

DESIGNING & IMPLEMENTING GAME CHANGING STRATEGIES FOR LIFESCIENCE

Lifescience Zone[®]

Powerful Business Education

Bio-Entrepreneurship

De-Risking Investments
in Medical Technology Innovation

Strengthening decision making and valuation
accuracy in seed and pre-seed
MedTech & HealthTech startups.

Bio-Entrepreneurship

Bio-entrepreneurship refers to the process of creating, developing, and managing new ventures or innovations in the field of life sciences, particularly those involving biotechnology, pharmaceuticals, medical devices, diagnostics, and health-related technologies.

Medical Technology

Medical technology refers to the tools, equipment, procedures, and systems used to prevent, diagnose, monitor, and treat diseases and medical conditions in human beings. Medical technology encompasses a wide array of tools and systems designed to enhance healthcare delivery, spanning several key categories. Medical devices include instruments such as pacemakers, infusion pumps, ventilators, and surgical robots, which are essential for supporting and restoring vital bodily functions. Diagnostic tools enable the detection and evaluation of medical conditions and include technologies like MRI machines, blood glucose meters, and genetic testing platforms. Therapeutic equipment such as radiation therapy machines, dialysis units, and laser surgical tools

is used to treat a variety of diseases and conditions. Monitoring tools—including wearable devices like heart rate trackers, as well as ICU monitors and Holter monitors—allow for continuous observation of patients' vital signs. The rise of digital health tools has introduced innovations such as mobile health applications, telemedicine platforms, and AI-based diagnostic algorithms, which support both clinicians and patients in managing care remotely and efficiently. Lastly, implants and prosthetics, including cochlear implants, orthopedic prostheses, and intraocular lenses, play a crucial role in restoring function and improving the quality of life for individuals with specific medical needs. Together, these technologies form the backbone of modern healthcare infrastructure.

De-Risking Investments in Medical Technology innovation

High failure rates of medical startups tend to discourage many potential investors, depriving the sector of precious financial resources. In the last two decades, managing early-stage medical technology ventures hasn't become easier: It still involves dealing with considerable complexity due to various factors, including the difficulty of predicting the behavior of numerous stakeholders with conflicting priorities, the stretched breadth of competencies required of medical entrepreneurs, and the ever-accelerating rate of growth of global medical knowledge. Medical entrepreneurs and innovators are required to make precise predictions and decisions in an extremely complex, uncertain environment, which poses specific challenges to the accuracy of decision-making and, ultimately, to the prediction of a medical innovation's economic value and the actual investment risk. These decision-related challenges strongly threaten entrepreneurial accountability, particularly the ability to deliver unbiased predictions of future adoption dynamics and, in turn, the capacity to craft and execute adequate monetization strategies.

This course was designed to offer practical solutions to entrepreneurs and investors in the medical field. It proposes an efficient, pragmatic approach to decision problem identification and solution based on essential research findings that have been tested with medical innovation startups in real-life settings. Research has shown that a scientific approach to decision-making can enable entrepreneurs to make better predictions while testing and launching their business ideas (A. Camuffo et al. 2019). It has also proven that a scientific approach can not only mitigate the cognitive biases that influence entrepreneurs' ability to efficiently collect, prioritize, and process the critical market information required for estimating the actual value of their product ideas (Cohen et al., 2019), but also provide them rational support while making important decisions (A. Camuffo et al. 2020; Kahneman, Lovallo, and Sibony 2019).

The use of this scientific approach to decision-making was tested by the author with early-stage medical innovation startups in the real world, verifying and validating the expected outcomes. Based on the knowledge gained through this fieldwork experience and the adaptability of the methodology to industry specificities, this course provides practical tools to both medical entrepreneurs and investors



seeking to maximize their probability of success by employing a scientific approach to decision-making. While presenting the fundamentals of the application of the scientific method to decision-making, the course also cites some examples and outlines ideas on how medical entrepreneurs can field-test some of the most common assumptions and decisions.

Centered on the application of the scientific approach, the methodology recommends the use of a map that visually frames and connects the numerous decision-related issues typical of medical innovation. This map is a valuable visual tool that guides the identification of all critical decision-related problems, adding efficiency and real-life usability to the methodology. Furthermore, the course suggests and exemplifies ways to implement selective prioritization and identification of the mapped decision-related challenges. Indeed, the author's fieldwork experience revealed that the application of the scientific approach to decision-making exhibits greater efficiency when it is selectively applied to a few decision-related issues in each phase of a startup's development.

The student will find practical tools that help navigate the entrepreneur's decision map and rapidly identify critical problems: those inhabiting the critical path that begins with an innovative idea and ends with the highly sought-after monetization. Addressing these problems with high-quality decisions can make the difference between successful value creation and expensive failure. Any medical venture that applies the suggested approach can expect to witness what both our field tests and the broader research have demonstrated. Compared to ventures that do not employ the scientific approach to decision-making, early-stage medical startups using the proposed methodology are:

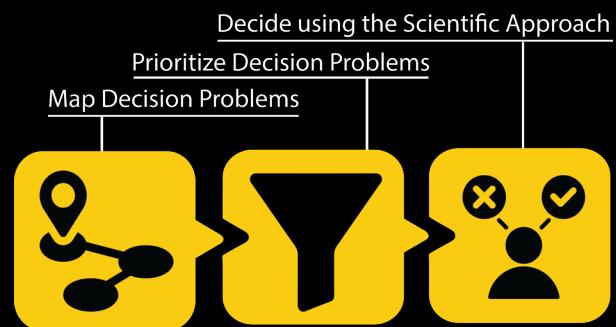
- Less likely to linger on projects that should be terminated
- More likely to make a timely exit
- More likely to pivot than not
- More likely to focus on only a small, manageable number of critical pivots and, therefore
- More likely to enjoy higher and earlier revenues

In summary, this course presents medical entrepreneurs, innovators and investors with an entirely new, efficient, and guided approach to decision-making: a methodology that is based on the latest scientific evidence and successfully tested in real-life.

The Approach to Entrepreneurial Decisions Process

The medical entrepreneur always starts with an idea about a possible innovation: this idea is likely to require a significant commitment of resources in the hope of an attractive but highly uncertain outcome in the future. At the earliest stage, the idea is still a draft vision, and it does not contain precise details such as the entire set of therapeutic features and indications or all the diagnostic targets and performances of the new medical solution.

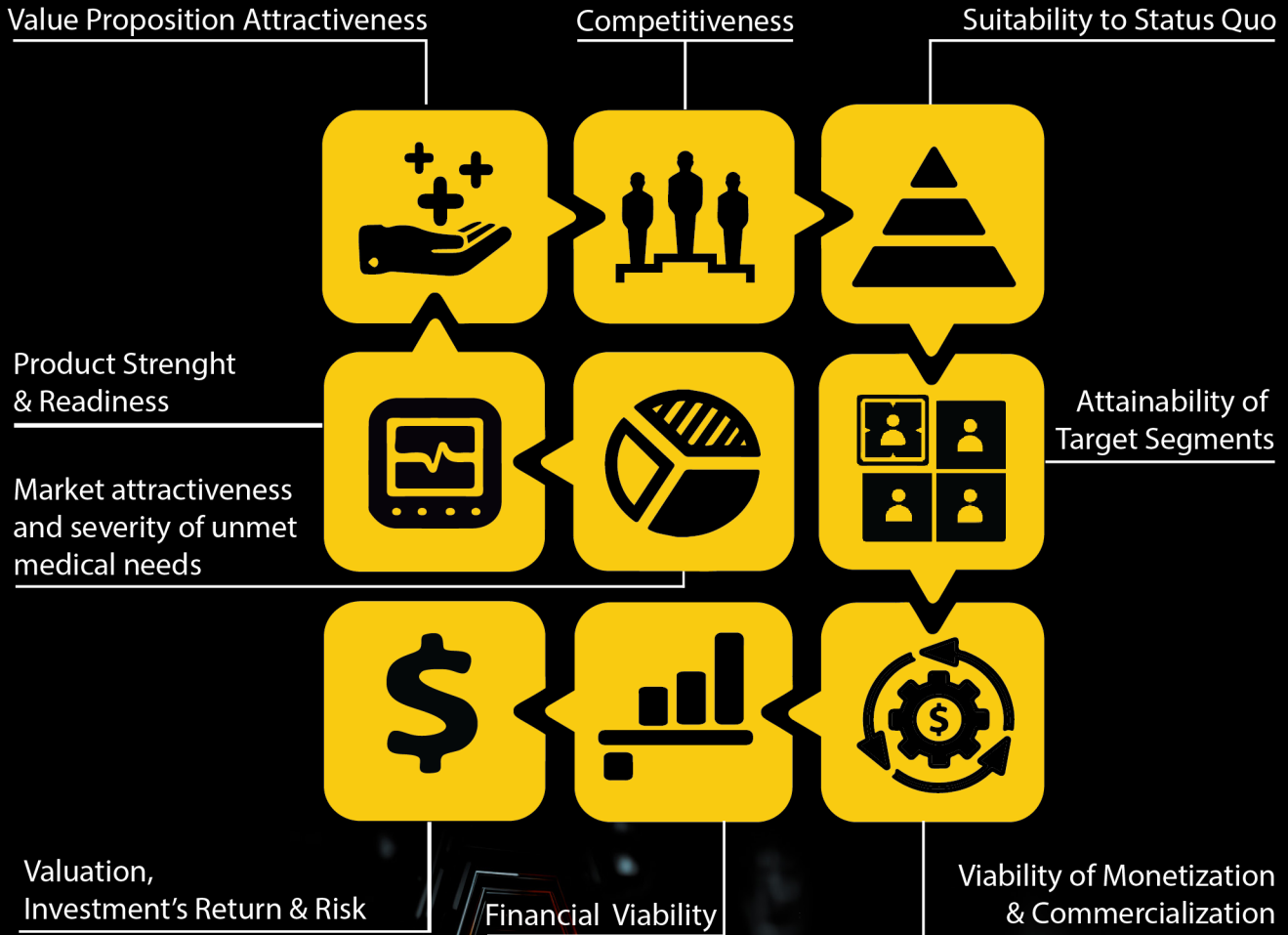
The process proposed in this course focuses on the decision-related problems that become relevant after the new medical idea is made explicit. In particular, it suggests using three sequential steps: mapping decision-related problems, prioritizing them, and using the scientific approach to address each prioritized problem.



The Decision Making Map

Cognitive psychology has shown that the mind best understands facts when they are woven into a conceptual fabric, such as a narrative, mental map, or intuitive theory. Disconnected facts in the mind are like unlinked pages on the web; they might as well not exist (Steven Pinker). This part of the course focuses on building a rationally organized map of the key, in

terconnected decision-related problems in medical innovation. The map of entrepreneurial decisions is a valuable visual tool that guides the identification of all critical decision-related problems, adding efficiency and real-life usability to the methodology. Each of the 9 decision clusters represents the tip of the hierarchical framework of less complex decision problems.



Prioritizing Business Decision Problems

Once the mapping process is thoroughly completed, the medical entrepreneur can finally refer to a complete chart in which important problems related to decisions and assumptions are visually linked and grouped in clusters. Understandably, the numerous, interrelated, and competing decision-related problems can disorient any decision-maker. The constrained resources of early-stage medical ventures do not allow a concurrent approach to multiple decision-related problems; therefore, it becomes necessary to prioritize and target all mapped problems. In other words, the entrepreneur must strive to make rational and explicit decisions about which problems to prioritize at any given time. We have observed several medical startups through this process, and we have learned that it is essential to recall this prioritization across decision-related problems:

- It is not a one-time, initial duty but a recurring process throughout the startup lifeline.
- It is not intended to exclude any problem from the map but to allow, over time, the identification of the most critical ones.

Sooner or later, all the map's decision-related problems will be confronted throughout the venture's path to commercialization.

They will acquire a different priority level in different steps of the venture's development. Prioritization of decision-related problems represents an ongoing, cyclical, and necessary effort to ensure that relevant decisions are promptly addressed and that the venture's constrained resources are rationally allocated.

In contexts of high uncertainty, such as the ones faced by medical startups, practitioners may be attracted by fast, instinctual prioritization approaches and dismiss the discipline required by a rational prioritization approach. Field experience has taught us that a rational approach is more necessary in contexts of great degrees of uncertainty. A constant tension toward rational decision-making remains necessary even when entrepreneurial perceptions of uncertainty suggest the use of "common sense" approaches.

Employing the Scientific Approach for Business Decisions

A scientific approach can not only mitigate the cognitive biases that influence entrepreneurs' ability to efficiently collect, prioritize, and process the key market information required for estimating the actual value of their product ideas (S. L. Cohen, Bingham, and Hallen 2019) but also provides them rational support while making important decisions (G. Camuffo 2019), (Kahneman, Lovallo, and Sibony 2019).

A scientific approach to decision-making better positions entrepreneurs to assess the value of their innovative ideas and make better decisions about future steps pertaining to their venture. This part of the course examines its precise prescriptions in the context of medical technology innovation. It focuses in greater detail on each of the six steps of decision-making using the scientific method:

1. identifying scenarios,
2. identifying actions,
3. mapping values in scenario-action pairs,
4. developing testable hypotheses,
5. testing hypotheses, and
6. making a decision.

The ability to design efficient experiments to test business assumptions is one of the most creative skills developed throughout this course.



COURSE CONTENT

Part 1. Context & Definitions

- Section 1.1. Definitions
- Section 1.2. The critical role of Valuation in Medical Innovation

Part 2. Why Medical Innovation is so Difficult

- Section 2.1. Medical Innovation holds specific complexities for decision-makers
- Section 2.2. Defining Medical Startup Failure
- Section 2.3. The cost of failure in medical innovation
- Section 2.4. The role of Biased Decision-making in startup failures
- Section 2.5. The Financial Risk of Medical startups

Part 3. The Methodology

- Section 3.1. Predictive vs. Non-Predictive Approaches
- Section 3.2. The Role of the Scientific Method
- Section 3.3. The Methodology's Vocabulary
- Section 3.4. The Methodology's Steps

Part 4. Mapping Decision Problems in Medical Innovation: the K9 Map

- Section 4.1. Why Mapping Decision Problems
- Section 4.2. Building a Value-centric Map for Medical innovation

Part 5. Prioritizing Business Decision Problems

- Section 5.1. The Theory: Using Prioritized Multicriteria
- Section 5.2. The Practice: A More Practical Visual Method

Part 6. Business Decision Making using a scientific Method

- Section 6.1. The Scientific Method for decision making
- Section 6.2. Real Life Examples from Medical Technology
- Section 6.3. More Complex Decision Trees & Alternative Options

Part 7. Deep-Dive into the Map of Decision Problems

- Section 7.1. Market Attractiveness & Unmet Medical Needs
- Section 7.2. Medical Product's (or service) Strength & Readiness
- Section 7.3. Value Proposition Attractiveness
- Section 7.4. Competitiveness
- Section 7.5. FIT to Status Quo
- Section 7.6. Segmentation, Targeting & Positioning
- Section 7.7. Business Model, Organization & Competences
- Section 7.8. Cash Flow & Financial Viability
- Section 7.9. Valuation & Exit



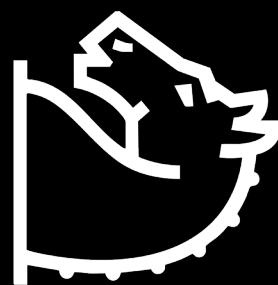
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Luigi Negri

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