1. Introduction

This proposal requests funds for the scaling up of ES227: Medical Device Design, a new course at SEAS that is focused on the design of medical devices to address needs identified by clinicians from Harvard-affiliated hospitals[1]. The course provides a unique pedagogical opportunity to trains students to be innovators and inspire them to work in teams and apply their engineering skills for the benefit of humanity. Students from the inaugural ES227 were successful in develop high quality and innovative prototypes: two student teams produced journal publications, and the other two student teams presented their work at conferences. Furthermore, two of the teams also filed provisional patents based on their class work and one of these teams represented Harvard at the finals of the National Collegiate Inventors Competition[2]. Overall, the course supports student e-team formation through the

1. Creation of teams comprised of students, clinicians and faculty
2. Requirement for a full prior art report to be submitted before idea generation begins
3. Education of students on real-world issues such as IP, regulatory, investing etc
4. Encouragement of students to use their engineering skills for the benefit of humanity

1.1. What are you proposing? How will this lead to the creation of student E-Teams?

We plan to expand on our current success in ES227 to further increase the opportunity for students to generate successful e-teams that develop innovative projects that they can translate beyond the classroom. Specifically, the NCIIA grant money will be used to (i) improve the quality of the projects that are selected for participation in the course, (ii) improve the clinical immersion experience for both students and physicians, (iii) run a pilot global immersion experience, (iv) expand the focus of the class to also include biomaterials design, (v) develop novel open source instructional medical device engineering "kits" and finally (vi) to create a healthcare innovation ecosystem to support students to translate their projects into products.

Toward aim (i), we propose to ***form a multi-disciplinary Biomedical Design Needs-Screening Committee***, composed of representatives from academia and industry. This committee will include perspectives from medicine, law, public policy, regulatory affairs, and venture capital, and will leverage the community of innovation and medical expertise existing in Harvard University. Clinicians will propose projects, and the committee will consider prior art, the market landscape, and relevant stakeholders. This committee will thus act as an initial "Stage-Gate" to validate student projects prior to the actual course, ***maximizing the opportunity for student teams to develop innovative products.***

Toward aim (ii), we plan to ***formalize a clinical immersion experience*** for ES227 students, and ensure that students gain exposure to medical terminology and current standards of care, as well as insight into needs finding and needs screening through a user-centric design process. We will do this through a series of workshops for ES227 students prior to the clinical immersion experience. These workshops will also be open to students who are not taking the course, thus broadening the impact that we can achieve across Harvard. We will additionally work with physicians to provide a structured schedule for each student's clinical experience; our goal will be that every ES227 student will have a clinical engagement that mirrors a medical student's clinical rotation. ***This experience will increase the likelihood that ES227 student teams will develop innovative, user-centered, and context-appropriate solutions to advance medical care.***

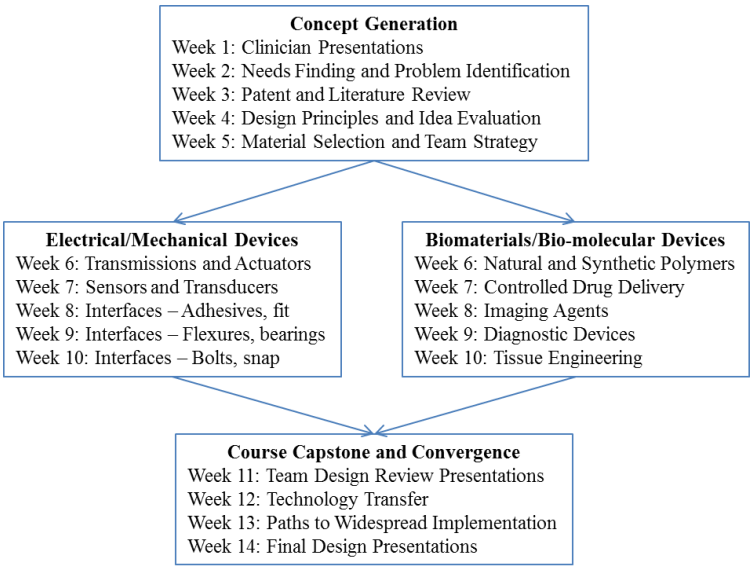
[1] http://news.harvard.edu/gazette/story/2011/09/surgical-precision/
[2] http://news.bostonherald.com/news/regional/view/2011_1112inventors_on_the_money_harvard_bu_teams_make_finals_in_15g_college_competition/

Toward aim (iii), we plan to ***pilot a global immersion component of the ES227 course***. Emerging markets such as India, China, and other developing nations are increasingly important to the medical device industry. More importantly, these populations are facing a double burden of infectious diseases and chronic diseases. We propose to send at least one student to India with the aim of

a) developing relationships with hospitals, key medical professionals, government and non-government organizations and engineering firms that will enable an ongoing collaborative program on health care engineering innovation

b) performing needs finding and needs screening to identify current pain points and opportunities for innovation in health care in India for electro-mechanically focused medical devices that could motivate projects in ES227.

Toward aim (iv), we propose to ***expand ES22 beyond its current mechanical and electrical engineering focus by incorporating chemical and biomaterials design***. In our envisioned course, eight student teams will collaborate with hospital-based physicians to develop innovative medical devices. At the outset of the course, all student teams will together participate in lectures and learning activities on problem identification, concept generation, design principles, and team strategy. The class will then split into a section on electrical/mechanical devices (led by Dr. Walsh) and a section on biomaterials/bio-molecular devices (led by Dr. Bhatia), so that students can learn necessary technical material for their proposed medical devices. Students will have the opportunity to attend both sections if they so desire. All students will then convene for the final weeks of the course to review team designs and discuss paths for implementation and dissemination of their innovations. ***Future medical device innovations will occur at the convergence of traditional engineering, so it will be important that students learn in a multi-disciplinary context.***



Toward aim (v), we propose to develop a range of novel instructional ***open source design "kits"***, including mechanical, electronic, materials science and chemical modules. The purpose of these kits is to enable technical literacy, build student confidence, and provide a means for students from all backgrounds to quickly prototype medical device designs. Some designs will inevitably require functionality beyond the capabilities of the kits and these modifications will then feed back into the ongoing development of the kits. The kits will also include an online knowledge database, containing both general engineering material and specific information regarding components. This database will be largely student-generated, but edited by teaching staff, and will continue to grow and be modified as subsequent cohorts of students pass through the course. According to legendary innovator Steve Jobs, design kits such as the Heathkits "gave one an understanding of what was inside a finished product and how it worked because it would include a theory of operation but maybe even more importantly it gave one the sense that one could build the things that one saw around oneself in the universe." ***With the proposed kits, we intend to foster a similar culture of exploration and innovation in the area of medical device development.***

Toward aim (vi), we plan to ***create an ecosystem of health care innovation*** around ES227 that brings together (a) students and faculty from the School of Engineering and Applied Sciences, Harvard Business School, Harvard Medical School, Harvard Kennedy School of Government, Harvard Law School; (b) physicians, fellows and residents from Harvard-affiliated hospitals and (c) investors, engineering firms and other medical device industry professionals. This ecosystem will be created through networking events, seminar series and invited lectures, workshops, and an online presence. ***This will create awareness of the ES227 course, and attract a diverse group of students interested in innovation in healthcare and provide a support network for projects to continue beyond the class***.

1.2. How will the most promising ideas/teams be supported beyond the classroom/program towards commercialization?

Harvard University has recognized the need to create students that understand innovation and entrepreneurship and that a strong engineering program is an integral part of this. Paul Bottino directs the Technology and Entrepreneurship Center at Harvard (http://tech.seas.harvard.edu) that will provide direct mentoring to student teams after the class is over. Furthermore, we will be launching a healthcare track to the Harvard College Innovation Challenge (http://harvardi3.org/) that will provide an outlet for students. Both TECH and the new Innovation Lab can provide student e-teams with incubation space to assist them with translating their products into products. After the class students will also be encouraged to participate in Harvard Business School classes such as Commercializing Science and Innovations in Healthcare to build business cases around their projects. For projects requiring further engineering development, students will have access to the PI's Biodesign Lab and the Wyss Institute, both of which have a focus on medical technology translation. Beyond Harvard, students will have access to a rich ecosystem of investors, industry and hospitals in the Boston area. Specifically, teams will present to the CIMIT Accelerator Program (http://www.cimit.org/services-accelerator.html).

2. History and Context

2.1. What, if any, courses or programs currently exist?

ES227: Medical Device Design is a new course in the Harvard School of Engineering and Applied Sciences that was piloted in the Spring of 2011. The course focuses on the design of medical devices to address needs identified by clinicians from Harvard-affiliated hospitals. In the Spring of 2011, 14 students (4 undergraduate and 10 graduate) participated in the course. In collaboration with Dr. Rajiv Gupta at CIMIT (www.cimit.org) we obtained 16 two-page project proposals from clinicians which were then down-selected to 8 that were presented to the students in the first weeks of the course. From these presentations, students selected four projects and self-assembled into teams based on which resonated with their skill-set and passion. Table 1 summarizes the outcomes of the class from last year. Students from the inaugural ES227 were successful in generating scholarly work: two student teams produced journal publications, and the other two student teams presented their work at conferences. Two of the teams also filed provisional patents based on their class work and one of these teams was a finalist in the National Collegiate Inventors Competition.

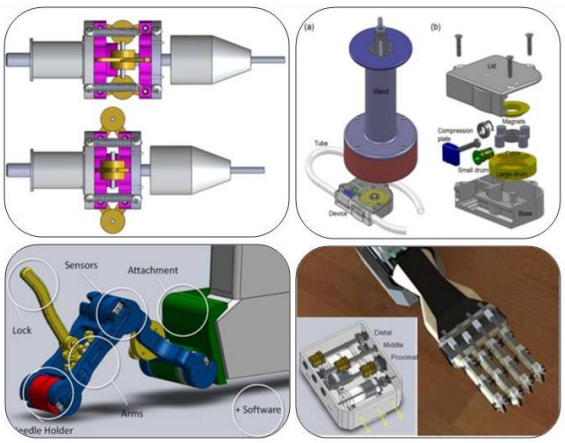


Table 1 Project descriptions and outcomes for pilot ES227 course in the Spring of 2011

Project	Student team efforts post class
Portable ultrasound needle guide	• Provisional patent filed • Presented paper and poster at the "Engineering in Biology in Medicine Conference" in Boston in September 2011 • Project continued in HBS Commercializing Science Class
Auto-retracting cranial drill	• Provisional patent filed • Paper submitted to ASME Design of Medical Devices Conference • Finalists at Collegiate Inventors Competition • Actively engaged with Stryker, Codman (J&J) and Synthes • Applying for NCIIA e-team grant
Wearable biorobotic hand brace for at-home rehabilitation	• Paper submitted to International Conference on Robotics and Automation • Poster presented at Brigham and Women's Hospital • Paper submitted to ASME Design of Medical Devices Conference • Student continued project over summer of 2011
Hemodialysis graft resistance adjustment device	• Paper submitted to ASME Journal of Medical Devices

2.2. What do you feel is missing?

The inaugural ES227 course was successful in generating innovative medical devices, as well as intellectual property and scholarly work. However, there are several improvements that can be made for ES227 to maximize opportunities for innovation. Our proposed six aims mentioned in the introduction highlight what we feel is missing by highlighting what we hope to improve through this grant.

2.3. What is in development?

Based on the success of a number of projects from last year's courses, we are actively talking to a number of large medical device firms. Some of these firms have expressed an interest in being involved in the course in future years. This active involvement of industry will help provide contacts to students that might assist them with licensing their projects or in securing internships or full-time jobs. Harvard has a rapidly growing engineering program with an increase of 38% of students declaring biomedical engineering as a concentration. With support from the NCIIA Ambassador program, Paxton Maeder-York is leading a student-led initiative to create the Harvard Healthcare Innovation Group. Divya Dhar, a medical doctor and a student at the Kennedy School is starting to establish initial contacts in India with the assistance of the Harvard Business School office in Mumbai. Donal Holland is a PhD student at Trinity College Dublin who is currently visiting Harvard for 6 months as part of a collaboration to improve how engineering design and innovation are taught in project-based engineering courses.

2.4. What support have you received for your work?

For the Spring 2011 course, we received a $25K sponsored research grant from the Center for Integration of Medicine and Innovative Technology. This grant was used to support a Harvard graduate student as a Teaching Fellow and for materials and supplies for students to build their prototypes. Since last year, CIMIT has received significant funding cuts and has since eliminated its Educational and Outreach Division and so it is unclear if CIMIT will be able to provide funding to support the course in future years. Even if we can receive some funding from CIMIT, this will not enable us to accomplish our six proposed aims outlined in the introduction of this proposal.

3. Work plan and Outcomes

Time	Tasks	Deliverables & Milestones
Jun-Aug 2012	***Aim 3:*** Run pilot global immersion for Divya Dhar in India ***Aim 4:*** Generate curriculum for new biomaterials component and integrate with existing ES227 course syllabus and structure ***Aim 5:*** Create designs of one "kit" for each of the two tracks in ES227 ***Aim 6:*** Create *beta* version of website for ES227 course	• Relationships established with Indian partners • Two-track, integrated syllabus finalized • Designs for two "kits" finalized • *Beta* website launch
Sept-Dec 2012	***Aim 1:*** Establishment of Biomedical Design Needs Screening (BDNS) Committee ***Aim 2:*** Collaborate with hospital staff and faculty to streamline the clinical immersion component ***Aim 5:*** Build "kits" for each of the two tracks in ES227 ***Aim 6:*** Run monthly seminar series from Harvard Medical Device Innovation Initiative ***Aim 6:*** Create *final* version of website for ES227 course	• BDNS Committee established • Clinical immersion documentation • Two kits built and demonstrated • Three seminars held • Website launched
Jan-May 2013	***Aim 1:*** Screening of Projects for 2013 Course Teach ES227 and implement the work to date on Aims 2, 4 and 5 and evaluate the effectiveness	• 8 projects selected for course • Documentation of use of kits
Jun-Aug 2013	***Aim 3:*** Run second global immersion for Harvard student (TBN) in India ***Aim 4:*** Refine electro-mechanical and biomaterials curriculum and improve documentation and handouts ***Aim 5:*** Refine designs for existing "kits" and create designs for an additional two ***Aim 6:*** Create *beta* version of website for ES227 course	• Two projects selected for 2014 course • Multi-disciplinary curriculum and syllabus documented • Designs for two "kits" finalized
Sept-Dec 2013	***Aim 5:*** Build "kits" for each of the two tracks in ES227 ***Aim 6:*** Run monthly seminar series from Harvard Medical Device Innovation Initiative	• Two additional kits built and demonstrated • Three seminars held
Jan-May 2014	***Aim 1:*** Screening of Projects for 2014 Course Teach ES227 and implement the revised work to date on Aims 2, 4 and 5 and evaluate the effectiveness	• 8 projects selected for course • Documentation of use of kits

4. Beyond the Grant

This NCIIA grant will help us create a bridge from our successful pilot offering of ES227 in the Spring of 2011 to a yearlong campus wide Medical Device Innovation Initiative. Based on our experience over this two year grant period we will evaluate the next steps for the course and for the Medical Device Innovation Initiative at Harvard. Given the significant interest in and expansion of Biomedical Engineering as a concentration within the School of Engineering and Applied Sciences and interest in innovation in general at Harvard we envision expansion to a two semester course that can serve two non-mutually exclusive purposes

1. A Capstone Biomedical Design Experience (for undergraduate students).
2. A design component for a Master's Program in Biomedical Design and Innovation or a new PhD program in bioengineering (for graduate students)