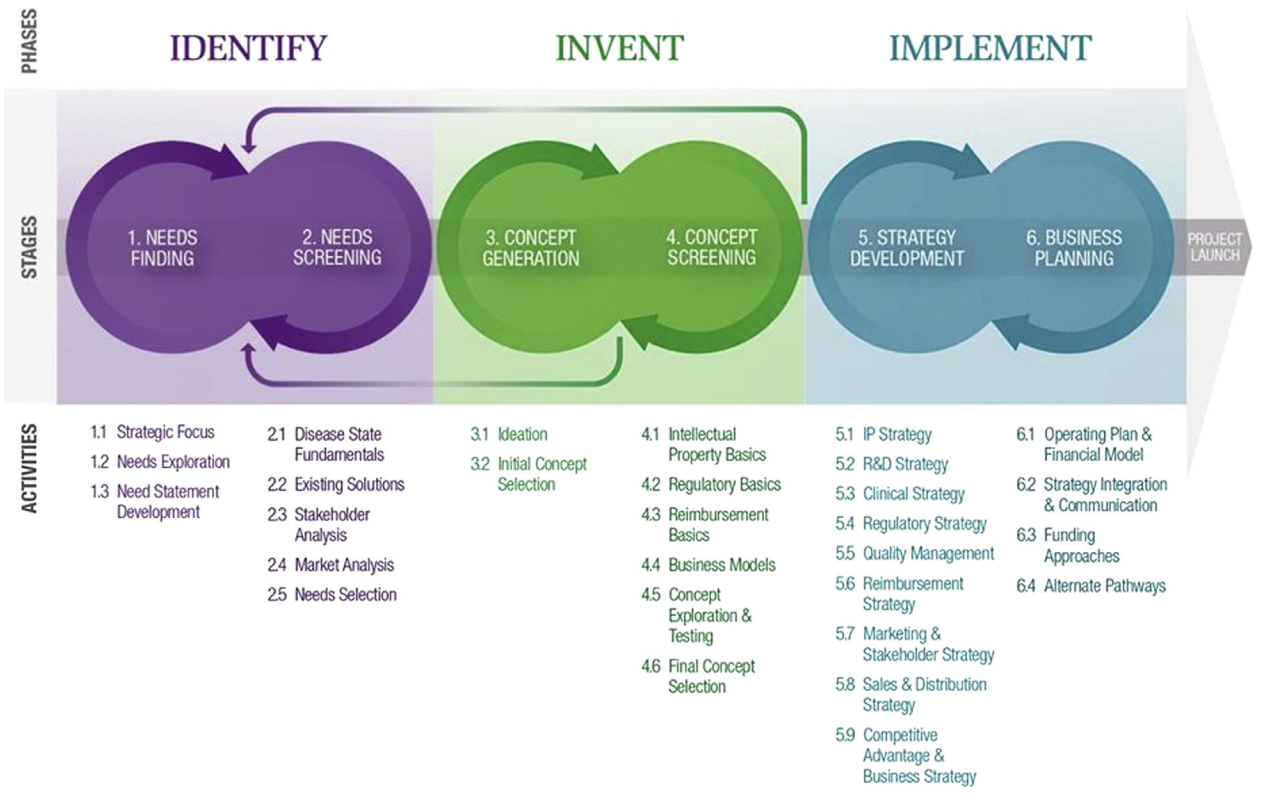
Currently, the fellowship group consists of 3 multidisciplinary teams of 4 fellows who follow the "3 I's" process each year (identify, invent, and implement) (Figure 1) as they evaluate and solve needs in a particular clinical area. Each phase is described in detail in this paper.

PHASE 1: IDENTIFY—CLINICAL IMMERSION, NEEDS FINDING

Shortly after the fellowship commences, the teams begin an intensive needs-finding process. Approximately 20% of the fellowship time is devoted to this vital stage, in which each team delves deeply into a specific clinical area by direct immersion in relevant inpatient and outpatient settings. Over the course of several weeks, the fellows document their clinical observations with the goal of creating a list of at least 200 needs.

The next step in the process is the development of a need statement. This single sentence is carefully crafted to capture the essence of the need. In effect, it is a mission statement, serving as the driving force behind the team's efforts to solve the identified need.

FIGURE 1 The 3 Phases of the Stanford Biodesign Process



The 3 phases of the Stanford Biodesign process (3 I's)—identify, invent, and implement—are outlined, with 2 specific stages performed during each phase. The process is both iterative and cyclical and often requires returning to prior stages and phases as new information becomes available through research. Key activities performed at each stage are detailed below each step in the process. Reprinted with permission from Yock et al. (4).