

Yale Center for Biomedical and Interventional Technology (CBIT)

ISAM
2016
Paper No.:
17

Alyssa Siefert, PhD¹, Joseph Zinter, PhD², Peter Schulam, MD, PhD¹, Chris Loose, PhD¹, Mike Dempsey¹, Ayesha Khalid, MD, MBA¹, Jean Zheng, PhD¹, Margaret Cartiera, PhD¹, W. Mark Saltzman, PhD¹

¹Yale CBIT; e-mail: firstname.lastname@yale.edu

²Yale Center for Engineering Innovation and Design (CEID)

Corresponding author: alyssa.siefert@yale.edu (CBIT Engineering Director)

INTRODUCTION

The Yale Center for Biomedical and Interventional Technology (CBIT) was founded in February 2014 by Drs. Peter Schulam (Urology) and Mark Saltzman (Biomedical Engineering) to catalyze biomedical innovation and improve patient care. CBIT achieves its mission by promoting active collaboration among clinicians, engineers, business people, designers, administrators, students, staff, and faculty members through **strategic connections**, such as those between Yale School of Engineering and Applied Science (SEAS), Yale School of Management (SOM), Yale School of Medicine (YSM), and Yale-New Haven Hospital (YNHH). Notably, many CBIT initiatives are amplified by its close partnership with the Yale Center for Engineering, Innovation, and Design (CEID), an impactful design studio and collaborative makerspace, as the CEID provides physical resources as well as technical guidance to prototype and test medical innovations. The broad goal of CBIT is to **promote an inclusive spirit of creative innovations to improve patient experiences and outcomes**. Operating on the talent-rich Yale University campus, CBIT aims to provide clinical pulls for many of the available technologies and resources.

PURPOSE

A. MISSION & ACTIVITIES

CBIT functions as an interface that matches clinical questions, often arising from YSM and YNHH, with technical and business solutions, usually developed within the framework of Yale SEAS and SOM, respectively. Many of CBIT's functions mirror those of CIMIT: Center for Integration of Medicine & Innovative Technology¹, a non-profit consortium of Boston-area universities and teaching hospitals, especially as the Executive Directors of CBIT are also members of CIMIT Executive Committees. With a focus on creating medical device, health IT, diagnostic, and data solutions, **CBIT first identifies clinical pain points and sources ideas around which to organize multifunctional teams**. CBIT occupies an important place in the Yale entrepreneurial ecosystem, engaging all stakeholders to develop viable solutions for validated unmet clinical needs. That is, CBIT focuses on identifying areas for improvement in the current healthcare system, primarily through direct interactions with clinicians (physicians and nurses), hospital staff (purchasing and sterilization decision makers), and patients. Twice a month, at least one CBIT team member attends a Patient and Family

Advisory Committee (PFAC) meeting at YNHH, in which approximately twenty passionate people who have been patients and/or caregivers provide ideas for improvements or feedback on current projects. **Project ideas are first vetted for clinical desirability by engaging clinicians and patients** before the economic feasibility is assessed through discussions with reimbursement specialists and/or insurance partners.

Once an important healthcare problem is identified and due diligence is performed, CBIT facilitates team assembly, either through direct connections of people with appropriate expertise, courses, or events. CBIT supports three courses: MGT/MD 657, Creating New Ventures in Health and Life Sciences (cross-listed in the Schools of Management and Medicine), MENG/BENG 404, Medical Device Design, and Medical Software Design. In each of these courses, teams form around clinician-identified problems to create business, device, or software solutions.

CBIT-led events include Healthcare Hackathons and Clinician Pitch Nights, in which physicians and nurses present pain points to form multifunctional teams to solve these problems. **We have found that events in which diverse groups of people congregate for focused discussions (often around free food) provide a fertile ground for team formation**, and therefore we aim to frequently bring together clinicians with students and faculty members of many backgrounds.

Healthcare Hackathons are CBIT's signature community-building and team-forming events, the most recent of which drew 125 participants to the medical school for 3 days during a blizzard. These hackathons are an excellent example of the **partnership model** that CBIT employs; the planning committees consist of people from MIT Hacking Medicine, neighboring universities, Patient and Family Advisor Committees, and YNHH in addition to Yale University. Attendees of the most recent hackathon, Patient Experience and Provider Engagement, selected from 370 applications, represented 38 institutions and corporations and formed 19 teams to create both physical and digital solutions; 7 teams continued to work on projects months after the hackathon, belying the sustained impact of these events. Even attendees who did not work on teams that continued projects reported that they enjoyed this energizing, inspiring event, and they left with new friends, professional mentors, and ideas.

¹ About CIMIT: <http://cimitcolab.org/web/cimit>

B. STRUCTURE & PARTNERSHIPS

Taking no equity in ventures created, CBIT provides an inclusive framework and resource for the entire Yale community, as it is not housed or owned in a single department, and its activities occur in many locations. While some CBIT staff offices are located in the medical school, others work in the engineering school, and one splits her time between the university and the hospital. A diverse, multidisciplinary research and clinical practice community, CBIT advances projects via education, team formation, guidance and mentorship (prototyping, regulatory, and business planning), collaboration among distant yet important stakeholders, and funding. To enable these activities, **CBIT has created key partnerships with the CEID**, as well as YEI and Yale Center for Clinical Investigation (YCCI). CBIT's advisory panel consists of leaders from YSM, SOM, SEAS, CEID, YEI, and Yale School of Public Health. Furthermore, **CBIT has created connections beyond campus**, most notably with the local Medtronic site; CBIT has developed an educational Clinical Immersion program that provides Medtronic engineers with didactic lectures, ranging from anatomy to hospital purchasing, and surgical observations. Entering its third year, Clinical Immersion Program participants report that exposure to Operating Rooms and discussions with surgical staff enable them to perform better at their jobs, and Medtronic staff have given training sessions on proper device use to YNH employees, leading to better patient outcomes and experiences. Given CBIT's focus on measurable clinical impact, CBIT engages biomedical innovators at every phase to enable relevant design of products, including Voice of the Customer (VOC) feedback studies with patients, surgical staff, and medical device and sterilization specialists.

C. MAKERSPACE TIES

The close partnership between CBIT and the CEID enables a **unique opportunity for the entire Yale community to develop and actualize ideas** in an academic makerspace equipped with full machine and wood shops, 3D printers, a laser cutter, electronics equipment, wet lab, and other useful equipment and materials for prototyping. Anyone in the Yale community can become a member of the CEID, after which they are granted 24/7 access and the ability to attend workshops and events ranging from bacterial transfection to Clinician Pitch Nights. The CEID has built a thriving community centered on innovation and entrepreneurship, partially due to its well-executed courses, events, and workshops. When assisting project teams, CBIT frequently points to CEID resources for prototype design, development, and bench testing.

Additionally, MENG/BENG 404, Medical Device Design and Innovation, represents a synergistic partnership between CBIT and CEID. Currently in its fourth year, MENG/BENG 404 is co-instructed by the CBIT Engineering Director and the Assistant Director of the CEID, Dr. Joseph Zinter. This is a particularly impactful course (that resembles courses at

Stanford² and MIT³) as it requires students to work with clinician clients to identify unmet needs and prototype solutions in the CEID to address those needs. Students also receive lectures from medical device experts ranging from surgeons to FDA employees. MENG/BENG 404 selected 20 undergraduate students from nearly 50 applications in Fall 2016, conveying the high demand for design-based coursework that solves real problems.

D. LESSONS LEARNED

Of the approximately 200 projects brought to CBIT, about 80 remain active. Therefore, by considering the varying successes of projects, several lessons have been learned. We have found that **thoughtful team formation is critical to a project's success**; generally, successful teams result from matching a clinician, engineer/programmer, and business person. Often, teams may start as two people (for instance, a physician guiding a Mechanical Engineering student in her senior design project), and grow to include a person with business expertise, such as an MBA student, as the project moves beyond proof-of-concept to proof-of-value. A success theme we've observed is **that a team must contain at least one passionate, motivated champion**; in our experience, these champions are either clinicians (mostly surgeons) who submit a project via the CBIT website or participate in a CBIT event, or students who enroll in CBIT-supported classes. While these initial project screening and team match-making activities are time-intensive, we've found that the upfront effort is a worthwhile investment for project sustainability.

Next, **a project must be sufficiently desirable, feasible, and valuable to succeed**. To assess each of these metrics, CBIT works directly with patients and clinicians to estimate desirability, and continues to engage these end-users through the development process. Feasibility is often assessed in partnership with CEID staff, who have expertise in design for fabrication, machining, manufacturing, and assembly, and project team members frequently use the CEID makerspace resources to prototype. Finally, potential value is measured by several mechanisms, including discussions with potential industry partners, market and business plan analysis in the context of MGT/MD 657, engagement with mentors and investors, or workshops.

Like many accelerators, CBIT assigns a mentor to each project team, either by leveraging the CBIT network or reaching out to contacts at the Yale Entrepreneurial Institute (YEI) or CEID, and **regular contact with mentors tracks with project sustainability**. Following the CIMIT model, a numerical score of Technical Readiness Level is assigned to projects upon intake such that progress can be measured. While current offerings and partnerships have been effective in terms of design, prototyping, market analysis, and business planning, **we've found that a gap exists in terms of software development and regulatory planning**. CBIT Leadership is therefore working to raise funds for regulatory strategists and software developers, such that the development of healthcare

²<http://biodesign.stanford.edu/programs/stanford-courses/biodesign-capstone.html>

³<http://web.mit.edu/2.75/>

solutions may be accelerated.

MENG/BENG 404 provides a useful case for pedagogical insights and development of best practices. The **teaching staff expends significant effort to source clinician projects prior to the semester**; this year, a Request for Proposals (RFP) was emailed to physicians, nurses, and other relevant hospital staff members in July, and interviews were held with clinicians who submitted potentially suitable projects. The teaching staff chose projects partially based on scope, with the goal of keeping a team of four undergraduate students busy while allowing them to reach significant milestones and feel successful by the end of the semester. The course aims to include a diverse range of students to promote creative problem-solving techniques, and thus 1/3 of students are Mechanical Engineering majors, 1/3 are Biomedical Engineering, and 1/3 are non-engineers. This year, the non-engineering majors include Computer Science, Molecular, Cellular, and Developmental Biology, American Studies, and Economics. While student project preferences were considered, the teaching staff structured teams around clinician-sourced projects to ensure that sufficient expertise existed on each team. For example, one team that is redesigning a primary care tool includes a Biomedical Engineering student, two Mechanical Engineering students, and an Economics student.

Finally, an important lesson from CBIT's experiences is that **an effective way to form partnerships with industry is by focusing on education**. Initially, people from Medtronic and Yale were hesitant to interact because of potential legal complications, and thus the first two years of the CBIT/Medtronic partnership was exclusively educational. Now that relationships and trust have been built, and each partner understands each other's policies, the CBIT/Medtronic relationship has evolved to allow for co-creation of biomedical solutions.

E. IMPACT

Bridging engineering, medicine, and business, CBIT has enabled numerous successes over the past 2.5 years. Over 200 projects have been proposed to CBIT, and 5 of these teams recently received \$30,000 grants through a partnership with Connecticut Innovations.

Examples of projects in which CBIT team members have participated include:

- Acantha is a team led by two undergraduate engineering students that is developing a better device for central venous catheterization; they won a \$15,000 VentureWell Debut Prize (2016). They have been supported by a CEID Fellowship and by CBIT mentoring on product development, intellectual property, and regulatory strategy. This group played a central role in the CBIT-led course, Creating Healthcare Ventures, in the Spring of 2016.

- Wellinks, founded in 2013, is a company started by three Yale students who worked with CEID, YEI, and CBIT. Wellinks has created a smart scoliosis brace that automatically adjusts and interfaces with software. This company recently closed a ~\$1M seed round for manufacturing. With CBIT, Wellinks worked on grants and intellectual property strategy.
- VIP Transplant is a project that developed from the Medical Device Design course in which four undergraduate students worked with a physician (the Chair of Transplant at YNHH) to develop a telehealth platform for transplant patients. They were supported primarily by CEID in device design and prototype development. CBIT contributed some support by connecting them with medical industry professionals and corporate advisors. This team is currently testing its software prototype and collecting clinical data.

Educational successes include the high class ratings and competitive applications for inclusion in CBIT-supported courses, in addition to 4 undergrad teams winning national and international prizes and 9 publications/poster presentations. Currently, at least 6 CBIT-supported teams have received external funding to commercialize their innovations.