



AVIO
Medtech Consulting

10 Common Mistakes Health Ventures Make (And How to Avoid Them)

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Agenda

- Market Validation
- People & Mission
- Cheaping on Reg
- Insufficient Evidence
- Data Security and Compliance
- Cost of Change and Sales
- Insufficient Capital
- Are you VC backable?
- Reimbursement Strategy
- Neglecting Reimbursement Strategy
- Lack of Understanding of Payer Landscape

BIG Caveat

- You're all professionals. Odds are, you know most/all of these things.
- These are my observations. I'm not a device entrepreneur.
- Even Messi practiced his shots.



Market Validation in the US

The single most common problem I see is the failure to validate the market in the US.

- Is there an unmet clinical need?
 - Is it unmet because the business case doesn't exist?
 - Do patients want it? Doctors? Nurses? Administrators? Payors?
 - Is the market large enough and profitable enough to build a business? At what scale?
-
- Market validation drives all the other work because it sets the constraints.



What to do?

- Talk to all stakeholders (docs, nurses, admin, PAYORS)
- 3rd party validation can help (we're all biased about our own thing)
- Understand the difference between something that fits workflow and requires changes/new workflow
- Get professional help



People & Mission

- We've all heard A team with a B tech over a B team with an A tech
- But also recognize that the team needs to change as the company changes. The right people *today* may not be right *tomorrow*
- Can you/your team execute?
- Do you/your team convey credibility to stakeholders?



Cheaping Regulatory

- Too many companies do the bare minimum for **clearance/approval**
- FDA authorization ≠ sales adoption

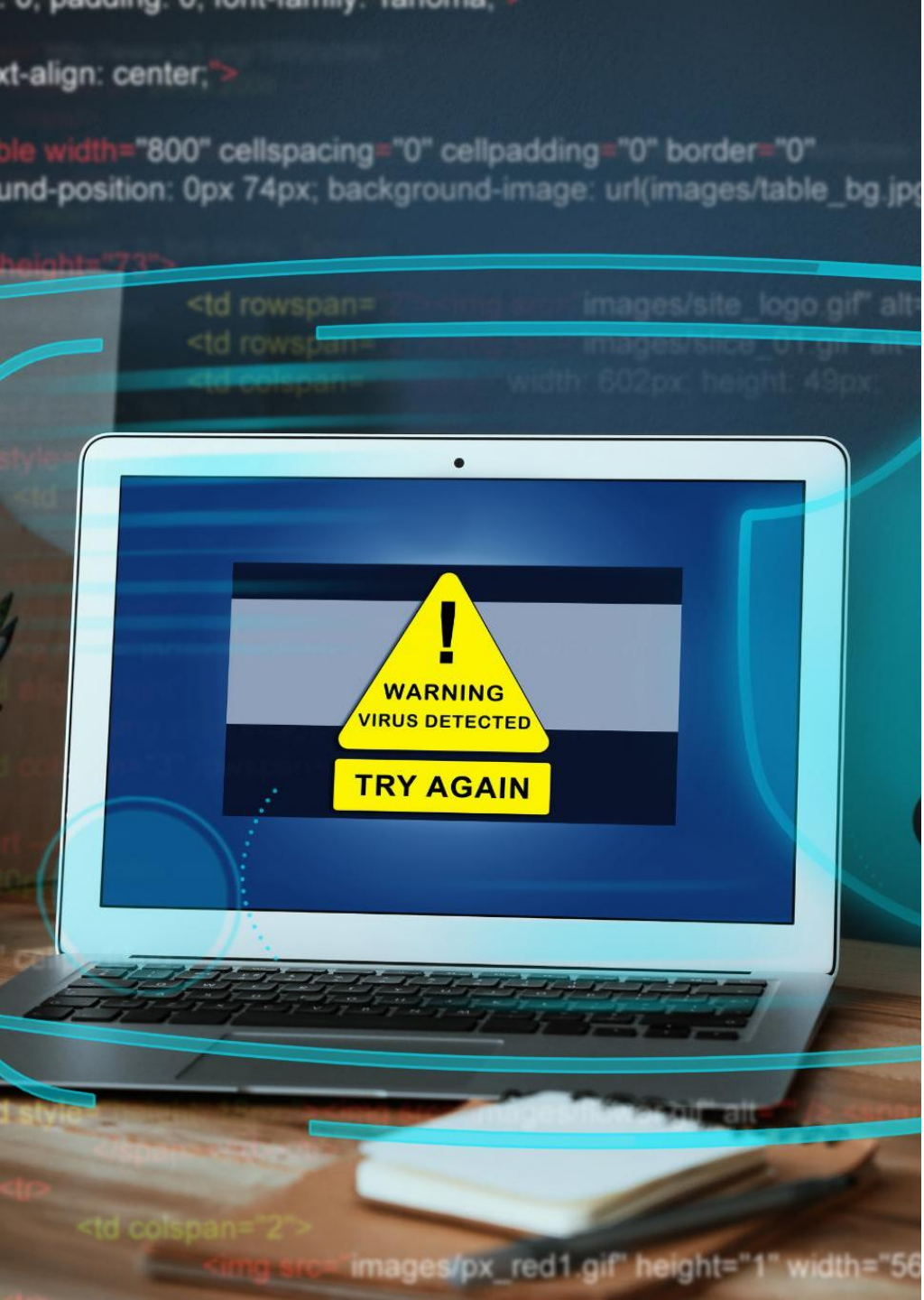
Integrate reg, clinical, reimbursement, sales/marketing to drive adoption

Insufficient Evidence

- Competing with thousands of other companies. Evidence is what wins.
- Need compelling value – clinical, cost, ease of use, productivity – which all require evidence.

Ensure you know what ALL stakeholders need to adopt your product and build evidence plans early.





Data Security and Compliance

It's all connected today

- Data security and compliance are manageable, but they are complex
- FDA requirements are one thing – don't forget about customer requirements, SOC2, HITRUST.

You'll have to repeat security audits over and over. Did you design for simplicity? Or will the fancy connection make sales even harder?

Cost of Change

- Is the clinical, economic, or other value sufficient for the doctor, patient, hospital, payor, to change?
- It always takes longer and costs more

Be small (niche) or big (transformative). Never in-between



Underestimating the Cost of Sales

Sales is expensive

- Great reps make great money
- Distributors need a big cut
- Distribution costs are high
- Inventory costs money
- The lack of clinical evidence is now really expensive

What to do? Leverage the limited market release



Limited Market Release

- Constrain sales costs
- Target one doc, one hospital, one market...to start
- Fail small, reinvest gains in market 2





Insufficient Capital

Everyone is broke!

- We know medtech is expensive. So why do you try to scrape along and raise the bare minimum?
- Why aren't you raising enough? Don't blame the markets or VCs. You're a leader, and you're in control. What can you do?

VC Backable?

Not all companies are VC Backable

- Too small of market, no path to grow fast, not aligned with strategic (exit) interests

Not being VC backable is ok. Now knowing it is not ok.

- Align financing strategy to the business, not the other way around





Know thyself Know thy Stakeholder

When I meet companies struggling to raise capital, their challenges usually are:

- Don't understand how VCs work: VC is a business. Know your customer.
- The team doesn't have credibility: I give you money, how can I trust you'll make a return?
- Investor materials have errors: I see hundreds of deals and need quick ways to say no.



Neglecting Reimbursement

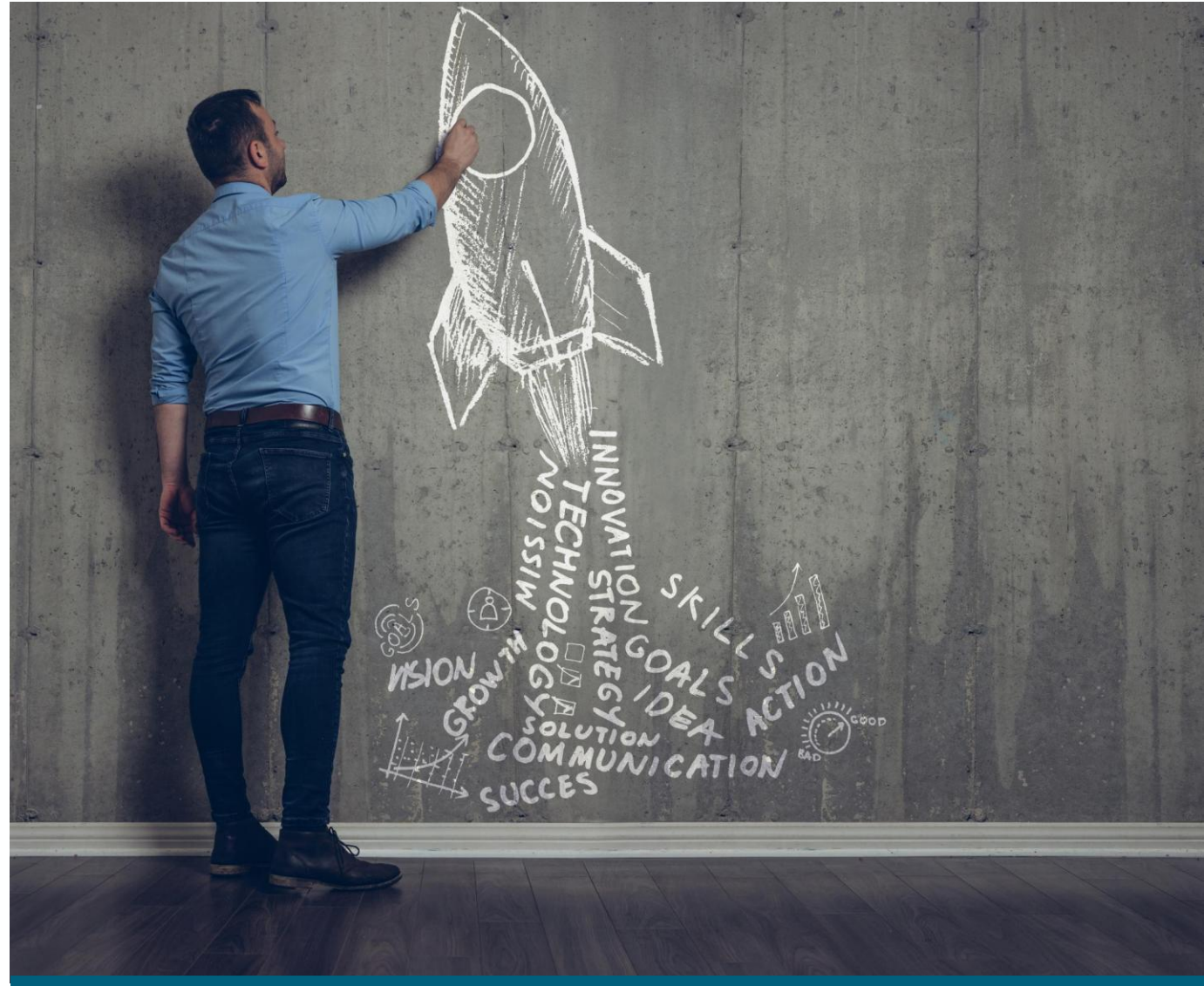
But how? We all know it matters.

- Because you didn't validate the market.
- Cheaped out on regulatory.
- Didn't have clinical evidence.
- Didn't address the cost of change.

It all connects when you get to reimbursement.

Neglecting Reimbursement

- Payors do care about clinical improvements, but they need PROOF
- Fun fact: UnitedHealth Group is bigger than the US medical device industry.
- Build health economics, value, and strong outcomes into your initial concept. Design for success.
- Work on solutions with big impact.



Startups are Hard

It's lonely, failure rates are high, money is tight, fundraising is slow, finding the right vendor/partner/employee is fraught with risk.

We get it

Founded by a medtech entrepreneur, for medtech entrepreneurs, we understand your challenges. And we've built Avio to meet them.

A better way to Increase Returns & Patient Impact



60+ Startups/Year

You benefit from the experience of working with only startups



Higher ROI

Raise less capital to reach milestones, preserving early investor ownership

Continuous Improvement

After each client we translate learnings into templates, playbooks, and best practices

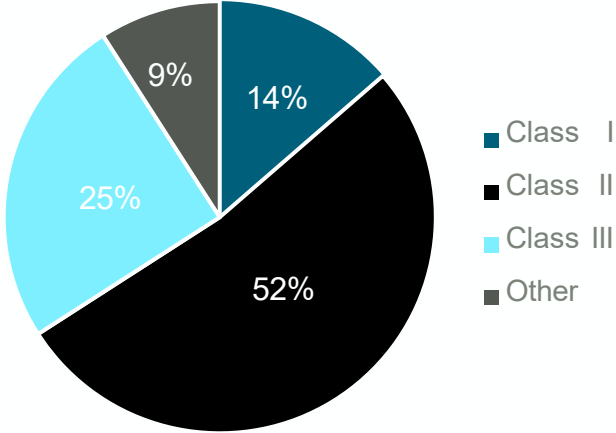
We Serve You

40%
Diverse Founders

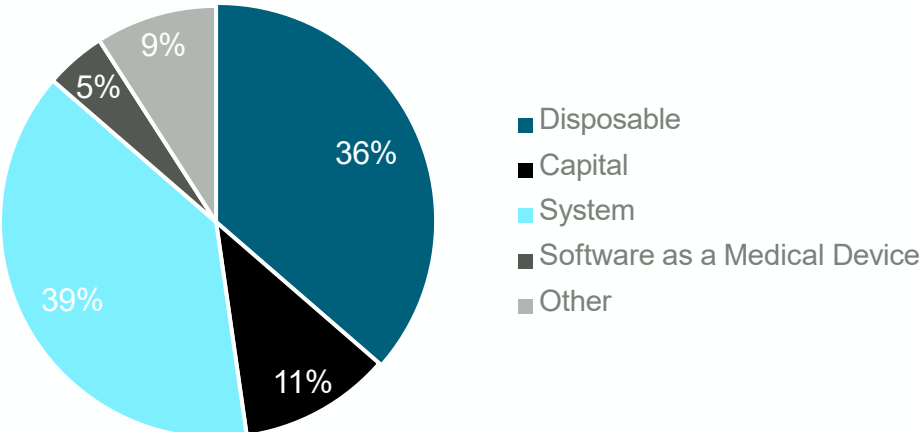
50+
Clients Served in '24

58%
First Time Founders

Regulatory Classification



Product Type





Thank You

Your work matters. You are trying to save and improve lives.

I appreciate you.

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