

## Bridging the gap between invention and commercialization in medical devices

Avik Som, Tauseef Charanya, Stephen W Linderman & Joshua S Siegel

At Washington University, students and faculty have addressed challenges surrounding biomedical innovation and training through a novel and low-cost platform.

In 2011, a sizable portion of our entering class at Washington University School of Medicine came from engineering backgrounds. As we gained clinical exposure, a number of us were surprised to find that some clinical tools appeared outmoded. In talking to one another outside of class, we started brainstorming simple technologies that could improve patient care. Delving deeper, we found a systemic problem: engineering students do not enter the hospital to see what problems they could tackle, and clinicians do not have an outlet to solve the challenges they see in daily clinical life.

To address this disconnect, we created IDEA Labs—short for Innovation, Design, and Engineering in Action—a biomedical design and entrepreneurship incubator inspired in part by several other design programs across the country<sup>1–3</sup>. IDEA Labs brings in clinicians to share clinical problems and gives students from multidisciplinary backgrounds the opportunity to work in teams to develop innovative solutions. In bringing these groups together,

this platform addresses a number of challenges seen in biotech and bioscience training: (i) 75% of biomedical graduate students do not reach tenure-track positions for careers in academia, demonstrating the need for alternative career training<sup>4,5</sup>, (ii) approximately 95% of inventions and innovations developed at universities sit unlicensed<sup>6</sup> and (iii) clinical care lags significantly behind technological innovations in the laboratory<sup>7</sup>.

To meet these challenges, we brought together over 100 students from different disciplines and collated a database of over 150 clinical and biotech problems. IDEA Labs provides a malleable infrastructure able to accommodate student needs, schedules and challenges. In less than 18 months, students in IDEA Labs have developed 12 prototypes and launched 6 new ventures. This article describes the infrastructure required for the platform, the student experience in the program, and the benefits to stakeholders in healthcare and biotech training.

### Platform infrastructure

**Clinical outreach.** Tractable clinical problems are often neglected. Healthcare professionals frequently see problems and inefficiencies but may not have the skills or time to solve them. Conversely, for engineers, it is difficult to gain access to the clinical environment. This disconnect contributes to the technological lag seen in medical care.

To connect clinicians and engineers, we enlisted several medical students to launch a systematic outreach to physicians at Washington University–affiliated hospitals: BJC HealthCare and St. Louis Children's Hospital. Many of the problems we identified came from firsthand experiences in hospital settings and were brought to light in brainstorming sessions with clinical thought

leaders. For example, one team began working with a neurologist to figure out ways to improve communication for her quadriplegic and speech-impaired stroke patient. The result is a modular device that converts body movements into cursor control.

Healthcare professionals who provide clinical problems are strongly encouraged to work with student teams in an advisory role. This setup provides a simple and organic bridge to bring problems rapidly from the clinic to students who have the skills and time to address them.

### Intellectual property and legal considerations.

Nearly 95% of university inventions in the US are never licensed<sup>6</sup>. Recognizing IDEA Labs' potential, Washington University in St. Louis (WUSTL) waives all university intellectual property (IP) rights for teams and companies spinning out of the organization. This novel policy facilitates smooth transition of IP to the commercial space.

Instead of following the standard university technology transfer route, teams receive *pro bono* legal support from national law firms Husch Blackwell and Polsinelli to create and file provisional patents and to establish limited liability corporations (LLCs). IDEA Labs' nonprofit status enables us to execute confidentiality and nondisclosure agreements to protect nascent teams, and to hold IP until teams incorporate.

### Facilities and funding.

Innovation training programs are typically difficult to implement due to their high complexity and cost<sup>1</sup>. In our approach, as a student and volunteer initiative, IDEA Labs is cost efficient with minimal overhead. We supported eight project teams in our pilot year for less than \$4,000, resulting in seven functional proof-of-concept prototypes.

Avik Som is at the Mallinckrodt Institute of Radiology, Department of Biomedical Engineering, Medical Scientist Training Program, Washington University in St. Louis, St. Louis, Missouri, USA; Tauseef Charanya is at the Mallinckrodt Institute of Radiology, Department of Biomedical Engineering, Washington University in St. Louis, St. Louis, Missouri, USA; Stephen W. Linderman is in the Department of Orthopedic Surgery, Department of Biomedical Engineering, Medical Scientist Training Program, Washington University in St. Louis, St. Louis, Missouri, USA; and Joshua S. Siegel is in the Department of Neurology, Medical Scientist Training Program, Washington University in Saint Louis, St. Louis, Missouri, USA.  
e-mail: soma@wustl.edu

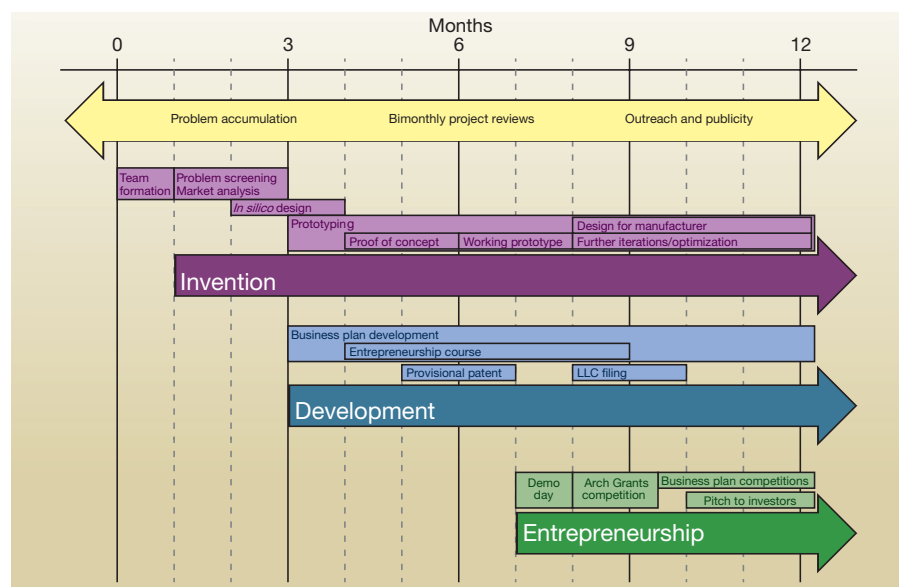


Figure 1 IDEA Labs timeline

Larger donations have allowed the program to improve and expand. IDEA Labs successfully transformed laboratory space donated by Washington University into functional prototyping space for students. Retrofitted with basic prototyping equipment, the space allows teams to go through the iterative design and prototyping process. Today, IDEA Labs' funding comes from departments in the university and associated hospitals such as BJC HealthCare. We continue to explore long-term funding mechanisms such as sponsorships, endowments and grants to further expand the program.

**Student and faculty leadership.** As a student-run organization, IDEA Labs adapts and develops rapidly with minimal bureaucracy and overhead. As new opportunities arise, we have enlisted student leaders to take on diverse but interconnected initiatives including clinical outreach to collate problems, curriculum development to enrich our talent pool, team recruitment and management, event and facilities logistics, and integration into local entrepreneurial systems.

In addition to its student leadership, IDEA Labs has an active advisory board composed of business, medical and engineering faculty at the university, alongside entrepreneurs and corporate leaders in the community. These advisors provide valuable feedback and help shape the overall initiatives and directions of the organization.

**Student experience**

**Team formation.** Applicants with sufficient experience and interest are interviewed for positions as project leaders. Project

leaders explore areas of interest (e.g., mobile applications, mechanical devices) and then work with the IDEA Labs executive board to assemble a team around that interest. Teams include at least one medical student, one graduate student and one undergraduate student (engineers and nonengineers) to ensure a breadth of expertise. Throughout the invention and development process, teams pursue entrepreneurial training and recruit business students.

In contrast to comparable programs, IDEA Labs does not offer any credit or payment to students. This has resulted in a self-selection of individuals genuinely interested and motivated by medical innovation or medical business development.

**Problem selection.** After team formation, we hold an event called Problem Day. Any faculty who has contributed to our problem bank is encouraged to present his or her problem and interact with newly formed teams. Teams work with clinical and business advisors to determine which problem to pursue based on clinical need analysis, market analysis and patent literature review. We have found that teams are only limited by the resources available to them. As we have improved our facilities, teams have solved larger and more difficult problems. In addition, some teams pursue social entrepreneurship opportunities such as global health problems and open-source licensing strategies.

**Training and timeline.** Once a problem has been selected, teams begin the 'Invention' phase (Fig. 1). This phase includes needs assessment, *in silico* design and iterative prototyping, guided

by a series of project reviews occurring every other month. At the first project review, teams must demonstrate that they have thoroughly evaluated clinical and market needs. After this, teams begin to develop prototypes. Successive reviews focus on *in silico* designs and prototyping for devices and applications. Each project review includes a panel of advisors with the appropriate expertise to guide teams through invention and team management.

During the 'Development' phase, teams receive mentorship in navigating the entrepreneurial side of product development. In some cases, business and law students are recruited onto teams. Teams are then guided through filing provisional patents and creating new LLCs, as well as developing business plans using either for-profit or open-source entrepreneurial approaches. When the decision to form a business is made, all IP is transferred from IDEA Labs to the new company.

The formal IDEA Labs invention and development process concludes with Demo Day, where teams present a working prototype and a 10-minute pitch to an audience of participants, judges and outside investors. Winning teams are given prizes, such as the opportunity to present in the final stage of Arch Grants, a venture capital competition. To facilitate continuation of projects over summer months, IDEA Labs provides a summer internship through the Washington University Skandalaris Center for Entrepreneurial Studies for two undergraduate or medical students.

Armed with functional prototypes and a business plan, teams transition out of IDEA Labs into the 'Entrepreneurship' phase. These budding ventures are connected with various entrepreneurial and design competitions, accelerator programs, angel investor and venture capital networks and other funding sources to propel their projects toward clinical implementation. To date, four teams have placed in or won national competitions, including business plan, pitch and engineering design competitions, and several of our teams are pursuing venture capital funding.

**Stakeholder benefits**

IDEA Labs provides students with experiential learning and exposure to alternative career paths. Students gain experience in problem identification, market research, business development, project management and iterative prototyping—skills applicable to both industry and academia but not typically taught in graduate training. For universities, IDEA Labs enables multidisciplinary collaboration at a grassroots level, circumventing departmental barriers. IDEA Labs also facilitates technology transfer of university-grown innovations.

On the clinical side, the IDEA Labs platform aims to improve care. Teams are tackling challenges to lower the cost of medical devices, increase patient safety, improve neurorehabilitation, ease patient transport and many others. After working with IDEA Labs, many clinicians realize that engineering and entrepreneurship are feasible outlets for solving clinical problems. We believe that this phenomenon unlocks latent creativity and spurs cross-disciplinary innovation.

For the startup community, investors and industry, IDEA Labs generates ventures and develops talent. IDEA Labs provides a hub for the community to interface with budding startups and student talent through advising, mentoring or investing. For larger, established companies, it also generates a skilled entrepreneurial talent pool and potential licensing or purchasing opportunities for innovative new technologies.

### Initial results

From December 2012 to May 2014, over 100 students in a total of 19 teams have participated in IDEA Labs. Of those, 16 teams completed the program, with 12 producing functioning or proof-of-concept prototypes, and 6 forming startup companies with products ranging from healthcare IT to medical devices. Those

groups that continue will need further support if their ideas are to reach patients. IDEA Labs is partnering with several entrepreneurial support organizations in the St. Louis region and across the country to provide a springboard to launch our teams forward.

### Conclusions

Universities are a renewable source of skilled and motivated students driven to apply their training to contribute to society. IDEA Labs leverages this talent pool to translate innovations into the entrepreneurial space where they can have an impact on healthcare. IDEA Labs continues to build its clinical problem database, develop its prototyping facilities and integrate further into the entrepreneurial ecosystem.

We hope to have the opportunity to spread our platform to other institutions. We think that other universities may find this model for cross-campus design valuable. Our experience navigating the university, entrepreneurial and legal systems to create a student-driven, collaborative initiative can serve as a guide to develop similar systems elsewhere.

### ACKNOWLEDGMENTS

IDEA Labs is made possible by the work and generous support of several groups. First, the authors applaud IDEA Labs teams for their commitment and drive to

produce excellent prototypes and generate successful companies. The IDEA Labs program was developed through substantial work by IDEA Labs executive team members from its founding in December 2012 through today. Specifically, IDEA Labs would like to thank the following members for their tireless efforts to develop this program from scratch: Sam Sun, LeMoyné Habimana-Griffin, Rohan Jalalizadeh, Ravi Chacko, Mrinal Pahwa and Jessica Fan. We would also like to thank our institutional partners: Washington University in St. Louis School of Engineering and Applied Science, School of Medicine, and Skandalaris Center for Entrepreneurial Studies; BJC HealthCare and St. Louis Children's Hospital; Husch Blackwell, LLP, and Polsinelli, PC. Finally, we are deeply appreciative of our many faculty and community champions who have helped develop and improve the program, a full list of whom can be found at our website, <http://ideas.wustl.edu>.

### COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

1. Yock, P. *et al. Sci. Transl. Med.* **3**, 92cm18 (2011).
2. Yazdi, Y. & Acharya, S. *Ann. Biomed. Eng.* **41**, 1822–1833 (2013).
3. Leuthardt, E.C. *Neurosurgery* **72** (suppl. 1), 182–192 (2013).
4. Tilghman, S. *et al. Biomedical Research Workforce Working Group Report* [http://acd.od.nih.gov/biomedical\\_research\\_wgreport.pdf](http://acd.od.nih.gov/biomedical_research_wgreport.pdf) (2012).
5. Schillebeeckx, M. *et al. Nat. Biotechnol.* **31**, 938–941 (2013).
6. Ledford, H. *Nature* **501**, 471–472 (2013).
7. Morris, Z.S. *et al. J. R. Soc. Med.* **104**, 510–520 (2011).