White Paper

Three High Risk Market Assumptions

(And How to Avoid Them)

Summary

Complex market dynamics have a profound impact on the commercial results experienced by medical products. Understanding these critical nuances will enable more effective growth strategies, helping deliver revenue expectations and maintain the confidence of investors and stakeholders.

Here are three common but dangerous market assumptions that can greatly undermine revenue growth for a medical technology.

Many compelling medical technologies never realize even a fraction of their full potential due to hidden but knowable market risks. According to one report, 88% of medical technology companies fail to deliver significant return to their investors.[1]

One of the major reasons companies fail to achieve their potential is that they try navigating the market by relying on historical experience, limited data, and intuition (the “golden gut”). While seasoned business leaders often have an innate ability to assess situations effectively and act decisively, even experienced executives are often unaware of market nuances that, if ignored, result in precious time and money wasted pursuing strategies that will never drive growth.

Chasing shadows

When a company encounters the inevitable market adoption and growth-related problems, a lack of reliable market analysis will lead to incorrect conclusions about cause and effect, resulting in

[1] Patient Capital, National Venture Capital Association's Medical Industry Group, at www.nvca.org

misdirected efforts to address the problems. Rather than a clear picture of the problems, leaders often see its shadow – a dip in sales, perhaps, or stubborn slow growth.

- In **companies with a commercial product**, this "chasing of shadows" frequently leads to a downward spiral of investor confidence, enterprise value, and available cash to fund growth. Without a turn-around, they may be forced to sell at a loss or close down.

- In **large companies**, struggling products may continue to be funded and will reach a plateau of sales far below their full potential. Business focus then shifts to other opportunities and the technology's unrealized potential remains untapped.

- In **pre-commercial companies**, decisions are made and capital spent based on assumptions about the market that can be far from reality. Entering the market without an appreciation of critical market realities threatens the entire enterprise. This can be readily avoided well before launch by developing a sophisticated understanding of how the market will respond, and why.

Here are three all-too-common assumptions that often result in failure to realize the full market potential of a medical technology. Read on to learn how to correct these assumptions, avoid chasing the shadows, and focus on conquering the *real* market challenges.

Three High-Risk Market Assumptions

1. **"I only need to know the rough size of the market."**
   Reality: Market size is a *dynamic response surface* – based on market characteristics, business models, and investment plans – rather than just a single number.

2. **"I need a really big market, in case I can only get a small piece."**
   Reality: You don't need a massive market to ensure a significant ROI for investors. However, you need to know the time, investment and revenue associated with key adoption inflection points in order to scale investments appropriately.

3. **"Once we launch, we will be able to drive growth quickly."**
   Reality: Early success does not reflect the realities of the total market. At launch, often less than 5% of the full market is accessible – potentially for many years.

1. A rough estimate of market size isn't enough

Many medical technology companies make decisions without an accurate assessment of the market. The attitude is, "even if we are off by a factor of four, it is still a great market." The reality is that market estimates are commonly off by a factor of 50 or more!

How can this happen? It is a direct result of the first troublesome market assumption: believing that market size is a single number, and that a rough estimate is sufficient. Some settle for a rough estimate because they believe that pinpointing the right number is impossible – and they are correct. The truth is, market size is the result of the interaction of many variables that all affect each other. Rather than searching for a number, market size is better understood through *response surface* analysis that factors in all these variables. In fact, the assessment that means the most to your company and your investors is **Annual Revenue Potential (ARP)**. Rather than a single, one-dimensional number, ARP is a multi-faceted response surface that is governed by both static and dynamic factors. It is rarely obvious and can be difficult to accurately assess, but the result is surprisingly intuitive.

Market size is not a single number, it's a *response surface.*

The ARP of a technology will be governed by some or all of the following variables:

- The incidence, prevalence and lifespan of people with the underlying condition
- The relative mix of indicated sub-segments within the target population
- The relative and absolute benefit (value proposition) of the medical technology
- The clinical complexity of target patients (e.g. elderly, co-morbidities, hard to diagnose)
- The distribution of patients in the healthcare system and around available sites of care
- Your business model (cure? treat? diagnose?) and the price for your technology
- The size and timing of growth investments that will drive adoption

There is a dynamic flow of patients in and out of the target indications: some patients progress from less severe to more severe, some have few co-morbidities while others have many. Some may be diagnosed and seeing a specialist, while others will be undiagnosed and not entering the healthcare system. These dynamics and more must be considered when developing an accurate assessment of *realizable* ARP.

> ***Example:*** A recent client analysis showed that for a disease that affects more than 60 million people, the company's net realizable potential treatment rates totaled about 200k/year, and the most attractive segment was just 60k/year. Fortunately, these patient volumes still represented a large ARP for the company. But 200k/year is far different from thinking about the market 'context' as 60 million patients. In this case the difference between "total market" and the "net realizable market" was a factor of 300.

2. There are very few big markets (but you don't need one to be successful)

In the $180 billion medical technology market, there are only about a dozen or so "billion dollar" medical technologies. Yet the industry spends about $50B annually (~30% of revenue) on R&D, sales and marketing. All this investment has resulted in very few blockbuster devices.

Most medical technologies have a realizable ARP response surface in the $50M - $700M range. Knowing the total ARP, the size of specific sub-segments, and the most capital-efficient way to access each segment are the most important insights a leadership team can have in order to make decisions that help maximize ROI and deliver commercial success in the marketplace.

Understood or not, the true ARP for a medical technology is a market reality, and using a 'gross size' estimate does not change that reality. So rather than trying to defend (and deliver?!) a illusory blockbuster opportunity, we believe the focus should be on understanding your true opportunity and how you and your investors can create a successful enterprise that generates an attractive return, providing real value to patients, the healthcare system, investors, and employees.

To maximize your enterprise value: ***describe a true market opportunity, invest appropriately, then deliver on it.***

Every commercialization decision is colored by assumptions about the market: its size, segments, and dynamics, as well as regulatory and clinical strategies, investments, go-to-market plans, and -- most importantly – growth expectations. Projecting a larger market than really exists leads to decisions that greatly compromise enterprise value.

3. At launch, early success may be the first sign of failure

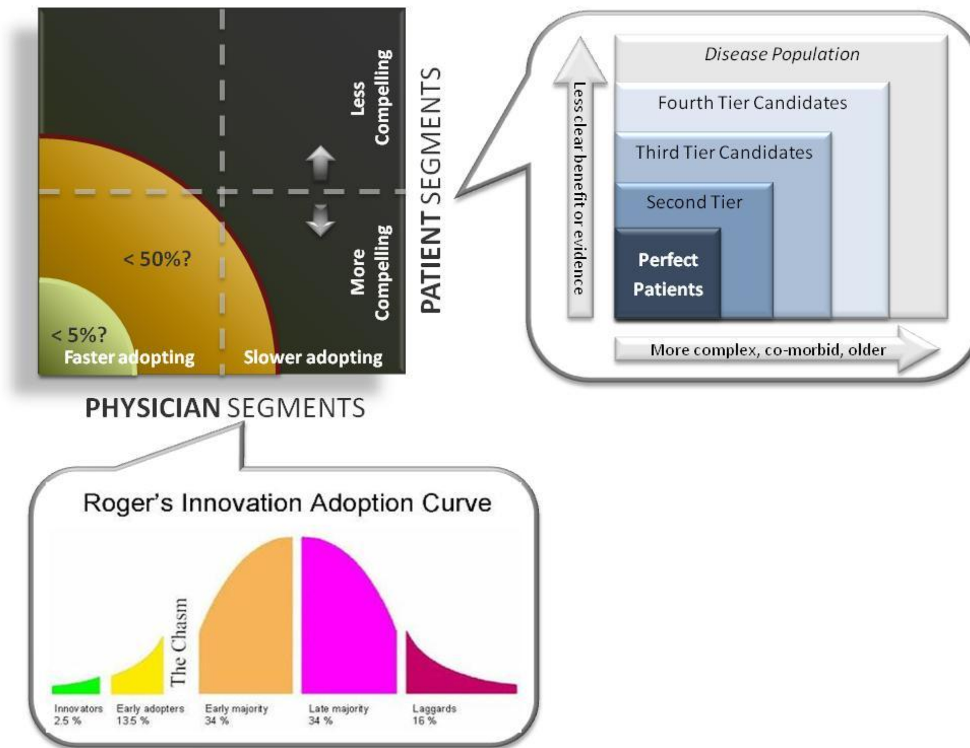
Market launch is the litmus test when hidden market risks surface. The scenario is common: you've invested years of effort and millions of dollars, primed the market, built inventory, and trained a sales force. Post-launch sales take off, and everyone cheers. Sales continue to increase, while at the same time an undercurrent of dissatisfaction emerges. Failed procedures or non-responsive patients pile up. A few customers stop using the product. But these market signals are easy to rationalize away, because other customers are still excited to purchase.

Eventually, growth rates stall. Should you hire more reps? Improve training? Spend more on promotional marketing? How do you separate the real problems from their shadows?

All the patient candidates for your technology will have a spectrum of clinical benefit/response, ranging from an optimum outcome ("perfect patients") to something far less compelling. There is also a spectrum of customer/clinician tolerance for risk (Figure 1). While some clinicians can

tolerate unexpected outcomes and easily manage patient expectations, others have zero tolerance for surprises or inconsistent outcomes.

Figure 1: Early market adoption dynamics



When a new technology is launched, there is generally little consideration for this spectrum of customer and patient dynamics – yet it dictates the market's response to the technology! When a low-tolerance customer treats three patients that all respond differently, you don't just lose a customer, you create a naysayer.

More than 60 years ago Rogers identified and quantified the famous and now well-established innovation adoption behavior segments (in Figure 1). The fact is that 85% of your customers have a relatively low tolerance for risk. On the patient side of the equation, often just 20% experience a 'wow' outcome. So paradoxically, the more successful you are in engaging the early market place, the faster your technology may be viewed as "not ready for prime time" by the majority of your customer base. Your technology may be deemed unreliable, inconsistent, or "for extreme cases only" – not because it is, but because you were unable to properly set expectations with your customers about how the spectrum of patients will respond.

If 15% of customers are 'early adopters' and 25% of your patients/procedures are 'perfect,' then at launch the practical early limit of your market is 15% x 25% = 4% (Figure 1).

When introducing a new technology to the market, it is essential to manage the sales process to maximize the customers' early *wow* experience. The only way to do this is to have a solid understanding of all patient segments that can benefit from your technology, especially the 'perfect patients', and to have a process to identify early adopter customers who can tolerate the inevitable surprises and still be advocates.

> ***Example:*** A client had two technologies that had been in the marketplace for more than 20 years. There was disagreement whether or not they were at full potential. We analyzed them both and discovered that the first had penetrated 80% of ARP, and that accessing the remaining 20% had a very low ROI. The second technology had penetrated less than 50% of ARP, largely due to identifiable gaps in meeting the needs of the early majority. For 20+ years the company had been targeting the shadows, not the real barriers. Our analysis gave the organization the information and, more importantly, the *confidence* it needed to more effectively allocate resources and focus investments to maximize growth.

Without understanding and addressing the needs of the **early majority** customers, your market adoption will be limited to just a small fraction of its realizable potential.

The market is complex, but knowable.

Having a good "30,000 foot" understanding of the market is a necessary first step, but it's insufficient to deliver commercial success. A detailed market landscape is essential. Only by examining nuanced market dynamics can you avoid chasing shadows and gain the control and confidence you need to steer your technology to success.

> **It does require significant time and resources to avoid the pitfalls of subtle market dynamics, yet your company's success – perhaps even its survival – *depends* on it.**

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