MIB Trieste School of Management

VENTURE FACTORY

The European House Ambrosetti

EXECUTIVE MBA IN BUSINESS INNOVATION

1st EDITION (2020 – 2022)

COURSE SYLLABUS

De-Risking Investments in Medical Innovation

SUPERVISOR

Luigi Negri

MIB Trieste School of Management

De-Risking Investments in Medical Innovation

Supervisor and Lecturer

Luigi Negri
E-mail: luigi-negri@UIOWA.edu
Office Hours: by appointment through www.luigi.thinkeen.com

Course Duration: 2 Full Days

Credits: ???????

Lecturer's profile

Luigi is Managing Partner at Thinkeen® Global Consulting, specializing in global business strategy for the Life Science industry, which he founded in early 2013. Through its international partners and offices, the firm focuses on global market access for the life science industry and on the valuation of innovative medical start-ups. In the previous twenty years, Luigi has succeeded in several international corporate assignments with both commercial and general management responsibilities in the biotechnology and medical devices industry across multiple global corporations. These included VP Northern & Central Europe for CR Bard, VP-GM Emerging Markets of Latin America at Baxter Health Care, Area GM for Poland & Russian Federation at Baxter Health Care . Luigi holds a MS in Engineering from the University of Bologna (Italy) and an MBA from the University of Kansas: he is currently a December 2022 doctoral candidate in Managerial Economics at Bocconi University and Adjunct Professor of Entrepreneurship and Marketing at University of Iowa's Tippie College of Business.

Course Objective

This course aims to give students the fundamental tools to approach the challenges of medical innovation. It is focused on providing both a basic understanding of the life science industry and the specific tools to analyze and successfully manage medical innovation.

Students will be confronted with the entrepreneurial challenge of reducing the very high risk of failure in medical innovation. The course aims to provide a practical understanding of the managerial issues underlying high failure rates and thus provide the tools necessary to address the same issues and maximize the likelihood of success.

This course and the managerial tools provided are specifically designed for medical entrepreneurs with the ultimate goal of maximizing both the probability of venture success and the venture value, while delivering reliable, credible financial valuations. The underlying philosophy consists in providing fact-based, rational decision-making approaches by extending the use of the scientific decision-making method typically restricted to the clinical field.

Course Contents

The course covers the following topics and assignments:

- Key Industrial confines and Definitions: i.e. Life Science vs. Health Care. i.e. MedTech vs. BioTech vs. HealthTech.
- Understanding the medical terms required by life science entrepreneurs.
- Global challenges of health care.
- Global trend in life science innovation.
- Identification of key health care stakeholders and their interactions.
- How public health systems function.
- Fundamentals of health technology assessment.
- Fundamentals of clinical trials and clinical decision making.
- Scientific approach to entrepreneurial decision making in medical innovation.
- Ethical issue of medical innovation.
- Causes of failures in medical innovation.
- Mapping and prioritizing all key decision problems in medical innovation
- assessing unmet medical needs and potential markets
- Defining Target Product Profile & assessing value proposition fit for medical devices
- Ensuring sustainable competitiveness in medical innovation
- Assessing barriers to entry in medical innovation
- Fundamentals of global segmentation, targeting & positioning for medical entrepreneurs
- Designing a global business model for medical innovation
- Assessing financial viability and value of medical ventures
- Grading business plans of medical ventures

Calendar

The course is structured in 4 (four-hour) training sessions:

1. **September 23rd 2022 (Morning)** – The Fundamentals of the Life Science Industry: definition of the relevant industrial sectors. Essential medical terminology for the life science business. Global Health Challenges. Global Innovation trends in Life sciences. Why medical innovation is challenging. Public Health Systems. Key health care Stake Holders, their incentives and mutual interactions.

2. **September 23rd 2022 (Afternoon)** – Basic notions of Health Technology Assessment. Fundamentals of Clinical Trials & Clinical Decision Making. The ethical aspects of entrepreneurial claims. Other key ethical aspects in the life science business. Applying the scientific method to entrepreneurial decision-making in life science ventures. Designing experiments for entrepreneurial decisions.

3. **September 24th 2022 (Morning)** – Causes of medical venture failures. Building a Map of Decision Problems for Medical Innovation. Prioritizing decision problems in medical innovation. Assessing Unmet Medical Needs & Market Attractiveness. Target Product Profile: product readiness, strengths, and accountabilities. Value Proposition Fit in medical innovation. Creating sustainable competitiveness in medical innovation.

4. **September 24th 2022 (Afternoon)** – Medical Innovation penetration challenges: the Status Quo. Global segmentation, targeting & positioning for therapies and diagnostics. The design of a global business model for new medical products. Forecasting Future Revenues and de-risking venture valuations. Critical evaluation of a new venture's business plan in life science.

Teaching Methods

The course will use a variety of methods, including lectures, case study discussions, and simulations. Reading the assigned material is required, and preparation for case presentations is essential. A willingness to discuss, critique, and challenge views is also necessary. Selected strategic cases cover a wide variety of situations and issues.

Ethics, Responsibility and Sustainability Issues

The social costs of the high failure rates of medical startups exceed by far the costs supported by the many entrepreneurs and investors who -too often- see their ventures literally disappearing before a commercially compelling product is made available. These very high social costs are liked to the medical nature of life science innovation: we have all recently witnessed the role that speed of medical innovation has played in our society during the COVID pandemic.
The frequent failures in predicting the actual value of medical innovation ventures seem to be linked to entrepreneur's cognitive biases, intellectual attitudes that short-cut the search for thorough information, reducing rational assessment in decision making (Kuntze and Matulich 2016). One possible structural cause can be found in entrepreneurs' motivations: contrary to managers of publicly traded companies who have the clear responsibility of maximizing shareholder value, entrepreneurs build their business to fulfill personal goals and normally aggressively seek investors to enable this fulfillment (Bhide 1996).

Starting from the explanation of this entrepreneurial ethical dilemma, the course focuses on familiarizing with a decision making process based on facts, experiments and rational decisions. In particular, the course tailors the process of scientific decision-making to the specific needs of medical innovation. Moreover, the course highlights the social responsibility of entrepreneurs whose impact is not limited to investors and employees but includes patients, their families, and even the wider credibility and financial attractiveness of medical innovation.

Course Intended Learning Outcomes

By the end of this course, students will be able to achieve these Intended Learning Outcomes (ILOs):

- ILO1. Learning the fundamental terminology and stakeholders of the life science industry while understanding the key challenges of innovation ventures.
- ILO 2. Learning how to use the scientific method to approach and solve high-priority problems in medical entrepreneurship.
- ILO 3. Mapping and analyzing the critical decision problems encountered by entrepreneurs in medical innovation.
- ILO 4. Learning how to build fact-based forecasts of future revenues and how to build credible venture valuations.

Contribution of the course to MBA generic target competences

This course will contribute to developing the participants' Analytical and Critical Thinking in Problem Solving focused on the life science industry. The course provides an additional view in the field of entrepreneurial feasibility analysis.

Grading and Assessment

Course grade: components and weights
The achievement of the expected, intended learning outcomes will be measured through two distinct sets of assignments:

20% Daily End-of-class Short Multiple ChoiceTest

20% Class participation

60% Final individual Open-Ended Exam

How Assessments combine with the Course ILOs

	Course's ILOs			
Assessments	ILO 1 Learning the fundamentals: terminology and stakeholder interactions	ILO 2 Using the scientific method to solve entrepreneurial problems.	ILO 3 Mapping and analyzing the critical decision problems in medical innovation.	ILO 4 Forecasting future revenues and building credible valuations of medical ventures.
Understanding the Fundamentals (end of Day 1)	V	V		
Mapping Decision Problems (end of morning of Day 2)			V	
Final Assignment	V	V	V	V

Teaching Materials

The course is based on a blend of materials, ranging from articles, teaching notes, and PPT presentations.

Here below a list of pre-readings:

TEACHING SESSION	TYPE OF READING: Articles
Day 1	Careers at Biotech Start-Ups and in Entrepreneurship
Day 2	Medical Device Innovation in the Era of the Affordable Care Act How to start a biotech company

Workplan

TIME-FRAME	ACTIVITY	DESCRIPTION AND READINGS
23/09/2022 9.00 – 13.00	**Fundamental concepts for the Life Sciences Industry** Lecturer: Luigi Negri	The Fundamentals of the Life Science Industry: definition of the relevant industrial sectors. Essential medical terminology for the life science business. Global Health Challenges. Global Innovation trends in Life sciences. Public Health Systems. Key health care Stake Holders, their incentives, and mutual interactions.
23/09/2022 14.30 – 18.30	**Decision-Making Methods for Life Sciences Entrepreneurs.** Lecturer: Luigi Negri	Basic notions of Health Technology Assessment. Fundamentals of Clinical Trials & Clinical Decision Making. Applying the scientific method to entrepreneurial decision-making in life science ventures. Designing experiments for entrepreneurial decisions. The ethical aspects of entrepreneurial claims. Other key ethical aspects in the life science business.
24/09/2022 9.00 – 13.00	**Mapping & Prioritizing Decision Problems for Life Sciences Entrepreneurs** Lecturer: Luigi Negri	Causes of medical venture failures. Building a Map of Decision Problems for Medical Innovation. Prioritizing decision problems in medical innovation. Assessing Unmet Medical Needs & Market Attractiveness. Target Product Profile: product readiness, strengths and accountabilities. Value Proposition Fit in medical innovation. Creating sustainable competitiveness in medical innovation.
24/09/2022 14.30 – 18.30	**Predicting and Maximizing Venture's Value.** Lecturer: Luigi Negri	Medical Innovation adoption: the Status Quo. Global segmentation, targeting & positioning for therapies and diagnostics. The design of a global business model for new medical products. Forecasting Future Revenues and de-risking venture valuations. Critical evaluation of a new venture's business plan in life science.