

## ENTREPRENEURSHIP IN HEALTH CARE INNOVATION

**Course # 1238.3010.01**  
**December, 2014, Module 2**

*Syllabus as of September 9, 2014*  
*Subject to Change*

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### **1.0 Meeting dates and times:**

1. SESSION 1: Sunday, December 14 at 6:00 PM to 8:45 PM in room 303 Recanati
2. SESSION 2: Monday, December 15 at 6:00 PM to 8:45 PM in room 303 Recanati
3. SESSION 3: Tuesday, December 16 at 6:00 PM to 8:45 PM in room 303 Recanati
4. SESSION 4: Wednesday, December 17 at 6:00 PM to 8:45 PM in room 303 Recanati
5. SESSION 5: Monday, December 22 at 6:00 PM to 8:45 PM in room 303 Recanati
6. SESSION 6: Tuesday, December 23 at 6:00 PM to 8:45 PM in room 303 Recanati

“Clinic hours” for project discussion, careers, etc. to be scheduled

### **2.0 Course Description:**

Health care services and products are rapidly expanding markets worldwide. The common wisdom is that aging economies, particularly in the developed world, will demand ever-growing need for care. While this is true, the emergence of the middle class in the emerging markets will be the driver of further growth. In either venue, the need for innovation for diagnosis and intervention is disease is growing dramatically; the needs, however, are for more cost-effective products, more efficient care, and demonstrable positive outcomes. In other words, the health care business is not business as usual – care will be redefined in ways that we can only begin to imagine. This course is designed to provide an intellectual and practical framework for those students interested in exercising their entrepreneurial energy to solve problems in healthcare. It is not necessary to have training in healthcare, biotech or pharmacy, information technology or biomedical engineering. While a background in any one of these fields provides insight into the underlying issues and potential solutions, the state of healthcare is such that creative and determines individuals who come into the field with a fresh perspective can make contributions and profits.

Virtually all health care ventures function in an environment where the buyer-seller relationships and value-chains are formulated differently

from most other industries. Moreover, companies in health-related industries often have multi-dimensional technology and market risks. New enterprises in the industry are heir to these same risks, which are often magnified in the early stages. Consequently, a relatively small number of entrepreneurs and venture capitalists that specialize in the industry, or even segments of the industry, start the new companies. Even given the specialized experience, a majority of health care startups either fail or never scale up or realize profitability. Conception and evolution of the business model, building and supporting the elements of the business plan, technology and regulatory planning and management, market and reimbursement analysis, investor due diligence, deal structure, compensation and capitalization of these enterprises require special preparation and experience. This course provides intellectual frameworks for the special issues associated with health care startups. Furthermore the course offers methods for self-assessment and development of business models and plans, techniques for technology assessment and strategy, develops a foundation for capitalization and partnering strategies, and creates a basis for best practices in company launch and plan execution.

The course material and lectures are a panoramic view of the components of the industry. Students will have the opportunity to “personalize” the course to their interests based on supplemental readings and selection of a course project.

Students can approach the class as:

**Generalists** who are new to the industry or those with education or experience who seek the big picture of needs and opportunities

**Pharmaceutical and biotechnology** aficionados or related fields such as stem cells

**Diagnostic** geniuses with interest in laboratory or chemical systems, imaging, physiologic monitoring, or other emerging diagnostic categories

**Device** mavens focused on therapeutic applications, prosthetics, extracorporeal systems or other emerging devices categories

**Health service** innovators with interest in information technology, health care finance, logistics (such as supply chain management or medicinal management), reimbursement, clinical trial management, human resource development or other areas affecting improved performance and outcomes in health services

**Health policy** “wonks” seeking knowledge of the interconnection of innovation and national or international health policies

**Developing world** explorers interested in adapting medical technology for use in low resource and underserved settings

### **3.0 Course Materials:**

#### **Course Pack Containing:**

1. CASE: “Deep Breeze Brings an Innovative Medical Device to Market,” A case produced by the INSEAD Israel Research Centre
2. CASE: “A Father’s Love”

#### **Textbooks:**

Textbook 1: Shreefal S. Mehta, *Commercializing Successful Biomedical Technologies*, Cambridge University Press, 2008. Kindle Edition available on Amazon.com for approximately USD 32.00

Textbook 2: Burns, Lawton R, editor, *The Business of Health Care Innovation*, Cambridge University Press, Second Edition, 2012. Kindle Edition available on Amazon.com for approximately USD 27.00

#### **Moodle Downloads:**

Case: Biocon: Oral Insulin

“India’s Health Biotech Sector at a Crossroads,” Frew, Rezaie, Sammut, et al. *Nature Biotechnology*, 25:4, April 2007

“Chinese Health Biotech and the Billion Person Market,” Frew, Sammut et al. *Nature Biotechnology*, 26:1, January 2008

“Brazilian Health Biotech: Fostering Crosstalk between Public and Private Sectors,” Rezaie, Frew, Sammut et al. *Nature Biotechnology*, 26:6, June 2008.

*Scientific American Lives: New Answers for Global Health*, Fall 2010, Richard Gallagher and Stephen Sammut, eds.

Other Course website postings

Instructor slide sets

### **4.0 Course Requirements**

#### **4.1 Lectures and analysis of readings:**

The course will have a demanding role of reading designed to provide the foundation for understanding the industry as well as provide a basis for the selection and development of the course project. The instructor will provide questions for consideration in advance of the readings and will use these to promote course discussion.

In addition to the specific questions, students should read the material with these general principles in mind:

**Description of Issues:** Cogent, concise recognition, description and explanation of the significant issues taught in the readings. Consider timing factors, historical context, trends, and potential consequences of the concepts promoted by the authors.

**Critical Analysis:** There is virtually no proven formulas for success; entrepreneurial energy rules! When reading and during class discussion students should use their critical sensibility and challenge the assumptions in the readings and take exception.

**Insight & Synthesis:** Implications of readings on decision making, actions, consequences, and alternatives. Opinion is welcome when supported with references to assigned readings or other persuasive, relevant references, and especially experience in the workplace. "Synthesis" refers to the valuable exercise of relating the material in the course to situations at work (when applicable) and other course work in the iMBA program. The instructor has a strong preference for critical thought and creative alternatives.

**Summary & Takeaways:**

Students should keep a running notebook or other catalog of lessons learned as the course progresses. This is a "private" exercise and will not be submitted, but students should always ask themselves "What should I remember?"

#### **4.2 Course Project and Project Presentation**

There are no exams or quizzes in this course. Participation will be a factor in differentiating student performance but the basis of the grade will be on a course project and the related presentation in the last session.

The time period for project selection, the proposal and development is obviously short. Students are invited to consider ideas and run them by the instructor prior to the course.

Projects can be done on either an individual or a group of up to four students. Obviously, students should align their interests in assembling a team and establish among themselves a development plan with tasks specifically assigned to each team member. Teams are expected to disclose “free-riders” and there will be a written declaration of equitable performance by team members.

**Project categories:**

The instructor offers three project types for your consideration. These are of equal learning value in the eyes of the instructor and a type should be selected on the basis of the particular interests of the students.

Option 1: Development of a business plan or a feasibility analysis for bringing a product or service innovation to reality. Unless a student has already spent time in developing a plan, a feasibility analysis will be the most practical project in this option. The instructor will establish contacts with local venture capitalists or university technology transfer offices for those students who do not have a technology of their own. If a student has a technology and is developing a plan, he or she is welcome to recruit classmates to work on the project

Option 2: Development of a case study (for possible use in future courses) on an early stage Israeli company active in the sectors covered by the course. The instructor will solicit the interest of venture capitalists and entrepreneurs in offering a situation worthy of study. The instructor will discuss the case study design based on the particular company or activity

Option 3: “Consultation” to a venture fund in due diligence or financial analysis of an opportunity of interest to them

Option 4: Development of a sector analysis or opportunity map in a particular market category (this will be a focused, “deep-dive” in a specific area)

Option 5: An imaginative project proposed by the student(s).

**The schedule for completion of the projects is as follows:**

1. Submission of a one page proposal identifying the team members, the Option category, the subject and your goals. Due date: start of Session 2. Instructor will return comments by Session 4. The instructor will define the deliverable, establish the basis on which the particular project will be graded, and have a “clinic session” either by telephone or in person on campus
2. Submit two to three page detailed project outline by Start of Session 5. Instructor will return comments by Session 6.
3. Submit final presentation via e-mail by 8:00 PM (TLV Time) Sunday, January 25, 2015.

#### **4.3 Grading will be based on:**

- 20% class participation, including course blog contributions
- 80% final project
- Final scores will be adjusted to meet the Sofaer’s grading guidelines

**5.0 Instructor Contact:** E-mail: [smsammut@wharton.upenn.edu](mailto:smsammut@wharton.upenn.edu)

#### **6.0 Instructor Biography:**

Stephen M. Sammut is Senior Fellow and Lecturer in Health Care Management and Entrepreneurship at the Wharton School of the University of Pennsylvania. He has a career that is both commercial and academic. During his private sector career, Mr. Sammut has been involved in the creation or funding of nearly 40 biotechnology, Internet, and information technology companies globally. He is on numerous Boards of Directors including Doctors of the World, the Center for Medicine in the Public Interest, Dynamis Therapeutics, CombinentBioMedical Systems, and served as a senior advisor to Mitsubishi Corporation’s Life Science Business Unit, the Royal Bank of Canada Strategic Technology Fund, and the Cornell Research Foundation. He is also a member of the editorial board the *Journal of Commercial Biotechnology* and is co-editor of *Scientific American Lives: New Answers for Global Health*.

Mr. Sammut previously held the positions of Vice President of Development of Teleflex Incorporated and Vice President, S.R.One, Ltd., GlaxoSmithKline’s venture fund. At the start of his career, Mr. Sammut co-founded and served as CEO of the Delaware Valley Organ Transplant Program (DVTP) over an eight year period building it into one of the largest organ banks in the world. While at DVTP he developed and spun out companies in diagnostics and organ preservation.

Mr. Sammut has extensive experience in technology transfer having served as Managing Director of the Center for Technology Transfer at the University of Pennsylvania, and a similar position at Thomas Jefferson University. This experience resulted in the creation of Access Partners, a venture fund focused on the formation of life-science companies based on university technologies. He has served as a member of technology transfer advisory boards to Partners in Health Care (MGH/Brigham), Yale University, the Cornell Research Foundation, the University of Chicago/ARCH, Johns Hopkins School of Medicine, the University of California System and Hebrew University in Jerusalem (Yissum). He is also the project leader for the international technology transfer facility under development at the World Bank.

In addition to his teaching in Health Care Management and Wharton Entrepreneurial Programs, he leads a project with the Latin American Venture Capital Association (LAVCA) on the study of venture capital and private equity activity and growth in the region and is developing a similar relationship with the Middle-East Venture Capital Association. He is also project leader of a World Bank project with the Finance Ministry Peoples Republic of China on government participation in venture capital.

His other academic activity includes research and publications on biotechnology company business. Mr. Sammut is significantly involved in global development. He is founder and chair of the International Institute for Biotechnology Entrepreneurship, a non-profit organization that offers intensive training programs throughout the world. These “Boot Camps” focus on the essentials of company formation and advanced management skills in life science companies. His activity with the World Bank/International Finance Corporation (IFC) includes co-authorship of their Bioindustrial Investment Ethics Framework and serves as a member of the bioethics advisory board. He created and chaired the Association of University Technology Manager’s startup business development course for many years. He lectures extensively at biotechnology and global health conferences.

He holds graduate and undergraduate degrees from Villanova University in biological sciences and philosophy, attended Hahnemann Medical College for two years, and holds an MBA from the Wharton School.

## 7.0 Session Agenda, Organization, Content and Readings and Guidelines:

Session	Topic and activity	Content & Learning Objectives	Required Readings and Deliverables
<p><b>1</b></p>	<p>The Healthcare value chain: Implications for business models and strategies</p> <p>The impact of national policies, international trade and treaties, and economic growth on health care innovation and entrepreneurship</p>	<p>Introduction to course. The healthcare sector has a peculiar set of economics and a commercial dynamic unlike any other sector. This session will describe the nature of the industry and what it means to entrepreneurs.</p>	<p><b>NOTE: Each session has an A and a B part with separate readings for each part</b></p> <p><b>Textbooks:</b>  <b>Mehta:</b>            Chapters 1 and 2, pages 1 to 60; chapter 3, pp. 63 to 103</p> <p><b>Burns:</b> Chapters 1 and 5  <b>Instructor slide set</b>  <b>Deliverables: None</b></p>
<p><b>2</b></p>	<p><b>Opportunity Analysis: the interplay of healthcare sectors and an introduction to intellectual property</b></p>	<p>This session will demonstrate how opportunities emerge, how they can be analyzed, and assessing the requirements for making opportunities real. Review of paradigms, inventories and strategies for rigorous assessment of technology and associated due diligence.</p>	<p><b>Textbooks:</b></p> <p><b>Mehta</b>, Chapter 4, New Product Development, pages 104 to 171</p> <p><b>Burns</b>, Chapter 2</p> <p><b>Instructor slide set</b>  <b>Deliverables: Project Proposal (see Section 4.2 in syllabus)</b></p>
<p><b>3</b></p>	<p><b>8:15 to 9:30:</b></p> <p><b>Building the Health Care Venture Business Plan and Navigating Regulated</b></p>	<p>This session will describe the disciplines, style, research and presentations necessary to make a compelling case for a health-related venture. It will build upon general approaches to business plan construction.</p>	<p>Required Reading:</p> <p>Textbooks:</p> <p><b>Mehta</b>, Chapter 8, Manufacturing, pp 226 – 258.</p>



	<b>Markets</b>	Second half of class: Planning systems and strategies for managing regulatory and approval matters and the market and pricing implications. Planning systems and strategies for managing regulatory and approval matters, all illustrated by Case Study Discussion	<b>Burns</b> , Chapter 3  <b>Case Study: “A Father’s Love”</b> There is no discussion guide for this case. The issues are described in the final section of the case study – read these carefully and think about the implications.
<b>4</b>	<b>Fundamentals of Marketing in Bio-Medical Companies</b>  <b>and</b>  <b>Case Discussion “Deep Breeze Brings an Innovative Medical Device to Market”</b> A case produced by the INSEAD Israel Research Centre	This session will apply the fundamental principles of marketing to health related enterprises.  The points will be illustrated through a discussion of the Deep Breeze Case.	<b>Thoroughly Prepare Deep Breeze Case; see Moodle for discussion guide</b>  <b>Textbooks:</b> <b>Mehta</b> , Chapter 7, New Product Development, pages 264-313.  <b>Burns, Chapter 4</b>
<b>5</b>	<b>Strategic Alliances and Partnering</b>  <b>and</b>  <b>Case Discussion: Biocon</b>	In health related ventures, strategic alliances and partnering are essential to the development and growth for most enterprises. This session will describe the strategies, structures, pros and cons of alliances.	<b>Biocon Case Study</b> on Moodle; see also sheet on issues  Textbook: <b>Burns</b> , Chapter 6

	<p><b>Oral Insulin</b></p> <p><b>and</b></p> <p><b>Health Care Innovation in the Emerging Markets: The Cases of India, China and Brazil</b></p>	<p>A Case Study, Biocon, will be used to illustrate some of the principles.</p> <p>The session will end with a survey of activity in the emerging markets.</p>	<p>Any one of the papers from <i>Nature Biotechnology</i> on Brazil, China, India or South Africa (see Virtual TAU – Library – “Cool Stuff on Emerging Markets” file)</p> <p><b>Deliverable:</b> Submit two to three page detailed project outline</p>
<p><b>6</b></p>	<p><b>Financing the health related venture</b></p>	<p>Health ventures have unique capitalization issues. Milestone preparation, capital needs analysis, the application of valuation methodologies, and the long-range capitalization strategies require special insights, planning and negotiation. Investors in health care ventures must examine issues unique to the domain, such as managed care insurance, physician influences, and FDA regulation. Session will demonstrate tools for assessing needs vis-à-vis strategy</p>	<p><b>Textbooks:</b></p> <p><b>Mehta</b>, Chapter 7, pp 264 – 313</p> <p><b>Burns</b>, Chapter 8</p> <p><b>Instructor slides</b></p>