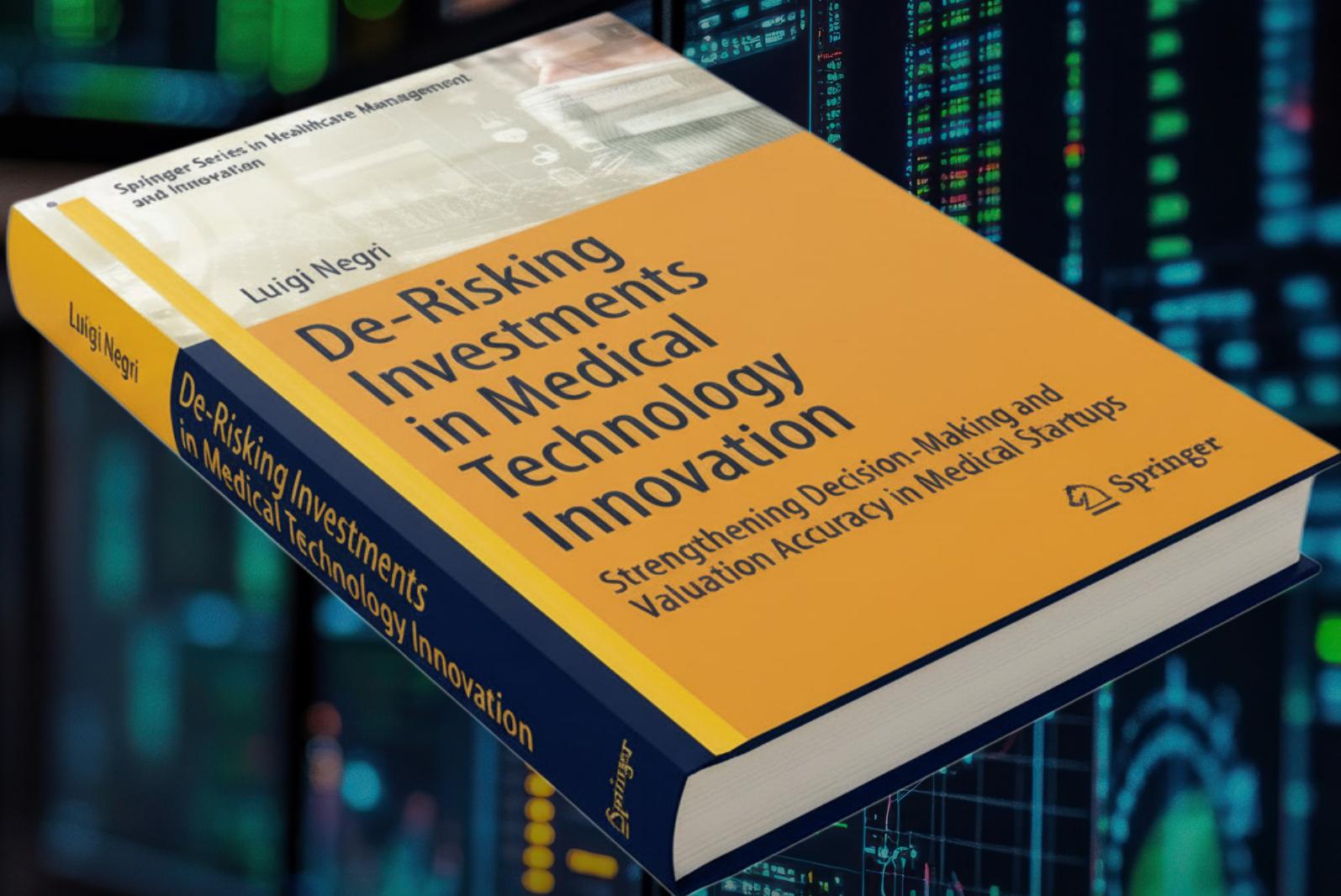




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Rethinking Bio-Entrepreneurship

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 devic-

es 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 book 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 book 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 book 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 book 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 reader 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:

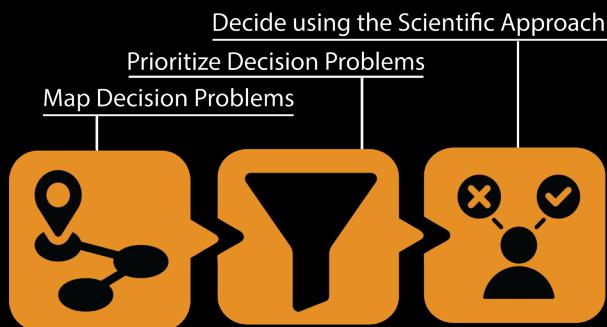
- Less likely to linger on projects that should be terminated
- More likely to make a timely exit
- More likely to pivot than not
- More likely to focus on only a small, manageable number of critical pivots and, therefore
- More likely to enjoy higher and earlier revenues

In summary, this book 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 field-tested process proposed in this book 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 book 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, Birmingham, 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 book 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 book.



BOOK CONTENT

1. **Introduction**
2. **The Vocabulary of Medical Ventures: The Anatomy of Success and Failure**
 - 2.1. Medical Innovation
 - 2.2. Failure of a Medical Startup
 - 2.3. Threats to Valuation Precision and Accuracy
 - 2.4. New vs. Innovative Medical Ideas
 - 2.5. Investigations vs. Decisions
 - 2.6. Decisions vs. Scenario Decisions
3. **Why Medical Innovation Is so Difficult**
 - 3.1. The Complexities of Medical Innovation
 - 3.2. The cost of failure in medical innovation
 - 3.3. Decision-making and Medical Startup Failures
4. **Minimizing Decision-making biases**
 - 4.1. Predictive vs. Non-Predictive Approaches
 - 4.2. The Role of the Scientific Approach
 - 4.3. The Scientific Approach alone is Not Enough
 - 4.4. The Stage & Gate Model Suggests Using a Sequential Map
 - 4.5. The Proposed three-step method
5. **Decision-Making using a Scientific Approach**
 - 5.1. The Scientific Approach to Decision-Making
 - 5.2. Endpoints and Benchmarks of the experiment
 - 5.3. More Complex Decision Trees
 - 5.4. Pivoting
 - 5.5. Real-Life Examples
6. **Mapping Decision-Related Problems in Medical Innovation**
 - 6.1. The importance of Mapping Decision-related Problems
 - 6.2. Building a Value-centric Map for Medical Innovation
 - 6.3. The Key Nine Clusters: The “K9 Map”
7. **Deep-Dive into the Mapping of Decision-Related Problems**
 - 7.1. Market Attractiveness and Unmet Medical Needs
 - 7.2. Product Strength And Readiness
 - 7.3. Value Proposition Attractiveness
 - 7.4. Competitiveness
 - 7.5. FIT to Status Quo Error! Bookmark not defined.
 - 7.6. Attainability of Target Segments
 - 7.7. Viability of Monetization and Commercialization
 - 7.8. Financial Viability
 - 7.9. Valuation, Investment Return, and Risk
8. **Prioritizing Decision-Related Problems**
 - 8.1. The importance and the principles of decision problem prioritization
 - 8.2. The theory behind the Practice



When Great Science Meets Good Business Decisions

By [Luigi Negri](#) for Forbes Business Council

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Across the life sciences industry, innovation is advancing at record speed. Artificial intelligence assists in diagnosis, sensors predict chronic disease before they occur and surgeons collaborate through augmented-reality platforms. Yet behind these impressive breakthroughs lies a sobering truth: 65% to 75% of medtech startups fail. This is often not because their science is weak, but because their decisions are. For every successful implant, diagnostic or digital-health platform that reaches the market, dozens vanish in the valley of death between invention and adoption. The root cause is not merely capital scarcity or regulatory complexity. It is how founders, boards and investors assess assumptions, allocate resources, interpret uncertain evidence and, finally, make decisions.

When Great Science Meets Poor Decisions

Highly specialized organizations are not immune to poor business decisions that compromise the future adoption of great science. Even well-funded multinational corporations with multiple layers of expert committees frequently make misguided bets.

The same pattern repeats in startups, but biased decisions are more fatal. In early-stage medical ventures, a scientist with a novel idea must act as a technologist, marketer and financier simultaneously. He or she must decide when an idea is good enough to form a company, justify valuation to investors and forecast clinical milestones, adoption curves and reimbursement probabilities—often with minimal data. Under this kind of pressure, intuition usually replaces both rationality and a disciplined search for evidence. Entrepreneurial optimism negatively affects the overall startup's performance. As a result, ventures tend to either over-promise to investors or under-deliver to patients and markets. The discipline of the scientific approach to clinical decisions is too often left in the lab (or in the clinical trial phases), so the same discipline that governs good science is hardly used to govern good business.

Taking The Scientific Method Beyond The Lab

The scientific method is humanity's most reliable tool for reducing uncertainty. It requires formulating hypotheses, testing them through experiments and interpreting the results rationally. When applied to management, it helps entrepreneurial management to move from acts of faith toward a more disciplined process of learning. Researchers at Bocconi University demonstrated this concept through randomized controlled trials involving hundreds of entrepreneurs across multiple industries. Those trained to think like scientists—to define falsifiable hypotheses about their markets and test them rigorously—were faster to abandon doomed projects, pivot effectively and reach profitability. The results were striking: companies that embraced the scientific approach were more likely to pivot early, exit on time and achieve higher revenue. Those clinging to intuition persisted longer in error.

Decision-Making As A Discipline In Medical Technology Innovation

My partners and I have put the above-mentioned theory to work in the context of medical technology startups and confirmed the Bocconi University findings. We observed that, when founders and executives structured their decisions scientifically—identifying assumptions, testing them and adjusting

accordingly—the quality of business outcomes improved dramatically. These results encouraged the development of a methodology specifically tailored to medical startups: a three-step framework for de-risking investments in medical technology innovation.

1. Map decision-related problems. Every startup faces hundreds of interconnected uncertainties: unmet medical needs, product readiness, value-proposition attractiveness, competitiveness, reimbursement viability, financial sustainability and more. To make the most effective decisions that best address these uncertainties, leaders need to understand how everything is connected. One approach is to draw a physical map that clusters together related concerns and challenges. These clusters can help leaders identify the most critical decisions and address those first, rather than just reacting to the loudest crises.

2. Prioritize the critical few. Limited resources mean not every question can be investigated simultaneously. The priority must go to the problems that combine high impact on venture value and high uncertainty. In early stages, this often involves proving genuine innovation (not incremental improvement), establishing adoption economics and clarifying the payer's incentive.

3. Apply the scientific method to each key decision. For every high-priority issue, formulate testable hypotheses, design small-scale experiments (e.g., targeted clinician interviews, pilot trials or simulated price-focused purchasing scenarios) and base go/no-go decisions on empirical results rather than enthusiasm.

We have witnessed how this approach encourages realism over romanticism. It does not demand years of research but only discipline in how evidence is gathered, interpreted and used to decide.

The startup world's most-known slogan, "Fake it until you make it," may suit social media apps, but it is reckless in healthcare. Patients, regulators and investors cannot afford confidence unsupported by data. A more sustainable mindset is: "Think rationally first, so you are more likely to make it later." This philosophy fosters accountability. Every assumption—about satisfaction of unmet medical needs, clinical adoption or market size—becomes a hypothesis to test, not a belief to defend.

Why This Matters For Investors

For venture capitalists and corporate investors, adopting a scientific lens can dramatically improve portfolio outcomes. When evaluating proposals, investors should ask not only "What is the market size?" but also: "How was this estimate tested?" They should examine whether assumptions have been validated through real-world experiments—such as interviews, pilots or early sales—not just desk research. In my consulting experience, funds that apply such scrutiny consistently allocate capital more efficiently and identify non-viable projects earlier, freeing resources for stronger bets.

A Framework For A Smarter Future

Medical technology has never lacked either creativity or purpose. What it has lacked is discipline in non-clinical decision-making—the ability to question assumptions with the same rigor used to test a new molecule or device clinically. Ultimately, the mapped, prioritized employment of the scientific approach is not about reducing risk to zero—innovation will always involve uncertainty—but about transforming uncertainty into knowledge.

In my experience, this approach has proven its worth. Ventures using it show faster proof-of-concept development, better market-entry performance, stronger cash positions and a higher probability of attracting third-party investment.

Authors



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These positions included VP of Northern & Central Europe for Becton Dickinson® (CR Bard), VP of Emerging Markets of Latin America at Baxter Health Care, and Area General Manager for Poland & Russian Federation at Baxter Health Care®.

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