

THE WHARTON SCHOOL
University of Pennsylvania
HEALTHCARE ENTREPRENEURSHIP
HCMG 867
SPRING 2016
Tuesdays 4:30-6:30 PM – JMHH Room 245
Syllabus Date: 11/09/2015

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OVERVIEW

The goal of the course is to give students the hands-on experience of establishing a healthcare or life sciences business by, among other things, working as part of a mentored group to craft and defend a business plan based on an actual technology or service in the space (defined as therapeutics, diagnostics, medical devices, or digital health services). Students, ideally working in groups of 4-6, will select a technology and present a proposed project description to the course instructors prior to the second class meeting.

During the course of the semester, students will be expected to prepare certain group-specific deliverables and to craft a business plan and investor presentation. Class discussions, led by course instructors as well as individuals drawn from the entrepreneurial, therapeutics, device/diagnostics, digital health and investor communities, as well as service providers, will present relevant major themes in life sciences/health care business strategy and tactics using current early stage ventures to illustrate these themes.

Non-Wharton Penn students or post-docs are welcome to take the class for credit or audit with permission from the instructors. If for credit, then students will need to make arrangements with their primary departments. Other Penn affiliates (e.g., MD, DVM, PhD candidates and faculty) or those not affiliated with Penn may also audit the course with permission from the instructors, and will be expected to fulfill all of the responsibilities of students taking the course for credit.

BUSINESS PLAN AND PRESENTATION

The primary deliverables are a pitch to a panel of investors (to include a PowerPoint presentation) and a written business plan highlighting the essential features of the business, market, competition, operating plan and financial projections, etc. and a separate executive Summary of the business plan. **The Executive Summary and the Investor PowerPoint presentation are due on April 24, 2016, and the final Business Plan is due on May 1, 2016.** Teams will be required to provide certain deliverables with respect to their interim progress in the form of written work or presentations.

PROJECT SELECTION – PRELIMINARY WORK

Students will evolve their projects and deliverables during the fall semester, but no later than the second class meeting. **Teams are required to prepare and hand in an initial project description which is due by the second class (January 26, 2016).** Course instructors, TAs, staff and mentors will assist student in selecting their projects, where needed, through relationships with Penn, Penn Medicine and other technology transfer offices, as well as through other support organizations and start-up and early stage companies.

TEAMS

Teams will ideally include 4-6 students at least one of who will have a relevant technical background. In addition, members of the Penn Biotech Group, other groups and individuals may act as consultants or participate as team members. With the prior approval of the instructors, non-Wharton technical members of the team will be permitted to participate in the class. The course instructors will assist each team in identifying an appropriate mentor to provide focus and to help identify appropriate resources within the life science community.

LECTURES AND “LUNCH & LEARNS”

Lectures will be held once each week and will deal with specific topics covered in a typical business plan or of significance to a life sciences or digital health venture. Lectures will include presentations by the instructors and experts on specific topics, with discussion facilitated by the instructors. **Since we are inviting experts from the outside, attendance at the lectures will be mandatory and monitored.**

In addition, we are planning to provide background on some core areas such as intellectual property, compliance, etc. through “lunch and learn” programs that will be recorded and then made available to students through Canvas for subsequent viewing. To be respectful to the speakers, we are asking that students attend at least one of these lunch and learns.

GRADING

Students will be evaluated on a combination of the final business plan, investor presentation and class participation, including the interim progress updates on the business plan in the following proportion: Business plan: 40%; Investor presentation: 30%; Class and team participation and interim deliverables: 30%. *Notes: (1) Students will also evaluate their own team members, with input factored into the participation grade. (2) The interim deliverables will count toward the participation grade and will be reviewed and returned with comments, but will not be evaluated on a graded scale.* Grading on a pass-fail basis is discouraged and will only be permitted with the consent of the professors.

ENROLLMENT:

Enrollment will be by application.

Class Schedule

Class 1– January 19, 2016 - Healthcare Venture Lifecycle

Healthcare ventures go through a number of phases from idea generation, proof of concept, initial market traction, expansion, and exit. In the case of a life sciences or digital health venture, the phases are more often characterized as research/design, proof of concept, clinical development and approval, and commercialization with exit a possibility at an inflection point, usually stage changes, influenced by market dynamics. Hybrids between the two also exist. In this lecture, we will discuss these phases, business models (including B2B, B2C, solutions, platforms, etc.), and the drivers for success at each stage. The goal is to provide context for crafting your plans and to set the stage for the rest of the course.

A portion of this class will also be dedicated to a course introduction and to assisting students select group projects.

Speaker: Gary Kurtzman

Class 2 – January 26, 2016 – Healthcare Ecosystem

Based on the ~\$3 trillion that the U.S. spends on health care, the U.S. health care system would rank as the 6 largest economy in the world. Uncontrolled growth is not sustainable, and neither spending nor cost-cutting will help us find our way out of this predicament. We need to find practical, as well as innovative, solutions that improve quality and save money. The entrepreneur's dilemma is to develop those innovative products and services within a rapidly shifting environment for customers. This lecture will serve as an overview of the perspectives and needs of the customers today and how these may change in the future. Case studies will be discussed.

Deliverable: Project Description

Speaker: [TBD – Awaiting Confirmation]

Deliverable: Project/Technology Description

Class 3 – February 2, 2016 – Start Up Space – Product Design

In this lecture, we will discuss the methodology for the design and development of new products and technologies by working collaboratively with academic health systems. In addition, the lecture will identify and address the risks and issues that often arise in this setting and will discuss strategies for mitigating the risks and overcoming the obstacles.

Speaker: [TBD – Awaiting Confirmation]

Class 4 – February 9, 2016 – Team Building

A team of Wharton students, engineers and scientists are a great start in the development of an early stage company, but investors may not be prepared to fund lightly experienced student entrepreneurs. Creating and nurturing the right culture, building the management team, developing a board, and evolving an HR strategy are critical for a focused life science/health services start-up.

Speakers: [TBD – Awaiting Confirmation]

Class 5 – February 16, 2016 – FDA Basics

Life sciences product development, manufacturing and commercialization is regulated by the FDA. Digital health products and services may be regulated by the FDA and are impacted by FDA regulations. In this lecture, we will provide an overview of the FDA's policies, regulations and practices with respect to product/service development and commercialization.

Speaker: Janice Hogan, Esq., Partner, Hogan Lovells

LUNCH & LEARN #1 – February 17, 2016 {Date Tentative} – IP & Branding

Every start-up needs to consider what barriers to entry it can erect to deter competition. For a therapeutics start-up, this can include intellectual property, regulatory exclusivity, and trade-secrets/know how. On the digital health and services side, barriers can be softer or even non-existent, and often the only advantage is branding, critical mass, or being the first mover. Intellectual property rights can create barriers to entry that may affect the economic viability of a venture. Just as important as understanding some basic patent law, the successful entrepreneur needs to develop and implement a successful intellectual property strategy. In this session, our guests will provide background information and developing an IP strategy.

Speakers: Joseph Guagliardo, Esq and John Zurawski, Esq,
Pepper Hamilton LLP

Class 6 – February 23, 2016 – Payers as a Customer

Many entrepreneurs, when talking about their customers, often speak of payers and provider organizations rather generically. As the adage goes, “if you understand how to sell to one provider, you understand how to sell to one provider.” The same goes for payers. In reality, these are complex organizations containing many potential points of contact each with their own motivations, budgets and priorities. The goal of this lecture will be to highlight the various constituencies and stakeholders within these organizations to better understand how to approach them with a product or service offering

Speakers [TBD – Awaiting confirmation]

Class 7 – March 1, 2016 – Providers as a Customer

The provider, whether it is a healthcare system, hospital, physician or other healthcare professional, makes decisions about what products and/or services get utilized. Providers make these decisions not only in the context of seeking to deliver quality care, but also in the context of other business considerations (operating efficiencies, resource optimization, profit/loss and risk mitigation). In this lecture, the class will hear the perspectives of this important customer.

Speakers: [TBD – Awaiting Confirmation]

LUNCH & LEARN #2 – March 2, 2016 {Date Tentative} – Data Privacy and Security

Government laws, rules and regulations can have significant influence on the business/revenue model of the venture, as well as its operation. These laws, rules and regulations are applicable to (and can impose risk on) the entrepreneur, as well as the venture. In this lecture, we will provide an overview of the fast-moving regulatory landscape of data privacy and data security.(HIPAA, data privacy, meaningful use, payer/pricing, reimbursement, and marketing), along with risk mitigation strategies.

Speaker: Sharon Klein, Esq., Pepper Hamilton LLP

Class 8 – March 15, 2016 – Pharma as a Customer

The business model of “big pharma” is under pressure as company’s struggle with the issues of product pipeline, patents and patent expiration, the regulatory environment affecting clinical development and product approvals, as well as pricing and reimbursement. Pharma companies are increasingly looking to information technologies, data and digital health technologies to

identify issues and formulate solutions. In this lecture, we will discuss the industry (internal and external forces) and the strategies and tactics for doing business with them.

Speakers: [TBD – Awaiting confirmation]

LUNCH & LEARN #3 – March 16, 2016 {Date tentative} – Regulatory Compliance

Similar to data privacy and security, other significant federal and state regulations can influence the business/revenue model of the venture, as well as its operation. Likewise, these laws, rules and regulations are applicable to (and can impose risk on) the entrepreneur, the venture and the exit. In this lecture, we will provide an overview of the regulatory issues that arise in connection with payer/pricing, reimbursement, and marketing. Regulatory schemes discussed will include self-referral (Stark), anti-kickback and fraud & abuse.

Speaker: Jeremy Frey, Esq., Pepper Hamilton LLP

Class 9 – March 22, 2016 – Digital Health

The next three lectures will be devoted to the stories of entrepreneurs and entrepreneurial organizations in sub-segments relevant to the theme of this course. The emphasis will be on experiences that highlight the practical, and often emotional, journey of launching and scaling the entrepreneurial venture.

Eric Topol, cardiologist and author of *The Creative Destruction of Medicine*, defines as digital technologies, social networking, mobile connectivity and bandwidth, increasing computing power and the data universe converging with wireless sensors, genomics, imaging, and health information systems to creatively destroy medicine as we know it. Digital health seed fund [Rock Health](#) further explains that digital health encompasses both Health 2.0 (B2C) and Digital health (B2B). This lecture will help further define digital health, discuss the issues in launching and sustaining a digital health venture, and provide some examples.

Speakers: [TBD – Awaiting confirmation]

Class 10 – March 29, 2016 – Life Science/Biotech Stories

The journey for a biopharmaceutical product is complex and risky. It typically begins with a scientific discovery in an academic laboratory, traverses a translational step from the lab bench to animal and then human testing through an often complex and costly clinical, regulatory and reimbursement process prior to its commercialization. This lecture will discuss this journey.

Speakers: [TBD – Awaiting confirmation]

Class 11 – April 5, 2016 – Medtech Stories

Medtech is defined as medical devices and diagnostics. While some of the products in this space can be developed rapidly and without a cumbersome regulatory process, others are more complex with paths more akin to biopharmaceutical products. As a result, the journey for a medtech venture is quite diverse and can be exceedingly complex. In this lecture, we will explore that journey and its drivers.

Speakers: **Bruce Shook, President & CEO, Intact Vascular**
[TBD – Awaiting confirmation]

Class 12 – April 12, 2016 – Organizational Considerations

After the idea, comes the time to organize the venture and seek funding. This lecture will describe the practical and legal considerations of starting a company including the basic elements of entity formation, intellectual property protection, risk management and financing structures and process.

Speaker: Jeff Libson

Class 13 – April 19, 2016 – Seed/Venture Financing and “The Pitch”

There are different strategies for financing life sciences and digital health ventures. In this lecture, we will present and discuss the continuum of financing for ventures and the implications of funding the company. We will discuss founder/angel and venture capital and other sources of equity and non-equity funding. We will also talk about “pitching” to funding sources and include a live pitch for the class.

Speaker: {TBD – Awaiting confirmation}

Class 14 – April 26, 2016 – Industry Trends and Course Reflection – Preparation for Investor Presentations

Speakers: Gary Kurtzman and Jeff Libson

Pitch Day – April 29, 2016- All Day

Business Plan/Investor Presentations – Group Times TBD***