Biomedical Entrepreneuring: Turning Ideas into Medicine (SCRB 130)

Wednesday mornings 9:10-12:00pm, September 7 to November 30, 2016
Sherman Fairchild, Room 062, 7 Divinity Ave, Cambridge, MA 02138

Prerequisites: Life Sciences 1a and 1b, MCB 52, or permission of instructor

Overview: Medicines and other therapeutics have revolutionized the treatment of many diseases. Few of us pause to consider how these products are developed from an initial discovery in the lab to the treatment of patients. This course will consider this journey by incorporating scientific, biotechnology, intellectual property, venture capital, and business perspectives. In addition to lectures, students will work on group projects to chart a strategy towards bringing a novel biomedical idea to the clinic.

Lecture Component: We will be joined by a series of distinguished guests that possess vast expertise and experience in all facets of the biomedical entrepreneurial realm (scientist innovators, venture capital, regulatory experts, intellectual property, business strategists). Each week, a student will be randomly called upon to introduce the speaker, so it is expected that each student be prepared for every class. The lectures may or may not be posted online (speaker dependent) so if you have questions, be sure to ask them during class. The class has limited enrollment to facilitate active engagement with the speakers.

Project component: Students will work in groups of 4-5 throughout the term with the goal of devising a novel biologics-based "virtual" therapy to an unmet clinical need and then charting a course to clinical application through the foundation of a start-up company. This will involve defining a clinical need and proposing an innovative strategy to address it, surveying the landscape of competing ideas/approaches and associated intellectual property, defining key experimental milestones, strategies for raising capital, navigating the FDA, and planning a clinical trial (optional). The teaching fellow, Jessalyn and I will meet with teams during class to discuss progress on the team projects. A mid-term progress meeting will be scheduled with each group to make sure the teams are on track.

Teams are encouraged to focus their projects on biologics-based therapeutics and/or regenerative medicine. This could include but is not limited to: protein or antibody based, RNA/DNA-based, cell/stem-cell/tissue-based therapies. Ideas outside of this box may also be considered. The projects should be founded on real science and supported by peer-reviewed scientific publication.

Timeline: Determining which biomedical indication student teams will focus on and how they will approach it is expected to take 4-6 weeks. 1-2 weeks should then be spent surveying the competitive landscape, and putting together an IP strategy that protects the team's "unfair advantage". Business plan development is expected to take 1-2 weeks, and developing a strategy for clinical application is expected to take an additional 2 weeks.

A midterm progress report (**2 pages**) is due on **October 19**. This progress report should outline the technological approach and clinical indication that each group has decided to focus on. Each student is expected to submit a progress report.

On the final day of the term, teams will present their projects to the class, with each team member taking the lead on presenting different aspects of the project. Presentations will be 45 minutes (including 10 minute question period). We hope to be joined by other SCRB faculty.

Grading: There is no final exam or tests in this course. At the end of the term, each student will write an independent 10-14 page comprehensive paper describing all aspects of the team project. This should include, but is not limited to, discussion of: the clinical indication you plan to treat, team's innovation/approach and the science behind it, pre-clinical studies, milestones, alternative approaches (plan B), competitive landscape, discussions with experts/thought leaders, your business plan and fundraising strategy, relevant intellectual property, your IP strategy, regulatory considerations (how to get through the FDA), strategy for patient recruitment/clinical trial (optional), and references (in addition to the 10-14 pages).

The dynamics of the team meetings, class participation, written and presented projects will form the basis of the student's grades.

Breakdown: Class participation 15%
Teamwork 15%
Midterm progress report 10%
Presentation 15%
Final Paper 45%

Attendance is mandatory and all absences must be communicated to Jessalyn/Derrick in advance.

Course instructor:

Derrick J. Rossi, PhD
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Office hours: 8-9am Friday mornings in Sherman Fairchild 055, other times (arrange by email) in my office at HMS (200 Longwood Ave, Warren Alpert 149e)

Teaching fellow:

Jessalyn Ubellacker
PhD Candidate in BBS, G4
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Office hours: 12-1pm Wednesday afternoons in Fairchild 055, or other times (arrange by email)