The Commercialization Readiness Gap in MedTech

What the evidence shows about where medtech stalls—and how to reduce avoidable commercial risk

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Executive Summary

Medtech success is decided less by a single breakthrough and more by whether a company's commercialization logic survives a series of external "gates"—funding diligence, regulatory pathways, hospital procurement, reimbursement, and operational adoption. The commercialization readiness gap is the space between what teams believe is true about their go-to-market and what must be true for institutions to commit money, workflow, and reputational risk.

Recent benchmarks show how selectively this system advances companies. In venture markets, only 15.4% of startups that raised a seed round in Q1 2022 reached Series A within two years (down from 30.6% for Q1 2018), indicating a materially tougher bar for "credible scale" narratives in the current environment.[1] In medtech-specific competitive funnels, one of the largest accelerators reports a 4% acceptance rate for its 2025 cohort, illustrating how sharply diligence filters apply even before traditional financing.[2] On the buyer side, healthcare AI benchmarking found that only 30% of completed proofs of concept reached production—a healthcare AI–specific dataset used here as a directional proxy for broader institutional adoption dynamics—reinforcing that pilots are common but scaled adoption is not.[3]

Importantly, "clearing a gate" is not the same as commercialization. In a peer-reviewed analysis of U.S. claims usage of medical AI procedures, the authors report "over 500" FDA-approved medical AI devices, yet adoption is "still nascent," concentrated in a handful of high-utilization procedures; only coronary artery disease assessment and diabetic retinopathy diagnosis exceeded 10,000 CPT claims in the dataset.[4] Separately, a 2025 cross-sectional study of 903 FDA-approved AI-enabled medical devices found that clinical performance studies were reported for approximately half the devices analyzed, while one-quarter explicitly stated that no such studies had been conducted at approval—an evidence-clarity gap that can directly weaken procurement and partnership confidence.[5]

This white paper synthesizes what these data imply: many "failures" are not technology failures; they are commercialization readiness failures—unclear buyer and budget logic, misaligned evidence relative to decision thresholds, reimbursement friction, workflow/integration barriers, and decision-making processes that are committee-based and risk-managed.

The Commercialization Readiness Gap

Founders and commercial leaders often experience “progress” as activity: pilots, LOIs, inbound interest, conference traction, strategic conversations, early champions. Institutions experience progress differently: as proof that a decision is defensible within their constraints. The commercialization readiness gap emerges when these two definitions diverge.

Medtech commercialization is best understood as a gate sequence. Each gate asks different questions, and passing one does not guarantee passing the next. Having a cleared device does not mean a hospital will buy it. Having interested clinicians does not mean procurement can find a budget line. Having pilot results does not mean payer economics or operational adoption are solved.

Concept → Validation → Clearance → Pilot → Contract → Repeatable Revenue

This gate structure explains why the most expensive failures feel sudden. The story “worked” until it met a different evaluator with a different threshold. A commercialization readiness approach therefore begins with a simple question: what must be true for the next gate to approve—and how do we know?

What the Data Shows About Selectivity and Stall Points

The strongest available public statistics do not usually label themselves “commercialization failure rates,” because commercialization is not one event and medtech categories vary widely. What we do have are validated proxies: how often companies clear funding progression gates, how often pilots become production deployments, and how often products are used at scale after authorization.

The first proxy is funding progression. A 2024 analysis of venture cohort outcomes reported that 15.4% of Q1 2022 seed-funded startups reached Series A within two years, compared to 30.6% for Q1 2018.[1] Medtech is not immune to this shift; if anything, long development cycles and higher proof requirements often raise the burden for follow-on diligence.

A second proxy is the pilot-to-scale bottleneck. A 2025 healthcare AI adoption index reports that only 30% of completed proofs of concept made it into production, with less than half of applications progressing beyond ideation or pilot stages.[3] While AI-specific, this pattern reflects broader institutional behavior relevant to software-enabled and capital-adjacent medtech: pilots are treated as experiments, while production decisions are treated as operational commitments subject to integration, workflow, and financial scrutiny.

A third proxy is post-authorization utilization. Wu et al. report that despite over 500 FDA-approved medical AI devices, usage remains highly concentrated, with only two procedure categories exceeding 10,000 CPT claims.[4] The implication is not about modality—it is that regulatory clearance alone does not ensure commercial uptake.

Traditional device commercialization data reinforces similar dynamics. It is well known that hospital capital purchasing cycles for medical equipment commonly range from 6 to 18 months, particularly when purchases exceed capital thresholds and require committee approval and budget allocation. Even after clinical validation, value analysis committee (VAC) processes introduce additional multi-month evaluation cycles, often requiring economic justification, workflow validation, and cross-department alignment before approval.[7] In practice, this means that early clinical traction or physician interest does not translate directly into contracts without alignment across finance, procurement, and operational stakeholders.

Gap note: There is no universally accepted, medtech-wide statistic for "percent of pilots that convert to contracts" across device categories. Buyer processes, reimbursement pathways, and definitions of "pilot" vary too much for a single number to be authoritative. The healthcare AI pilot-to-production metric (30%) is used here as a directional proxy, not a direct medtech conversion rate.[3]

Why Medtech Commercialization Stalls

The evidence above points to a consistent pattern: the system rewards commercialization coherence, not effort. The most common stall points are structural.

1. **Committee-based purchasing and stakeholder misalignment**
   Hospital purchasing processes for high-cost devices involve multiple stakeholders across clinical, engineering, procurement, and finance functions, with documented risks of delay and conflict when stakeholders are not aligned early.[7]

2. **Budget ownership and capital allocation constraints**
   Capital equipment and physician preference items (PPIs) often require alignment with predefined budget cycles, meaning that even validated technologies may be delayed if they fall outside planning windows or lack a clear budget owner.

3. **Reimbursement and economic uncertainty**
   A 2025 systematic review found that fragmented reimbursement pathways and insufficient cost-benefit evidence can materially slow or prevent adoption, particularly for disruptive innovations.[8]

4. **Regulatory timing and capital pressure**
   Pioneer devices experience longer approval timelines and associated cost increases, which heightens the importance of a credible commercialization plan under constrained runway conditions.[9]

5. **Evidence mismatch relative to decision thresholds**
   Even when products are technically validated, evidence may not meet the level required for procurement or reimbursement decisions, creating a gap between "approval-ready" and "purchase-ready."[5]

These are not unpredictable barriers. They are recurring constraints that can be assessed and addressed earlier than most companies attempt.

Early Commercial Validation and Diagnostic Pressure-Testing

Evidence from medtech benchmarking suggests that organizations investing earlier in market understanding tend to outperform on commercialization outcomes. Deloitte and AdvaMed report that top-performing companies generated three times more revenue from recently launched products and invested more heavily in early-stage market understanding activities.[11]

This relationship should be interpreted directionally rather than causally. The data does not prove that early validation causes better outcomes, but it is consistent with a broader pattern: companies that align buyer, evidence, and economic logic earlier are less likely to encounter downstream commercialization friction.

In practice, early commercial validation focuses on resolving a small number of critical uncertainties before they become expensive:

- **Who actually signs and pays**
- **What evidence threshold is required for approval**
- **Where budget originates**
- **What operational burden adoption creates**
- **What must be true for repeatable revenue**

Addressing these questions early does not guarantee success. It reduces avoidable failure.

About RŌG Health

RŌG Health works with medtech and medical device teams at commercialization inflection points—fundraising, pivotal pilots, strategic partnerships, and early revenue conversion—when external stakeholders will pressure-test the company's commercial logic whether the company is ready or not.

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Endnotes

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