

The Value Creation Roadmap for Medical Technology Innovation

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Translating clinical research and medical technology innovation into a sustainable company is a complex and far-reaching process. First-time entrepreneurs, clinicians, and engineers often don't appreciate the importance of the many factors involved—most medical startups fail to commercialize their product and many critical solutions never reach patients. Emerging companies in other sectors face technical and market risks, but medical innovation includes the barriers of regulatory approval, reimbursement, clinical trials, and a complex sales channel strategy.

A comprehensive strategic and tactical roadmap for medical innovation is key to successful commercialization. The sooner this can start, the better—adhering to a roadmap throughout the funding process largely determines long-term success. Thinking through the complete sequence of ideation, development, approval, and commercialization will help decrease “risk-attracting” capital and increase “smart money.” There are key inflection points and decision tradeoffs to consider along the way. Recognize the elements representing a more comprehensive Medical Technology Value Creation Roadmap when developing a plan—the 12 Roadmap Factors of comprehensive medical technology; identifying risks, key inflection points, and decision tradeoffs; dealing with the major changes in healthcare market dynamics; and constructing a financing plan with the best chance for success.

Every medical device startup should build The Roadmap to create value and reduce risk. It highlights the most common factors for success and helps develop a successful business plan:

1. The clinical need to be addressed or the problem you are solving
2. Defining the proposed solution and how it addresses the clinical need
3. Can this proposed device solution be developed? Is the technical risk high?
4. Clinical requirements and options

5. Intellectual property and freedom to operate
6. The total available market, the portion served, and the projected share
7. The go-to-market path to maximize value creation
8. Manufacturability and is it scalable?
9. Reimbursement and payment path
10. Executive team experience and breadth
11. A comprehensive business plan
12. A milestone-based financing strategy

Each of these is important to understand and represent where investors “risk reduce” startup valuations to protect investments. Valuation may reduce for novel technology without a good pre-clinical model to prove feasibility and if you don't convey the importance of “first-in-man” clinical trials. A business plan lacking a recurring revenue model or a flawed strategy to obtain a new CPT code may also reduce value. Each Roadmap Factor should include detailed “deep dives” to ferret out and address gaps. These should relate chronologically to the funding process and valuation milestones and highlight key inflection points and decision tradeoffs.

Most startups understand the presence of risks, but often resources and expertise are limited and sometimes compromises are made or short cuts taken in the name of capital efficiency. Analyzing risks in detail and in light of key inflection points informs better business decisions and tradeoffs.

To build credibility as a viable medical device company, demonstrate understanding of the unique risks, recognize risk reduction is essential to building value, and have a plan to mitigate these risks. Besides obvious technical risks, there are intellectual property, clinical, regulatory, reimbursement, commercialization, marketing, financing, manufacturability/scalability, business strategy, and executive management team risks. Then, of course, there is always timing.

We've asked many startup CEOs, “knowing what you know now, would you go back and do it over again?” Many say no, partly because unaddressed risks accumulate. Risks must be evaluated, addressed, and retired from the beginning—a continuous and often tedious process. Consider the ophthalmology startup going to clinical trials prematurely and unintentionally injuring patients' eyes. Eventually, the executive team was ousted and the company re-capitalized.

Strategic Decision Tradeoffs

Whether a new regulatory plan, development tradeoff, or business pivot, a strategic decision often affects valuation. Strategic tradeoffs can shorten time to market, but also represent associated risks. Consider the imaging company run by researchers unwilling to hire an experienced CEO. Other examples include:

- When can the first-in-man trial in the clinical process be achieved? How effective will the solution be in humans vs. the associated health risks? What decisions can be made with limited clinical experience?
- How extensive must the clinical plan be? What are the critical endpoints?
- When to freeze a design vs. additional feasibility work?
- When to transfer company leadership to an experienced commercialization executive team?

Valuation Milestones

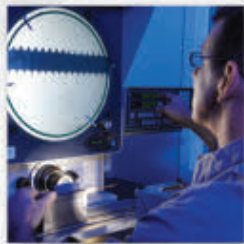
Performing to milestones increases credibility, but progress is often an iterative, discovery process with unpredictable outcomes. Investors understand this, but executive teams may not. A roadmap must accommodate these detours. Realistic gap analysis and achieving valuation milestones aids continued funding tranches. Milestones include defining the clinical need, proposed solution, and value proposition; achieving proof of concept and design freeze; KOL



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validation; intellectual property—patents filed, freedom to operate, patent issued; FDA approval; and finalizing the market strategy and integrated business plan.

Medical technology innovators must also consider major shifts in market dynamics. The healthcare industry is transitioning from a fee-for-service payment model to a value-based purchasing model.

Historically, physicians heavily influenced purchase decisions, fostering a “clinical progress at any price” mentality focused on improving clinical outcomes with little regard to costs. It was successful because fee-for-service payments were based on the physician making the primary purchase decision independent of various payers. As a result, many medical devices came to market with only incremental improvements. This is no longer the case.

With purchasing decisions shifting from physicians to integrated health systems and other payers, value-based purchasing

models are prevalent. A new medical device must clearly demonstrate measurable savings with acceptable or better patient outcomes. Understanding this transition can be a tremendous opportunity to correctly position new devices. Consider the diagnostic company providing early sepsis detection in a point-of-care instrument, preventing non-reimbursable hospital readmissions.

Medical technology entrepreneurs also face the challenges of securing investment capital. Careful up-front planning to create a financing plan linked to key milestones and risk reduction has the best chance of attracting investment, minimizing dilution, and optimizing value creation. The optimal capital structure determines the amounts and potential sources of financing required during various milestone-based funding tranches. Always develop the plan with a realistic, valuation endpoint in mind.

The business plan’s pro forma model should define investment amount and tim-

ing. Careful structuring in funding tranches around valuation inflection points majorly impacts risk reduction in future financing rounds. For example, achieving first-in-man to shorten the go-to-market time positively affects capital efficiency. Consider the non-invasive body sculpting startup proving feasibility in humans during Series A, reducing its largest risk.

Including as many Roadmap Factors early in fundraising activities demonstrates understanding of the complete medical innovation process to investors. Once listed chronologically, they can be linked to the various funding stages. All Roadmap Factors should be developed by the C Round.

Who are the best investors at various company development stages and what are they looking for? Although most startups don’t have the benefit of picking their investors, understanding the various groups’ investment criteria is important to create a financing path. Each has their own bench-

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marks of when they get involved, expected ROI and ownership percentages, typical investment amounts, and percentage of equity given up at various growth financing stages.

Develop a plan with the exit in mind and identify milestones that position the company for attractive exit options. There are two types of investors to consider. Strategic investors typically pay a premium and scale the business once validated in the market. Financial buyers, such as private equity funds with defined matrices based on established financial performance history, evaluate your ability to project future financial performance and milestone achievements.

Focus on Roadmap Factors and associated valuation milestones is warranted in light of frequent startup failures. Strategically addressing these factors lends credibility to an executive team and tactically increases the probability of success. A financing strategy built around a value creation roadmap creates a comprehensive plan for investors. Executive teams build trust and attract capital by understanding the healthcare environment and investor motivation.

We are passionate about this Roadmap approach based on over three decades of collective experience working with medical innovation companies. Most fail because founders, doctors, or engineers fail to recognize successful medical innovation as more than creating an important solution to an unmet therapeutic or diagnostic need. It requires understanding the full medical technology innovation and commercialization process, including handing over leadership to a commercialization team early. Consider three drug delivery device companies—one which raised \$70 million, one that achieved a \$300 million public valuation, and one that could not complete a C Round. All three failed primarily because the CEO and Board didn't understand this Roadmap. Hopefully this approach will be useful to those bringing important new products to market. ❖

Steve Maylish has been part of the medical device community for more than 30 years. He is currently chief commercial officer for Fusion Biotech, an Orange, Calif.-based contract engineering firm that brings together

art, science, and engineering to create medical devices. Early in his career, Maylish held positions at Fortune 100 corporations such as Johnson & Johnson, Shiley, Sorin Group, Baxter Healthcare, and Edwards Lifesciences.

Scott Hutchinson has been a financial advisor to growth companies in all aspects of financing, developing, and implementing value creation

strategies and M&A for more than 30 years. He has completed approximately 50 transactions representing \$600 million and over 50 financial advisory and consulting assignments. Hutchinson is currently focused on helping emerging medical device firms developing important solutions to unmet clinical needs prepare and secure institutional growth capital.

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