

# CREATING A BENCHMARK MEDICAL TECHNOLOGY ENTREPRENEURSHIP COMPETITION

## The University of Utah Bench-to-Bedside Medical Device Design Competition

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### ABSTRACT

In this paper, we present our experience in creating a benchmark medical technology innovation and entrepreneurship competition, entitled Bench-to-Bedside, through cross-campus interdisciplinary and industry-academic collaborations. Our faculty-guided, student-run program is industry-sponsored and has engaged over 207 health sciences, engineering, business, and law students in the first three years of the program. During this period, we have provided over \$300K in development funds and milestone-based awards, generated 39 provisional patents, and seen the creation of 48 novel technologies and 12 new business ventures. This program has energized the University of Utah's innovation culture and cemented long-term industry partnerships.

### Introduction

The University of Utah Bench-to-Bedside Medical Device Design Competition is a vibrant program designed to introduce medical, engineering, and business students to the world of medical device innovation. Student teams form into multidisciplinary "start-up" companies and are given the task of identifying an unmet clinical need. Teams are given access to over 100 university physicians, as well as an industrial board composed of local community business leaders, who serve as their consultants, key opinion leaders, and stakeholders. The teams have six months and a \$500 development fund to evaluate the IP landscape, prototype their design, and construct a pre-business plan. The program culminates in a formal presentation of all team projects at an annual awards competition. The team projects are evaluated and scored for business strategy, design quality, and healthcare impact. The top teams are awarded \$70,000 in prizes intended to provide initial funding to support further project development.

### Competition Infrastructure

The Bench-to-Bedside medical technology and entrepreneurship program began in the summer of 2010 as the vision of a University of Utah medical student interest group: The Translational Research and Venture Development Interest Group (TRAVDIG). TRAVDIG recognized the lack of formal medical school training in the fields of innovation and entrepreneurship, as well as the need produce clinician-innovators in addition to clinician-researchers. The group believed that exposure to these areas was critical in preparing students to advance the future of healthcare. Through their passion for medical device innovation, TRAVDIG developed the concept for Bench-to-Bedside. They brought together a dynamic team of experienced faculty innovators and student representatives from across the disciplines of engineering, business, law, and



medicine to develop a basic blueprint for the competition. The concept rapidly gained momentum and support from both university and community leaders. Local organizations, including a prominent local bank and the Utah Science Technology and Research Initiative (USTAR), saw the importance of a multidisciplinary medical device competition and provided financial support. The competition has evolved to include the following infrastructure:

### **Student Development**

As a student-run medical device design competition, Bench-to-Bedside is overseen by two University of Utah medical students who serve as the Student President and Student Vice President. The student presidency oversees all aspects of the competition, as well as a student committee composed of two Engineering Chairs, one Graduate Engineering Chair, four Health Sciences Chairs, two Business Chairs, and a Committee Coordinator. Each chair is a student from the represented college – Engineering Chairs are students from the College of Engineering; the Business Chairs are students from the David Eccles School of Business; the Health Sciences Chairs are medical students from the School of Medicine. The role of each chair is to aid in student recruitment from their respective colleges, as well as to plan workshops related to their field of study.

### **Health Development**

Although Bench-to-Bedside is functionally student-run, the competition resides within the University of Utah Center for Medical Innovation and is overseen by the Director of the Center for Medical Innovation. The Director's role is to act as a liaison between university faculty and students, recruit investors and secure funding, develop commercial sector mentorships on behalf of student teams, educate students, and serve as a representative to business, physician, and community leaders.

### **Business Development**

All business support for the competition arises from the Lassonde Entrepreneur Institute at the University of Utah. The Executive Director of the institute oversees the pre-business plan components of the competition, business judging on competition night, and further development of business plans through other university resources and competitions.

### **Legal Development**

Each year, the Center for Medical Innovation appoints two S. J. Quinney College of Law students to serve as law fellows and provide legal support to teams. An Associate Professor of Law who specializes in contracts, patent law, and intellectual property oversees the law fellows and provides faculty support. The law fellows help teams explore the intellectual property landscape and develop claims worthy of submission to the United States Patent and Trademark Office (USPTO).

### **Engineering Development**

Since the inception of the competition, three associate professors from the University of Utah College of Engineering have served as engineering advisors. The role of the engineering advisors is to meet with teams and assess the feasibility of prototyping their solution and to ensure that each project has the appropriate level of engineering. The advisors oversee engineering judging requirements and serve as judges during the competition night.

### **Resource Development**

Members of all three libraries at the University of Utah (Spencer S. Eccles Health Sciences Library, S. J. Quinney Law Library, and the J. Willard Marriott Library) have joined forces to help students find the information and resources needed to get their projects off the ground. This library innovation team consists of sixteen people with specialties in: literature searching, scholarly communication, research strategies, engineering standards, statistics, technology commercialization, web/mobile

development, business and marketing research, patent searching, and intellectual property. The librarians' role is to familiarize students with library spaces and resources, as well as the creation of a central place on CANVAS, the University of Utah's online classroom software, where teams keep, share, and discuss their work remotely.

### Industrial Development

The Center for Medical Innovation has established an industrial board composed of community business leaders who have been involved in product development and innovation throughout their careers. These leaders comprise a vast array of specialties, ranging from catheters to software to biotechnology. Each participating team is assigned one mentor from the industrial board who serves as an advisor and director.

### Competition Timeline Team Formation

Formation of teams participating in Bench-to-Bedside is not assigned by leadership, but rather teams are self-selected via student interests and project needs. Starting in August of each year, student leadership begins recruiting students from each respective school: engineering, health sciences, and business. Students are invited to attend a "kick-off" event, which provides a social environment for team formation. Students mingle at the event, share interests and ideas, and submit a team formation document by the end of the evening. One of the keys to the competition's success is diversity, which can be seen in the increasing cross-college collaboration effort involving many academic and professional disciplines (Fig 1).

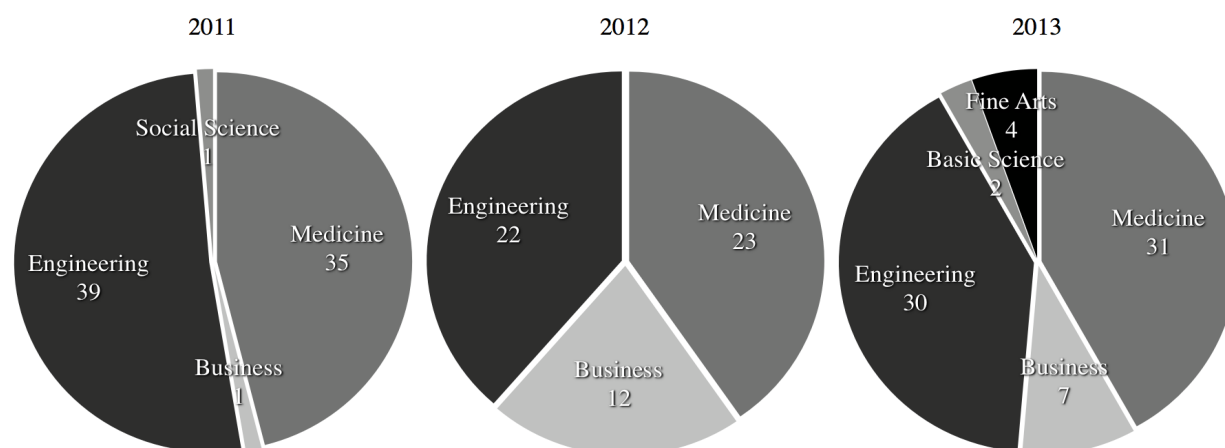


Figure 1. Team participant breakdown by representative college for competition years 2011-2013. The total number of participants was 76 for 2011, 57 for 2012, and 74 for 2013.

Taking the ideas of teams and turning them into working prototypes that serve to further medical knowledge requires great skill and the proper tools to see the project through to completion. To aid students in this process, Bench-to-Bedside has developed crucial workshops from idea generation and market feasibility to prototyping and patent filing. These workshops are paramount to the success of teams in the competition and beyond in the medical device field. Bench-to-Bedside has identified core workshops to address each area within medical device design. These workshops are linked closely to the two phases of the competition: Concept Generation and Prototype/Product Development (Fig 2).



BENCH-TO-BEDSIDE TIMELINE							
CONCEPT GENERATION PHASE				PROTOTYPING/PRODUCT DEVELOPMENT PHASE			
September	October	November	December	January	February	March	April
Team Formation	Idea/Clinical Need Identification	Pre-Business Plan	Pairing with Industrial Board	FDA Regulations	Patent Development	Venture Capitalism	Competition
		Prior Art Search	Idea Submission	Engineering and Design Prototyping	Term Sheet Negotiations	How to Product Pitch	

Figure 2. The Bench-to-Bedside Competition begins every September and runs until April, with the Concept Generation Phase running from September-December and the Prototyping/Product Development Phase running from January-April. Approximately two workshops are held per month, as outlined above.

### Concept Generation Phase Idea Generation Workshop

During this workshop, teams are invited to listen and interact with faculty of the Center for Medical Innovation. They are instructed on the importance of seeking out clinical problems through exploration in the clinical setting. University of Utah Healthcare has been an integral partner with Bench-to-Bedside by opening their clinics, operating rooms, administrative offices, and computer systems to help students identify clinical problems in areas that interest them.

### Meet the Mentor Workshop

During this workshop, teams meet with community CEOs that make up the Center for Medical Innovation's industrial board to discuss their product ideas and secure a business mentor for the competition. Teams are rotated through several rounds of mentor meetings in a style similar to "speed dating." During this time, teams and mentors share their ideas, resources, and interests with the goal of pairing teams to mentors in a mutually beneficial partnership.

### Pre-Business Plan Workshop

Following the generation of a great idea, it is important to discover whether there is space for the end product in the market. Teams participate in a pre-business plan workshop in which guest speakers from the Lassonde Entrepreneur Center and the David Eccles School of Business teach teams how to explore market research focusing on four integral areas: identifying a pain point; defining the product or service; evaluation of the market including size, growth, drivers, competitors, segmentation, and customers; and finally, development of a value proposition.

### Prior Art Workshop

Faculty and fellows from the S. J. Quinney School of Law, as well as librarians specializing in patent research, several of whom have experience working at the USPTO, help students navigate the world of patents. Their goal is to provide resources for students by helping identify prior art, existing patents, and space for patentability of their product.

## Prototyping/Product Development Phase

### Quality System Regulation Workshop

Students learn about the Code of Federal Regulations Title 21 regarding medical devices and approval through the Food and Drug Administration (FDA). Faculty from the College of Engineering present this workshop.

### Engineering Design/Prototyping Workshop

After learning of the specific FDA requirements for the development of their product, teams begin designing and prototyping. Teams are given instruction on the engineering feasibility of their projects, 3D design, software application development, and the prototyping resources available through the university.

### Patent Workshop

Securing protection in the marketplace is key to any new product, and medical devices are no exception. Teams work with the S. J. Quinney College of Law faculty and fellows to learn about the varying types of patents, develop claims, and submit their filings with the USPTO.

### Term Sheet Negotiation Workshop

Business and entrepreneurship faculty work with teams on an individual basis to develop terms of agreement between varying members regarding their intellectual property holdings. Teams also learn about common pitfalls that new companies and developers face in meeting with venture capitalists and business leaders to secure ongoing funding and/or license their product. They also gain a sense of the negotiation process that takes place within the business and venture capital spheres.

### Venture Capital Workshop

Venture capitalists are invited to instruct teams on topics including seed funding, vetting of specific products, general and limited partners, and the common returns

expected when securing funding. Teams are given an introduction to the process and are later invited to meet with business and entrepreneurship faculty for further instruction before heading into future negotiations.

### How to Pitch Your Product Workshop

Teams learn about making an elevator pitch of their product in preparation for the final competition. They are instructed on key points to emphasize based on their target audience. A communications specialist from the College of Business and other faculty with experience in product pitching present the workshop.

### Competition Night

Months of work culminate with the opportunity for participants to share their prototypes with faculty, mentors, business leaders, venture capitalists, and influential community members in the hopes of taking home the competition's grand prize of \$15,000. Teams present abstracts, posters, multimedia, and most importantly their prototypes to selected judges from medicine, business, engineering, and industry consumers. Teams are judged on whether (1) they achieve their stated end product, (2) they design and develop unique prototypes, (3) they successfully demonstrate the technology and how it works, and (4) whether the technology is viable in the healthcare sphere.

### Prizes

**Grand Prize (\$15,000):** Awarded to the team that represents the very best of the Bench-to-Bedside competition. They will have excelled in all areas of the competition and represent the best integration of business, engineering, and medicine.

**(2) Runner-up Award (\$10,000):** Presented to the two teams that deserve top recognition for their efforts in all areas of the competition and who had outstanding projects overall.

**Best Entertainment Arts & Engineering Award (\$5,000):** Given to the team with the most outstanding achievements in the field of



entertainment arts and engineering. This team has shown the greatest achievements in software design, proof of concept, and deliverables.

**Best in Engineering Award (\$5,000):** Given to the team with the most outstanding achievements in the field of engineering. This team has demonstrated novel and/or sophisticated engineering design above all others.

**Best in Business Award (\$5,000):** Given to the team with the most outstanding achievements in the field of business. This team has presented the best pre-business plan and marketing strategy for taking their project to a higher level.

**Best in Medicine Award (\$5,000):** Given to the team with the most outstanding achievements in the field of medicine. This team's concept has the greatest impact on healthcare.

**Best Global Health Award (\$5,000):** Presented to the team whose device best addresses the health care needs of the developing world. This team will embody the true spirit of humanitarianism and entrepreneurship.

**Best "Green" Award (\$5,000):** Presented to the team that shows the largest positive impact in "green" technology and/or resource management.

**Consumer's Choice Award (\$5,000):** Judged by potential consumers and users of the medical devices. The prize is given to the team who best designed their product with the user in mind.

## Funding

When Bench-to-Bedside began in 2010, the competition's goal was to obtain \$1,000 in prizes generated from collaboration between the different schools: engineering, business, and health sciences. Committed to the next generation of innovators and entrepreneurs, Zions Bank and USTAR became financial sponsors. In the first three years, their support has accounted for over \$300K in development funds and milestone-based awards. Ongoing efforts via the Center for Medical Innovation include securing funding from the National Institutes of Health, as well as other private donors.

## Results and Progress

In the first three years, 207 students participated in the competition, accounting for 45 different teams and 48 medical devices (Figure 3). In total 39 provisional cover letter patents have been filed, four utility patents have been filed, and 12 Limited Liability Companies have been formed. Now, in the middle of the fourth year, the competition has registered 70 teams comprising 300 students.

COMPETITION RESULTS			
	2011	2012	2013
Participants	76	57	74
Teams	13	14	18
Devices Developed	14	14	20
Provisional Patents Filed	12	13	14
Utility Patents Filed	1	3	-
LLCs Formed	1	5	6

Figure 3. Bench-to-Bedside competition results from 2011-2013. LLC = Limited Liability Company.

## Success Stories

(shared from the Bench-to-Bedside Competition Report 2013)

### LIYEN

The LIYEN Inhaler, or Last Inhaler You'll Ever Need, first competed in Bench-to-Bedside in 2011, but the team didn't win or place in the competition. The following year, the team once again entered the competition, and this time they were awarded the 2012 grand prize. Since the competition, the team has filed four provisional patents between October 2012 and March 2013. With their Bench-to-Bedside winnings, they were able to build more realistic prototypes and secure legal and regulatory consulting to help them refine their go-to-market strategy. Since Bench-to-Bedside, the team has participated in other competitions, including Westminster University's Opportunity Quest Business Plan competition, where the team took first place. The duo has also been a part of the University of Utah's Entrepreneurship Club, where they have raised additional funding to develop their device. As for investors, the team's mentors have put them in touch with the Park City Angels and the Salt Lake Life Science Angels. They are also planning on working with Kickstart Seed Fund. Individual investors, including physicians and biotech veterans, have expressed interest as well. The team is currently finishing testing required for FDA clearance by the end of 2013, which would allow them to market their item in late 2014. "The Bench-to-Bedside competition has led to a complete shift in my career plans," says one of the participating team members. "Before developing this device I was planning on working for a large medical device company after graduation, but since starting this project I have decided to pursue the entrepreneurial path."

### LIGHT LINE

The LIGHT LINE, an innovative catheter designed to reduce hospital-acquired infections, has made great strides since the team competed in the 2012 Bench-to-Bedside competition. The idea behind the LIGHT LINE began after a discussion of one of the largest problems in healthcare: hospital-acquired catheter infections. The team initiated discussions with clinicians and patients who used these catheters to better understand their experiences and general methods of infection. After months of research, the team and their colleagues came up with the idea of using high intensity visible light therapy. Previous studies using similar treatment proved to be 99% effective at killing bacteria, but the treatment had never been used in a catheter residing inside a patient. In April 2012, the LIGHT LINE team's concept won Bench-to-Bedside's Best Engineering Award, Best Visual Aids/Poster Award and Startup Center for Students Award, earning a total of \$9,000 in the competition. In the summer of 2012, the team began working with Veritas Medical, LLC, as the parent company for LIGHT LINE. A few months later, the team was selected as a top 10 finalist in Utah's statewide techTITANS competition for young inventors. It wasn't long before they teamed up with a patent attorney. In March of 2013, the team submitted a utility patent that, if approved, will enable the LIGHT LINE to be a patented medical device in the fall of 2014. The team credits the University of Utah for their successful start: "Through the gracious help of many departments and laboratories at the U of U, we have been able to narrow down to a few versions of our next generation prototype." As inventors, the team says they hope the LIGHT LINE is just one of many devices they will patent. The team is already moving forward with new ideas even as they work on manufacturing the next generation prototype of LIGHT LINE. Their goal is to have the LIGHT LINE as a key medical instrument in hospitals across the United States by 2016.



## AdvanceCath

Since Bench-to-Bedside, the AdvanceCath team has seen their device honored by multiple agencies across the United States. The technology is a urinary catheter intended for patients requiring indwelling catheterization for longer than one day due to urinary incontinence, urinary retention, or other bladder dysfunction. After the 2012 competition, the team went on to win Utah's statewide techTITANS competition for young inventors, placed third at Opportunity Quest, ranked in the top 10 at the Utah Entrepreneur Challenge, and finished in the top 20 at Grow America. Through these competitions, the team was awarded an additional \$9,000. In addition, the team was awarded \$40,000 from the state of Utah. The team has filed an international patent application and has used its prize money to help pay for prototyping and consulting. The team is eager to enhance their design and make it widely available. According to team members, there are currently several entrepreneurial investors who have shown interest in the product. AdvanceCath's most recent feedback included, "All these experiences opened up several career and networking opportunities for me that would have not been possible had we not developed this device during Bench-to-Bedside."

## Conclusions

Beginning in 2010 with the goal of recruiting enough student interest to form five teams, Bench-to-Bedside has grown to encompass multiple colleges and hundreds of students in the development of new and innovative medical devices. With the increasing demand for new medical innovation within an ever changing and expanding healthcare field, our academic medical center has evolved to train clinician-innovators alongside clinician-researchers. Other universities, communities, and governmental organizations have noted the need for this type of student innovation training. We have demonstrated that not

only is there a need but also great student interest in pursuing this shared goal. We therefore conclude that academic institutions will greatly benefit from pursuing the development and implementation of similar medical device design programs to train future healthcare innovators.

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