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Outcomes from a Postgraduate Biomedical Technology Innovation Training Program: The First 12 Years of Stanford Biodesign

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Abstract—The Stanford Biodesign Program began in 2001 with a mission of helping to train leaders in biomedical technology innovation. A key feature of the program is a full-time postgraduate fellowship where multidisciplinary teams undergo a process of sourcing clinical needs, inventing solutions and planning for implementation of a business strategy. The program places a priority on needs identification, a formal process of selecting, researching and characterizing needs before beginning the process of inventing. Fellows and students from the program have gone on to careers that emphasize technology innovation across industry and academia. Biodesign trainees have started 26 companies within the program that have raised over $200 million and led to the creation of over 500 new jobs. More importantly, although most of these technologies are still at a very early stage, several projects have received regulatory approval and so far more than 150,000 patients have been treated by technologies invented by our trainees. This paper reviews the initial outcomes of the program and discusses lessons learned and future directions in terms of training priorities.

Keywords—Medtech, Medical device, Invention, Needs-based, Fellowship, Multidisciplinary.

INTRODUCTION

The Stanford Program in Biodesign was launched in 2001 as a unit of the interdisciplinary biosciences or "Bio-X" initiative at Stanford. The program grew out of the Stanford Medical Device Network, which had been formed a few years earlier to promote education and mentoring in the area of biomedical technology innovation. The name "Biodesign" was suggested by students, with the idea that this would align with the Bio-X nomenclature and emphasize the design aspects of the program. From the beginning, a core feature of the Biodesign Program was a 10-month postgraduate fellowship where interdisciplinary teams could experience a full cycle of needs identification, invention and early-stage implementation. To our knowledge this was the first university postgraduate fellowship model of explicitly interdisciplinary, team-based medtech innovation training. The most distinctive feature of the training approach is the intensive focus on needs finding and characterization by the team. This paper outlines the structure of the program, describes the outcomes in terms of the trainees' career paths and the technologies they have created and reviews some of the lessons derived from this experience to date.

PROGRAM DESIGN AND ORGANIZATION

Each year the fellowship program begins with an international search for engineers, scientists, physicians and business graduates who want to pursue careers in medical technology innovation. Most clinical candidates have completed their MD degree and typically have some specialty and even subspecialty training. Roughly half of the clinicians have formal engineering education at the undergraduate or Master's level. A large majority of engineering and science candidates have completed either a Master's or PhD degree, most commonly in biomedical, mechanical, electrical or chemical engineering. Some candidates from both the clinical and engineering side have earned MBAs and/or have had consulting or operational experience in industry. From an applicant pool of 100–120 candidates we select approximately 25 finalists, who are brought to Stanford for an intensive two-day sequence

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of interviews. One unusual feature of the interviews is a set of invention challenges where the candidates are asked to respond to a description of a clinical problem vignette with a clear identification of the need and a brainstorming of possible solutions. Currently we select two teams of four fellows (consisting of a mix of engineers and physicians) who are assigned to the core clinical area selected for the year. We are experimenting with a new "specialty team" format which at this point consists of an engineer and clinical fellow pair who do needs finding in the fellow's clinical area. Figure 1 shows the percentage of fellows by field of study.

The fellowship schedule launches with a month-long "boot camp" which is an intensive, largely didactic phase with four basic components (see Fig. 2 for an overall timeline). First, fellows get an initial exposure to the clinical area they will be pursuing. The clinical

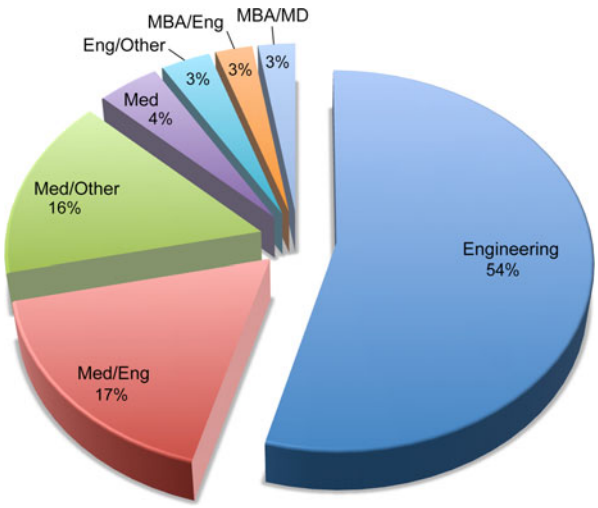

FIGURE 1. Distribution of previous fields of study for the Biodesign fellows. Fellows with BS degree had significant corporate or start-up experience before coming to the program.

Fellowship Timetable	
Aug	"boot camp" (intro to clinical area)
Sept, Oct	clinical immersion, needs finding
Nov, Dec	need specification & filtering, brainstorming
Jan, Feb	concept development & early prototyping
March	externship
April-June	project planning, early testing, fundraising

FIGURE 2. General timeline for the Biodesign Fellowship.

focus changes each year and is selected based on the willingness and capacity of the host clinical departments to provide an immersion experience and mentoring for the fellows. During boot camp, faculty members from the clinical departments lecture on their area of practice and research. This exposure provides a good opportunity for the fellows to develop a relationship with the clinicians whom they will be observing and working with during the year. The second component of boot camp is a set of introductory lectures on engineering and business fundamentals of medical technology innovation. Topics include relevant medical science, collaborative design thinking, prototyping, market analysis, intellectual property, regulatory and reimbursement issues, funding strategies and quality systems. The program draws from a group of over 150 experts in these areas who work in firms located close to the Stanford campus. The fellows also begin their use of the Biodesign textbook and eBiodesign web resource that we have developed over the years as a step-by-step guide to the medical technology innovation process.[13] The third and critically important component of the boot camp is a "mini-project"—basically an intensive and accelerated cycle through the process of characterizing a pre-selected need, inventing solutions and selecting a best approach to take forward. This exercise provides a preview for the year's activity and orients the team to the rhythm of the process and challenges ahead. The final component is team building. The fellows participate in both formal and informal sessions in which they share their goals, strengths, weaknesses and personality types. The teaching team includes a psychologist with extensive group therapy as well as executive coaching experience, who meets with the fellows during this time to introduce some of the basic issues of team dynamics. Team sessions with the psychologist continue on an average of once every other week for the remainder of the year.

Following boot camp, the teams begin a two-month clinical immersion as the first step in the need identification process. The teams split into pairs and spend time with physicians, nurses, staff, patients and families in different inpatient and outpatient settings, including operating rooms, intensive care units, hospital wards and clinics. During this phase the teams are charged to come up with at least 200 needs based on direct observation of clinical practice. Following this initial need gathering experience the teams move into a phase of need validation, where the fellows focus on developing a better understanding of their needs through further research and networking with experts. The fellows usually return to the clinic in this phase to validate their observations and test the initial reaction of their clinical advisors to the importance of the

needs. We employ a method of summarizing the need in the form of a ''need statement''– a single sentence that characterizes the clinical problem and points toward an improved outcome (for example: ''…a safe and effective method to reduce the apnea and hypopnea episodes experienced by a patient with obstructive sleep apnea/hypopnea syndrome'').

The next step of the needs identification process is needs filtering, which is a uniformly challenging phase of the fellowship. The goal is to sort through the large list of needs to identify a small handful of especially promising opportunities. The process involves accumulating enough supporting information about the needs to prioritize them and jettison the needs that have less potential for yielding useful inventions. The additional information generally comes from further exploration of the clinical context (What is the real prevalence and impact of the disease? What are the competing approaches to treatment?) and further understanding the market characteristics (Basically, would a solution to this problem generate sufficient revenue to be interesting for a company or venture investment?). The most promising needs are further characterized by generating a ''needs specification.'' This is similar to a customer specification for a non-medical product in that it identifies the important components of the opportunity that need to be satisfied by the ultimate product –but it takes into consideration the needs of all of the stakeholders (including patients, providers and payers) in the complicated medical technology ecosystem.

It is only at this point—4–5 months into the fellowship—that the fellows are given the go-ahead to begin inventing new approaches to their needs. Each team moves forward with its top 12–16 needs into a concept creation phase. The fellows brainstorm a large number of potential solutions and are asked to select at least three of these concepts per need for early-stage prototyping. Together these concepts are put through a second set of filters, which includes intellectual property, the likely regulatory and reimbursement pathways, technical feasibility and business model. The fellows use a Pugh ranking method,[8] assigning relative values to these different filters. The assignment of these values is ultimately decided by the fellow teams, with input from the internal and external mentors of the program. For example, a team will typically review their prior art and freedom to operate searches with one of the patent attorneys who serves as an advisor to the fellowship. Among the dozen-plus candidate concepts, a single best concept across all needs is selected by the fellow team to take forward into implementation. This implementation planning process consists of a detailed analysis of the intellectual property landscape, regulatory pathway, potential for reimbursement, engineering challenges, specifics of the business model and venture or corporate funding potential. Throughout the fellowship we have discussions about the ethical and policy implications of medical technology innovation, including case discussions centered around clinical trials, conflict of interest and other issues. In March the fellows have an opportunity to leave campus for an ''externship'' experience where they work in a local medical technology company or venture firm or travel to one of the global Biodesign program affiliates.

In parallel with their own process of inventing and planning for implementation, the fellows serve as mentors to a graduate student class that convenes for the second half of the fellowship period. The class of approximately 50 students is drawn equally from the schools of business, engineering and medicine. Business school faculty members are involved as lecturers in the class as well as serving as mentors in the fellowship program. The students form small interdisciplinary teams and select from the needs that the fellows have characterized but have chosen not to pursue themselves. The graduate school teams then go through an accelerated process of re-characterizing the need, inventing and planning for implementation. By the end of the academic year, both the fellow teams and graduate students have developed the equivalent of a business plan for a start up or a detailed plan for licensing of the invention. The teams also create prototypes that vary in their complexity and degree of finish, but are sufficiently sophisticated that they can be used for raising seed funding or initiating licensing discussions.

In 2008 we expanded the fellowship program to include a training program for Indian nationals (Stanford-India Biodesign) in collaboration with the All-India Institute of Medical Sciences and the Indian Institute of Technology in Delhi and with sponsorship by the Department of Biotechnology. The overall training methodology in the SIB program is very similar to the US fellowship, with an interdisciplinary team of four fellows being selected from a national search in India. The SIB fellows spend their first six months at Stanford in an intensive introduction to the Biodesign process which consists of participation in the graduate student class and an accelerated needs finding, characterization and invention process in a clinical area different from the US fellows. The SIB fellows then return to India for a year of needs finding, invention and planning for implementation. In 2011 we initiated a second global program in Singapore (Singapore-Stanford Biodesign) with a model and schedule similar to the India fellowship. This fellowship is structured as a collaboration between Stanford and the Agency for Science and Technology and Research (A*STAR) and the Economic Development Board of

Singapore, partnering with the National University of Singapore and the Nanyang Technical University. The global fellows are paid stipends and travel support from their respective governments at a level that is consistent with the standard of living for the US and home country phases.

OUTCOMES

The most important criterion for assessing the training program is the career trajectory of our fellows and students. To date we have graduated 106 fellows who have followed the career pathways shown in Fig. 3. Close to one-third of the fellow alumni are in leadership roles in companies that they founded directly from the program. Another one-sixth of the fellows are in start-up companies not directly founded within the program (though some were founded by the fellows themselves subsequent to their Stanford experience). A significant percentage of the fellows have gone on to academic positions or to further post-graduate training leading to academic or clinical/academic positions. Several alumni have established and/or are helping to lead medical technology innovation programs at other universities. A number of the alumni fellows have taken positions in large medtech companies, a pathway that we encourage as an important grooming phase in the career of a medical technology innovator. In addition to the fellowship, over 500 graduate students from business, engineering and medicine have completed the two-term Biodesign Innovation class. The fellows and students have formed an active alumni community, with frequent meetings and other networking opportunities.

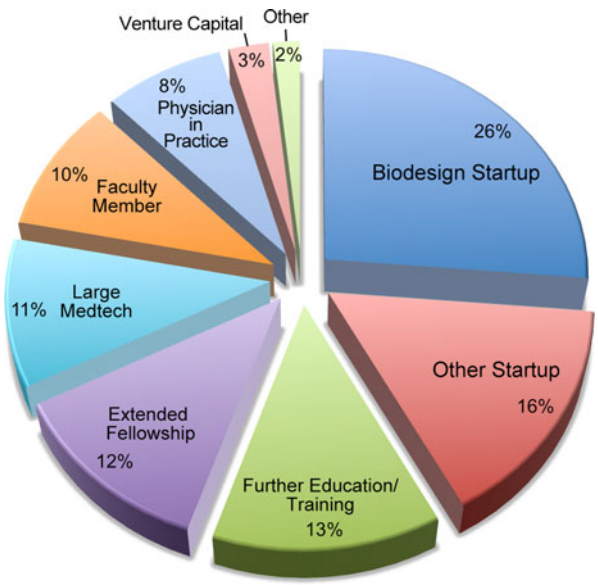

FIGURE 3. Distribution of careers following the Biodesign fellowship, categorized by primary description. A number of alumni in non-corporate categories (e.g., faculty members and physicians) are involved as part-time consultants to start-up companies.

A second metric of the program is the output of inventions that are on a pathway to patient care. With respect to patents filed, we ask fellows to write their own provisional patents as a part of their training process. In a survey conducted for this paper 69 fellowship alumni respondents reported that their teams filed a total of 141 provisional patents while in the program. Beyond the provisional submissions, this group filed 38 utility or methods patents during the program, with an unknown number filed subsequent to the program in association with the companies formed (information that is in at least some cases confidential). All patents developed from work during the fellowship are the property of Stanford University and are managed by the Stanford Office of Technology Licensing.

A number of technologies invented during the program are moving forward into patient care. To date the fellows and students have founded a total of 26 companies based on projects directly from the Biodesign program (see Electronic appendix). Some of these technologies have already received regulatory clearance in Europe and/or the US Figure 4 shows examples of four devices that are in clinical use. So far over 150,000 patients have been treated by inventions from these first-time innovators. Funding has been provided by a wide range of government, foundation, angel, venture and corporate sources, with the large majority coming from series A and B venture rounds. All together, over $200 million in funding has been raised by these companies; over 95% of this funding is from venture or private equity firms, the rest from government and other sources. The new businesses originating from the program have resulted in over 500 new jobs at the present time. It is clear that only a small proportion of the new companies will survive to a business "exit" (particularly given the current, relatively harsh climate for young medical technology companies). Our firm belief is that for these first-time medtech innovators, the role of founding and leading a company is an invaluable "real-world" experience that provides an important launching platform for a career, whether or not the first enterprise is a commercial success.

The costs of the educational component of the program described here are difficult to parse out precisely, since Biodesign has other, overlapping functions including research and administration of seed grants. We calculate that the cost of a year of fellowship is approximately $100,000 per fellow, which includes the fellow's stipend (currently $44,000 plus benefits for the year), staff time, supplies, and some faculty time. This underestimates the true program expense in that the

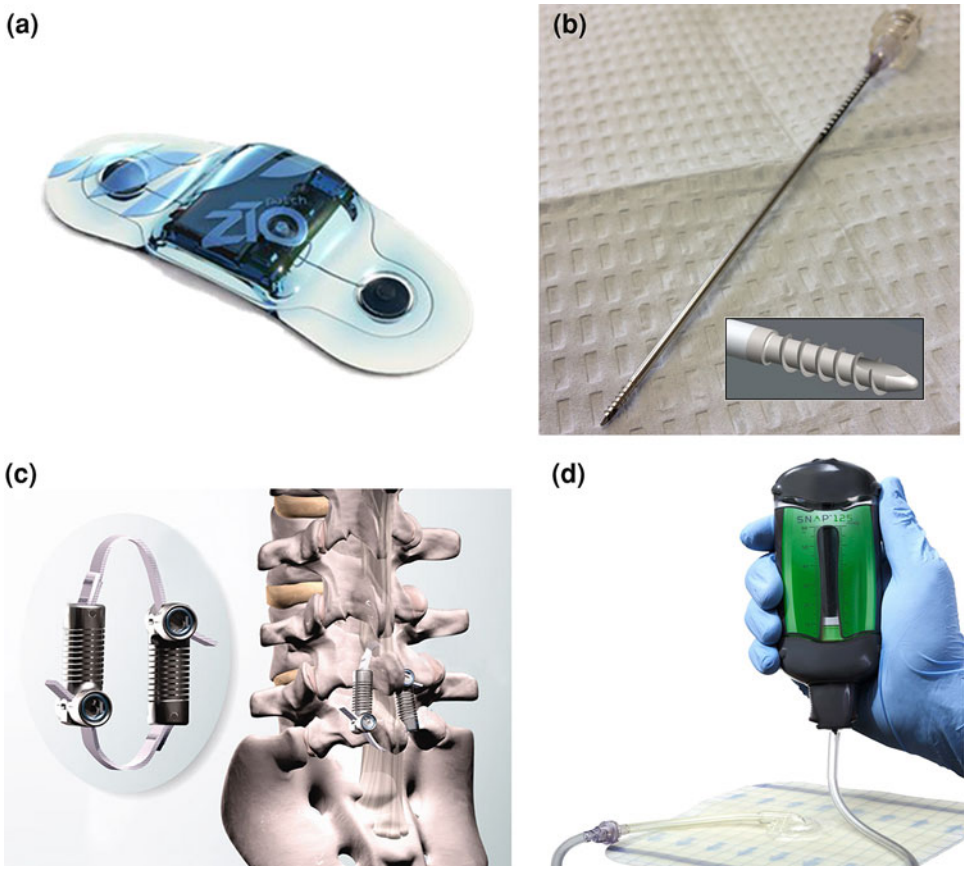

FIGURE 4. Technologies in clinical use that have been invented by Biodesign trainees. (a) Zio® patch for cardiac rhythm monitoring (iRhythm Technologies, Inc.)[10]; (b) Epiphany Epidural Access System for controlled access to the spinal epidural space (InSite Medical Technologies, Inc); (c) LimiFlex™ spine stabilization system (Simpirica Spine, Inc.)[5]; (d) SNaP® device for portable negative-pressure wound healing (Spiracur, Inc.).[1,4]

majority of the 15 core faculty members in the program volunteer their time without specific reimbursement from Biodesign. Fellow teams are provided an initial prototyping allowance of $500 per year and a travel budget of $1000 for the team. All current funding for the program is raised from sources external to the University—approximately an even split between three sources: philanthropic gifts from individuals, gifts and grants from companies and venture capital firms and foundation/international government support. The program is headquartered in a 4000 square-foot space within the Bio-X building, which features flexible desk and bench spaces, a brainstorming room, a prototyping shop and a wet laboratory for tissue testing.

LESSONS LEARNED

In our first 12 years as a program we have had the opportunity to mentor hundreds of projects involving fellow and student teams. A few key principles and tactics stand out as being particularly important and useful.[14]

Without question, the most critical component of the program is dedicated mentorship. Faculty mentors are drawn from the schools of medicine, engineering and business and have direct experience in inventing technologies and/or founding companies in the medical technology space. It is worth noting that in addition to following the Stanford University Faculty Policy on Conflicts of Interest and Commitment, our program policy is that faculty members do not participate financially (by means of investment, equity grants or payments) in any student or fellow projects while the students are at Stanford and for 1 year subsequently. In addition to the faculty mentors, the fellows interact with over 150 outside experts during their year, most of whom are local. Forms of interaction include visiting lectures/seminars, coaching sessions and community events all of which are on a volunteer basis (not reimbursed). Among these experts are venture capitalists and "angel" investors. Although the sources of investments in the Biodesign alumni companies are in many cases confidential, our sense is that a majority of investments are initiated *via* contacts made through this network of outside experts.

Despite the availability of this group of experts, we have found that the fellowship runs most effectively with one clear leader (the "Fellowship Director" in our program) who is responsible for setting milestones and holding fellows accountable for deliverables. The role of this lead mentor has several distinctive features compared to that of the leader of a research laboratory or clinical research team. First and most obvious, the mentor has to be comfortable directing a truly multidisciplinary team. It is helpful for the leader to have a background in both engineering and medicine (and, optimally, to have direct experience in commercializing technology). Second, the leader needs to be able to point the team in a productive direction without engaging too actively in the work product of the group—that is, to be more of a process guide than a content expert. This is most clear in the area of intellectual property, where the experienced mentor will hold back from inventing personally but will steer the team in a way that the members can invent successfully. Finally, it is worth emphasizing that mentoring in this type of program is very time intensive. The lead mentor should be prepared to meet with the fellows/students at least on a weekly basis and more during periods of high demand or team conflict. She/he needs to create specific schedules for each phase of the process and hold the fellows and students strictly accountable for deliverables and deadlines.

A second principle that has become clear to us over time is in the area of team composition. We have realized that in forming medtech innovation teams it is important to look for more than just a mix of different engineering and medical backgrounds. In selecting our teams we now look for a combination of "innovation personalities" which can be independent of the type of formal training the fellows or students have received. We think in terms of four main profiles: (1) the builder, who is facile with design and prototyping; (2) the organizer, who has the skill to keep the team on track; (3) the researcher, who will dig into the clinical, engineering and business literature; (4) the clinician, who understands the complex issues around bringing a technology into clinical practice. A team member may have more than one of these phenotypes, but all four need to be represented in the team for it to be highly functional. The faculty who select the fellows screen for these profiles in both the applications and the in-person interviews, and we correlate our impressions in the selection committee discussions at the end of the interviews.

We believe that a third important principle in this kind of training program is the need to manage uncertainty and risk. Uncertainty is of course a characteristic of the entire innovation process[2,3,7] but it manifests early at the stage of need identification and filtering—where there is seldom complete information available to make the decision about which needs to pursue and which to drop. This uncertainty can be particularly frustrating for high-functioning trainees who are accustomed to finding the "right" answer. It is at this stage in our process where we typically see a flare-up of team dynamic issues, a phase described as "storming" in Tuckman's stages of development[11] The mentor has a particularly important role in coaching the team through this tricky patch, setting clear deadlines and deliverables and helping the team to work through its conflicts. The issue of risk becomes most prominent in the concept filtering and planning for implementation stages. Here two tactics of managing the process have proven useful. First, the fact that there are multiple concepts competing to become the final project provides a natural mechanism for "killing quickly" those concepts that have higher risk. It is relatively easy for the team to abandon an invention when there is a more promising alternative to pursue. Second, we emphasize that the ability to identify risk early is an essential skill for the successful innovator. We ask the team to find the most important risk that can be evaluated with the least outlay of resources—and celebrate when they make a decision to abandon a concept based on this risk assessment.

The issues of managing interpersonal dynamics and communication within a multidisciplinary design team deserve special mention. Innovators are often challenged during the process of working in these highly motivated and flattened hierarchy teams, where leadership is shared. We consider the process of learning to navigate potential conflict in the course of the Biodesign project to be one of the most valuable training experiences for our fellowship and student programs. We actively pursue team-building activities from both a personal and professional perspective. We encourage the teams to interact socially but also have them present scientific work to each other so that they develop an appreciation for the depth of expertise each team member brings to the program. We also have the fellows work with the Biodesign team psychologist regularly in a group setting so they have the opportunity to revisit conflicts and explore approaches to managing their issues.

MOVING FORWARD

It is not an exaggeration to say that in the past several years we have come to an historic turning point for medical technology innovation.[12] Several factors have converged to create a "perfect storm" in the United States from the perspective of medtech innovators: the economic crisis has decreased the risk

capital available for investment in technology development, particularly in the life sciences; the push toward health care reform has put a spotlight on the high costs associated with the uptake of new health technologies; and the rate of device approvals by the FDA has slowed under pressure from Congress and the press to avoid risk. In short, the next generation of medical technology innovators will be confronting a challenging and uncertain set of conditions.

In the setting of these powerful new environmental factors, we see an opportunity to re-engineer our training process in two broad respects. First, it is essential that the next generation of innovators focuses on technologies and processes where there can be a clear and convincing case made for cost effectiveness. There will still be tremendous opportunities for inventions that enhance quality and length of life—but these will need to be delivered at a cost that is justifiable compared to other health technologies and services. One of the key challenges for innovators is to be able to forecast the cost implications of a new technology early in the innovation process, before there are substantial data from clinical trials for a formal cost-effectiveness study. At a minimum the inventors of new technologies need to be familiar with the principles and methods of cost effectiveness analysis so that they are able to use "value" as an early filter for selecting the clinical needs to pursue.

The second broad direction for change in training is to incorporate the expansion of global opportunities for medical technology innovation. The markets for medical technology in the advanced developing countries are growing at a rate that is many times the growth in the US and Europe. The emerging middle classes in these countries are demanding high quality medical equipment at a reasonable price point. Local companies are emerging to satisfy this demand and the large multinational corporations are developing major in-country research and development branches. A great deal of attention is being focused on the concept of reverse or *Jugaad* innovation, where cost-effective technologies developed for emerging market needs are brought to the US.[6,9] Together these factors provide a tremendous opportunity for young innovators who are willing to learn about the needs and markets in these countries and potentially spend time in their career development experiencing these conditions first-hand. The opportunity that this presents for university training programs is also clear. Many universities have extensive global connections already, with a pool of international students and years of experience in cross-cultural education. The convergence of engineering, medicine and global health under the university umbrella provides a wonderful set of natural resources for developing effective programs in biomedical technology development. It seems clear that the perfect storm may offer the perfect opportunity to fundamentally change our training paradigm—incorporating both a heightened awareness of cost effectiveness and a new understanding of global market opportunities in helping to launch the next generation of medical technology innovators.

ELECTRONIC SUPPLEMENTARY MATERIAL

The online version of this article (doi:10.1007/s10439-013-0761-2) contains supplementary material, which is available to authorized users.

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