FOSTERING STUDENT SUCCESS DURING AND AFTER A MEDICAL TECHNOLOGY ENTREPRENEURSHIP COMPETITION:

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

Gregory Gardner, Ashley Langell, Patrick Loftus, Craig Elder,

Troy D'Ambrosio, John Langell

CENTER FOR MEDICAL INNOVATION. UNIVERSITY OF UTAH

Abstract

Student entrepreneurship competitions have become a popular and significant means of providing experiential medical technology commercialization education. One of the greatest challenges facing these programs is providing aspiring entrepreneurs the tools, guidance, and resources to facilitate successful new venture development once these competitions end. To help address this issue, we have provided our "Bench-to-Bedside" entrepreneurial teams with experienced mentors from the regional commercial medical technology sector to advise them during and beyond the competition period. We have also created a new post-competition venture fund to provide milestone-based funding to ensure that teams are able to refine their prototypes according to realistic, incremental goals. To date, our performance metrics have shown that the Bench-to-Bedside competition has had a great impact, resulting in 55 provisional patent filings, \$310,000 in funding to teams, and subsequent technology validation at numerous other national and international entrepreneurial competitions.

Introduction

Now in its fifth year, the Bench-to-Bedside Medical technology design competition at the University of Utah is an exciting and vibrant program designed to introduce students from a variety of disciplines and backgrounds, including undergraduate and graduate students in engineering, medicine, law, design and business students, to the fascinating world of medical device innovation and entrepreneurship. The Bench-to-Bedside program has been carefully designed to help students overcome the common pitfalls and stumbling blocks frequently encountered by first-time innovators by providing them with the appropriate resources and tools to enable them to develop a functioning prototype and supporting documentation, and in some cases take their device to market. At the outset, students form into multidisciplinary "start-up" companies and are tasked with identifying and solving an unmet clinical need over the course of six months, with the assistance of a \$500 development budget. Over the course of the competition, teams are responsible for evaluating the intellectual property (IP) landscape, developing a proof of concept prototype, and developing a viable business plan for their technology. Over 100 university physicians and 50 regional entrepreneurs from the biotechnology sector have made themselves available to serve as consultants, working one-onone with each team for the duration of the competition and beyond. The program culminates with teams unveiling their medical technology and prototypes in a formal presentation at an annual competition in the spring, where teams qualify for \$70,000 in milestone funding to









support further development and refinement of projects. The continued success of the Bench-to-Bedside program lies in its ability to provide young medical technology entrepreneurs with the appropriate tools, mentors, and resources to succeed in today's challenging and dynamic medical technology industry. In this paper, we outline the tools and resources that we have found to be particularly helpful to students as they complete the Bench-to-Bedside program and look to further refine their innovations in the post-competition period.

Competition Overview Organization

The Bench-to-Bedside competition began in 2010 as the vision of a University of Utah medical student and was subsequently spun out of a medical student interest group dedicated to introducing medical students to translational research and entrepreneurship. These students recognized that there was a lack of formal curricular training for medical students in the fields of medical technology design and entrepreneurship. The inaugural Bench-to-Bedside program rapidly expanded to include students from the engineering and business schools on campus. Many faculty and students across the Schools of Medicine, Engineering, and Business supported or participated in the early stages of the program. Support for this vision and competition quickly extended beyond the campus boundaries. A prominent regional bank and the Utah Science Technology and Research (USTAR) initiative, a state-funded effort dedicated to increasing innovation in Utah, recognized the importance of this vision and provided financial support. In its current form, the competition has continued to grow to include students from many departments across the university campus and a large backing from faculty and regional companies from the biotechnology, innovation, and entrepreneurship communities.

The competition is currently a program within

the University's Center For Medical Innovation and is run by two second-year medical students who serve as co-presidents. The co-presidents dedicate a minimum of several hours each week to overseeing the various aspects of the competition, from educational workshops and recruiting student participants to staging the final competition night and arranging for subject matter experts to judge the completed projects. They are assisted by a committee of students composed of four first- and second-year medical students, four engineering students (two junior or senior undergraduate and two graduate), two senior business students, and one committee coordinator. Each student has prior experience with Bench-to-Bedside and knowledge of the objectives and structure of the competition. The role of each committee member is to oversee student recruitment in their respective college and planning and conducting workshops in their fields of study.

Timeline

The Bench-to-Bedside program begins in September and spans a six-month period, during which interdisciplinary teams attend educational workshops to provide them the baseline skills necessary to successfully navigate the complexities of medical technology commercialization, perform a market analysis, evaluate the IP landscape, and create FDA-compliant design history files and proof of concept prototypes of their technologies (Table 1). The program begins with the participant sign-up and team formation phase, continues with a series of preparatory workshops, and concludes in the spring with a final night at which all teams showcase their projects. The Bench-to-Bedside program officially begins in the fall of each school year with a series of kick-off events. We hold a large, main kick-off event to which any curious students and prospective participants are invited. We provide a short overview of the program and invite several faculty and past-participant speakers. The

attendees are then encouraged to intermingle and discuss potential project ideas. The large kick-off event is then followed by subsequent events held in the Colleges of Engineering, Medicine, and Business. These events serve three purposes: provide an overview of the Bench-to-Bedside program, allow participants to meet and mingle with interested students from a variety of backgrounds and areas of interest, and student self-assembly into interdisciplinary teams. Student teams are not formed or assigned by the Bench-to-Bedside leadership, but rather are self-selected based on project requirements, student skill sets, and student interests. The success of Bench-to-Bedside lies in the diversity of its participants, especially their areas of interest and skill sets. We have seen a steadily increasing crosscollaboration amongst the different colleges and programs of study on campus.

Table 1. The Chronology of Bench-to-Bedside Workshops and Resources

tool and resource for the students. However, the number and timing of the workshops must be carefully planned to fit within the academic schedules of this diverse population of students from across campus. We have seen that having too many workshops can be daunting for students and stifle their ability to complete the competition. On the other hand, not having enough workshops leaves the students woefully unprepared to transition their idea to a fully functioning prototype with all the required supporting documentation and analyses. We have found that limiting the workshops to one per month provides a nice balance between providing the necessary baseline information to succeed in a crash course in medical technology entrepreneurship while avoiding burnout for the student participants. For the current competition, we have condensed and combined the workshops to reduce the total number of workshops from nine to four. The

BENCH-TO-BEDSIDE TIMELINE												
	CONCEPT GENERATION PHASE				PROTOTYPING/PRODUCT DEVELOPMENT PHASE				POST- COMPETITION			
	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	March	April	Summer & Next Year			
Workshop	Team Forma- tion	Idea Gen- eration	Meet The Mentors		Prior Art and Pat- ents		Product Pitch	Final Competi- tion Night				
Resources Available to Teams	Competition workshops Faculty subject matter experts								-All prior resources -Prize money -Milestone funding -Other competi-			
	Center Fo	tions										

Once teams have formed, they are invited to a series of educational workshops, which provide them necessary baseline skills for medical technology innovation and entrepreneurship. These workshops are held on weeknights and run for 1.5–2 hours each. The workshops are an excellent teaching

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workshops are as follows:

Idea Generation Workshop

For participants, one of the toughest parts of Bench-to-Bedside is identifying a legitimate clinical problem for which a medical device can be developed. This workshop allows students to hear from and interact with faculty within the Center For Medical Innovation and professional design consultants from outside the university. Students are introduced to the design process and instructed on the importance of seeking out clinical problems by exploring the clinical setting and vetting ideas with clinical health care practitioners. The University of Utah Health Care System has been, and continues to be, an integral clinical partner by opening their clinics, operating rooms, and administrative offices to help students identify clinical problems in areas that interest them. While the students may reach out to faculty and physicians to validate their chosen clinical problems, the proposed solutions are solely generated by and property of the Bench-to-Bedside teams. The design consultants are individuals with extensive experience guiding companies of all sizes through the design process as they refine existing and develop new products. These consultants walk the students through methods for systematically selecting viable clinical problems and ranking potential solutions.

Meet the Mentors Workshop

Mentorship is a critical component of the Bench-to-Bedside teaching process. At this workshop, teams meet with the regional C-level executives (e.g., CEO, CFO, CIO) who compose the Center For Medical Innovation's industrial board. These board members have agreed to mentor the teams in a one-on-one fashion; they help guide the teams through the course of the competition and provide them with invaluable insights from their extensive expertise relative to entrepreneurship, innovation, and medical technology. Throughout the course of the

event, teams rotate through several short 10-minute sessions with potential mentors, in a style similar to "speed dating." This format allows teams and mentors alike to share their ideas, goals, interests, and resources while evaluating the prospects of a mutually beneficial partnership.

Prior Art and Patents Workshop

One of the most important recruitment factors for Bench-to-Bedside is the program's ability to offer students free patent filing services and advice on patents and prior art. This workshop teaches students about the basic of patents and prior art while introducing them to the Bench-to-Bedside legal team: faculty and law fellows from the S.J. Quinney College of Law and the library system. Students are able to work with the Bench-to-Bedside legal team to draft reasonable claims for their device, submit their filings with the US Patent and Trademark Office (USPTO), and secure protection for their ideas and IP. This workshop is instrumental for teams to learn how to navigate the dynamic landscape of prior art and existing patents so as to carve out space for the patentability of their product.

Product Pitch Workshop

The ability to promote and sell a device or technology is an essential tool for any entrepreneur. At the final workshop of the series, the Bench-to-Bedside faculty and selected speakers from the University of Utah Business School teach the students how to make an elevator pitch for their device in preparation for the final competition night. They are instructed on how to identify their target audience, the importance of tailoring their message to their target audience, and key points to emphasize about their technology. Communications specialists with experience in business and engineering, along with faculty from these colleges and the Center For Medical Innovation, instruct the student teams on pitching their products.

Final Competition Night

The competition culminates in a final night where all teams come and present their projects to the Bench-to-Bedside faculty, family, friends, community mentors, national media, and invited quests from the local political, business, entrepreneurial, and medical communities. We reach out to the faculty at the University of Utah and leaders from the local entrepreneur and biotechnology communities to attend the event and judge the projects. Teams are judged according to a series of grading rubrics assessing each project's completeness and advancements in the areas of medicine, business, and engineering. Specifically, the judges evaluate if teams achieved their stated end point; the design, development, and documentation of unique prototypes; the functionality of the prototypes; and the projected viability of the device. The top prizes are awarded to the teams that excelled in all areas. Additional prizes are awarded to teams with projects that excelled in one of the competition's core fields of study (engineering, medicine, or business). Each year we also provide awards for teams in areas that don't strictly fall into the core fields of study. For example, we have awards for teams who implement "green" technology or demonstrate a commitment to global health. The prizes are monetary funds that allow the teams to further develop their device and protect their IP. The monetary prizes provide motivation to the students to complete the competition with well designed and developed prototypes, while also providing a vehicle for further product development and continued success beyond Bench-to-Bedside.

Resources for Student Success During the Competition Faculty Subject Matter Experts

Health Care Faculty

The Bench-to-Bedside program has a close relationship with the University of Utah Health Care System. The physicians, nurses, and other health care practitioners graciously open the doors to their operating rooms, clinics, and offices to meet with student teams, guide them toward relevant clinical problems, and vet the feasibility of their proposed solutions. These specialty-based faculty members further serve as expert clinical consultants for the unmet clinical need being addressed by each project and as key opinion leaders for technology research and commercialization endeavors.

Engineering Faculty

Since the inception of the competition, three associate professors from the University of Utah College of Engineering have served as engineering advisors. These advisors meet directly with teams to assess the feasibility of prototyping their devices, ensure compliance with the appropriate federal regulations (e.g., Title 21 CFR part 820 and appropriate ISO standards), and ensure sound engineering resides behind each device. The advisors play a critical role in judging each of the devices from an engineering standpoint.

Business Faculty

The business support behind the competition is primarily derived from the Lassonde Entrepreneur Institute. The Executive Director of the Lassonde Institute personally oversees the business plan and market analysis components of the completion. Business faculty members are instrumental in helping the teams understand the commercial market, appropriate business model development, business plan development, and refining "elevator-pitches" for their technologies.









Law Faculty

Bench-to-Bedside works directly with faculty from the University of Utah College of Law with expertise in contracts, small business development, and IP law to appoint senior law students to serve as law fellows for Bench-to-Bedside. The law fellows serve as legal advisors under the guidance of experienced faculty to help teams explore the IP landscape and develop well-constructed patents for submission to the United States Patent and Trademark Office (USPTO). The New Venture and IP Law Clinic created by the university's Center For Medical Innovation assists teams in filing their IP protection prior to their public disclosure.

Library Innovation Team

The library system at the University of Utah is home to a team of experts who specialize in areas such as literature searching, scholarly communication, research strategies, and prior art searches. They provide an invaluable resource for students as they research their clinical needs, previously published studies, and market data relevant to their particular technology. The Library Innovation Team also manages an online resource where students can access program resources, communicate with one another, and submit required program components and documentation of their technology for judging purposes.

Center For Medical Innovation

Although Bench-to-Bedside is functionally student-run, the competition and all of its resources ultimately reside within the University of Utah's Center For Medical Innovation and are overseen by the Center's Executive Director. The Director is a liaison between the student leaders and university faculty and staff and is responsible for securing investors and funding for the program, recruiting industrial sector mentors and partnerships, and working hand-inhand with the business, physician, legal, engineering, and community leaders. The Center is also home to a well-appointed

prototyping lab and its staff of prototyping experts, who can guide the students as they design their device and show them how to physically construct the components of each device. Student teams participating in Benchto-Bedside can use the Center's prototyping facilities at a deeply discounted rate.

Community Mentors

The University's Center For Medical Innovation helps form bridges between Bench-to-Bedside and the regional entrepreneur and biotechnology communities. Specifically, the Center has established an industrial board composed of regional C-level executives who have experience in medical technology product development and commercialization. These leaders cover a vast array of specialties and business sectors, ranging from catheters and software to biotechnology, venture capital, and legal advising for start-ups. Traditionally, each team was paired, based on common interests and a desire to work together, with a mentor from the industrial board who served as an advisor during, and potentially after, the competition. Experience and team feedback from previous years suggested that it would be advantageous to allow teams access to mentors with a specific area of expertise on a short-term demand basis to help them overcome small, highly technical speed bumps throughout the competition. In response, this year, we have reworked the mentor program to include both long-term and short-term mentors. A team can request a short-term mentor for a 4-week block of time, as needed. This dual mentorship approach allows the teams to tap into a variety of specialty experts, while affording them the continuity of a long-term consultant. We have observed wide variability in the utilization and effectiveness of teammentor relationships. We find that teams who meet with their mentors at least twice a month and have clear strategic goals are most effective. The industrial board also has a "payto-play" fee for members. Board member fees

financially support devices developed during the competition. In return, board members are granted access for early buy-ins to technologies emerging from the competition.

Resources for Student Success After the Competition

Continuation of Resources After the Competition

Nearly all of the resources that are made available to Bench-to Bedside participants during the course of the competition continue to be available to students after it concludes. This allows teams to continue to refine their prototype and advance their projects to market. Specifically, students have access to the clinical, business, legal, engineering, and library subject matter experts. They can continue to work with them one-onone to obtain any personalized assistance and guidance that they require. Students who have completed Bench-to-Bedside also retain access to the Center For Medical Innovation prototyping facilities, as well as other engineering and design labs on campus. This gives the student teams a conduit to low-cost and well-equipped prototyping and design facilities. Arguably the most important resource for the students that continues after the competition is the community mentor pool. The relationships formed between the teams and their individual mentors during the competition continue to drive team success after the competition. The community mentors provide a constant source of guidance, advice, and resources, which the teams continue to benefit from after the framework of the competition has been removed. We have observed that the mentors continue to be actively engaged in encouraging and making it feasible for motivated teams to pursue their projects further. While not all teams continue to utilize their team mentors, we have witnessed that those teams who continue to work with their mentors after the competition are much more likely to reach a more polished final product and ultimately proceed to

commercialization.

Prize Money and Milestone Funding

While the monetary prizes awarded at the final competition night provide a nice motivation for teams to participate in Bench-to-Bedside and produce well-developed solutions to unmet clinical needs, they also serve as an initial source of funding. Prizes generally range from \$1,000 to \$15,000. These funds are awarded to the team via reimbursement of any costs for further prototyping, professional services, and commercialization resources. While we have many deserving projects presented at the competition night, we are limited by the total funding available to award. In order to ensure that every team with a high-potential innovation has access to further development funding so that they may pursue commercialization of their projects, we have created a small new venture fund to provide milestone funding. Under this system, teams submit a brief proposal outlining the current status of their project, anticipated needs going forward, incremental goals for their project, and a budget detailing how the requested funds would be used. The Bench-to-Bedside leadership team reviews and discusses the merits of each proposal before awarding full or partial funding to the teams on a competitive basis. The team uses these funds to achieve the incremental goals outlined in their proposal. Once the funds have been expended, teams can apply for further funding. Their request is evaluated through another round of proposals and awarded based upon merit and how well their previous milestone goals and objectives were met by the provided funds. This system allows us to provide teams with continued funding to transition them into funding sources, such as other competitions, licensing agreements, and industrial or university support.

Other Entrepreneurial Competitions

Participating in subsequent medical technology innovation and entrepreneurship competitions is an excellent way for teams







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to further polish their projects and obtain additional and much needed funding. The Lassonde Institute at the University of Utah is the hub of entrepreneurship and innovation for students and oversees many of the entrepreneurial competitions on campus. The different student-run competitions in the Lassonde Institute meet regularly so that we can coordinate calendars and align the goals and expectations of our programs. This ensures that teams completing Benchto-Bedside can funnel directly into other competitions on campus. Similarly, teams from other competitions can enter and participate in Bench-to-Bedside. This relationship with the Lassonde Institute also allows all the student groups to network and provide information on entrepreneur and innovation competitions occurring at other colleges and even internationally. We have found that teams from Bench-to-Bedside who compete in subsequent competitions tend to do very well and often receive prize money for their efforts. The student success stories at the end of the paper include two Bench-to-Bedside teams who have gone on to place in subsequent competitions.

Results and Progress

In the first four years of Bench-to-Bedside, 394 students have participated in the competition (Table 2). These students formed 87 different teams, which went on to develop 91 medical devices. The program has awarded \$280,000 dollars in prizes and an additional \$30,000 dollars in milestone funding since the implementation of our new venture fund. The milestone-based new venture funding has helped seven teams who completed Benchto-Bedside to further develop their projects toward commercialization. Several teams have also entered and achieved success in other national and international entrepreneurial competitions following their participation in Bench-to-Bedside. Bench-to-Bedside teams have gone on to obtain 55 provisional patents (at a cost of roughly \$17,000), with

subsequent filing for 15 formal utility patents from the USPTO to protect their IP. Over the course of the past four years, Benchto-Bedside teams have also formed 24 new companies around their projects, many of which are still in business. In the current year, we have 211 participants registered across 61 teams. We anticipate an increase in the amount of milestone funding we will award and the number of patents that we will file this year.

Table 2. Bench-to-Bedside competition results from 2011-2014

COMPETITION RESULTS									
	2011	2012	2013	2014					
Participants	76	57	74	189					
Teams	13	14	18	42					
Devices Developed	14	14	20	43					
Provisional Patents Filed	12	13	14	16					
Utility Patents Filed	1	3	5	6					
Companies Formed	1	5	6	12					

Success Stories

(Shared from the Bench-to-Bedside 2013 and 2014 Competition Reports)

AdvanceCath

Following their completion of Bench-to-Bedside, the AdvanceCath team has seen their device honored by multiple agencies across the United States. Their device is a urinary catheter that reduces bacterial film formation on the exterior of the catheter. Their device is 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 about the program 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."

Veritas Medical – The LIGHT LINE Catheter

The team at Veritas Medical is the driving force behind the LIGHT LINE, an innovative catheter designed to reduce hospital-acquired infections and the first antimicrobial urinary catheter to be self-sterilizing while residing in a patient. They have made great strides since they competed in the 2011-2012 Benchto-Bedside competition. The idea behind the LIGHT LINE Catheter began after a discussion of one of the largest problems in health care: 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 occurrence. After months of research, they 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 the Startup Center for Student's Award, earning a total of \$9,000 in the competition. In March of 2013, the team submitted a utility patent for their device. Since then they have filed numerous additional provisional and utility patents related to their technology. They have competed and won

awards in several competitions, including the Utah Entrepreneurial Challenge, the Baylor New Venture Competition, the Collegiate Inventors Competition, and most recently, winning the grand prize at the International Business Model Competition, amounting to \$75,000. They have been featured in dozens of national and international publications and are currently working with investors to fund their seed round through the FDA clearance. 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," says one team member. 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.

Conclusion

Navigating the complexities and requirements involved in medical technology innovation and commercialization can be daunting tasks for even the most seasoned veterans. To help introduce these topics to college students from a wide variety of backgrounds, we formed the Bench-to-Bedside medical technology entrepreneurship competition. Now in its fifth year, Bench-to-Bedside has grown rapidly to encompass hundreds of students from multiple colleges at the University of Utah, producing a wide array of new and innovative medical devices. The program owes much of its success to its interdisciplinary nature and strong relationships with faculty on campus and local industry. We have also developed a range of tools and resources, such as mentors from the community, milestone funding, and teams of subject matter experts, to help students succeed. Other universities, communities,









and governmental organizations have noted the need for this type of student innovation training. We have demonstrated not only the need for such training, but also that there is a tremendous amount of student interest in this specific field, and in experiential education in general. Based on our experience, we conclude that many academic institutions will greatly benefit from pursuing the development and implementation of similar medical technology design programs as a means to more effectively prepare the next generation of health care innovators.

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