

# Validating Your Business Opportunity

WPI Bioengineering Institute

Med Tech Grand Rounds

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Supporting Member of the  
WPI Bioengineering Institute

Technical success is a great and hopeful milestone!



Now you must determine:

1. Whether it's worth bringing your potential medical product to market
2. Exactly how that's to be done

# What is validation?

- Deciding what business you're really in
- Assessing market potential
- Analyzing options and selecting the best business model
- Assessing resource requirements to determine what's really possible and what initiatives to kill
- Deciding on outreach requirements and alliance relationships
- Assessing regulatory pathways
- Devising customer access tactics

**Validation is critically important!**

# Why validate?

- Correctly sets expectations of yourself, your investors, your colleagues and alliance partners
- Stimulates exploration of alternative business models and organizational structures
- Avoids commercializing the wrong product
- Avoids developing a product for too small a market or one that cannot be effectively accessed

**If you don't validate, you will find a way to fail!**

# When to validate?

Bright idea

Early concept testing

In-licensing due diligence

Market testing

Seed funding

Technical feasibility milestone

Business planning/modeling

A-round funding

Development milestone

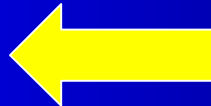
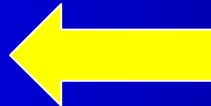
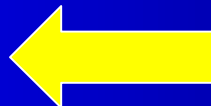
Business planning/modeling

B-round funding

Partnering/alliances milestone

C-round funding

Initial marketing & sales



**Validate early and often!**

# Agenda

- What's the product?
- Serving an existing market
- Serving a new market
- Who's the customer?
- Market research
- Testing customer attitudes
- Available market
- Adoption dynamics
- Accuracy of estimates
- Market access
- Distribution
- What next?

# What's the product?

- Must define the product precisely in order to:
  - Correctly assess its market opportunity
  - Develop the right product
- Who's the user, and what are the benefits of use?
- Who's the payer, and what “value” (reimbursement) will be set for the product?
- How is it like and unlike competitive products or the status quo — exactly?
- Does it significantly save healthcare \$\$ overall?

# Serving an existing market

(meeting a need better)

- Market expansion unlikely; generally must take share; how will you do that?
- More accurate estimates are possible
- Easier to describe product to prospective customers and users
- “Feet on the street” often wins; how will you do that?

# Serving a new market

(meeting an unmet need)

- Must create the market
- Little or no immediate competition
- Must face up to the adoption process
- Greater scrutiny; must overcome inherent conservatism of clinicians and third-party payers
- Likely need for greater marketing investment, but perhaps less sales investment

# Who's the customer?

- The essential question: Who must be satisfied in order to achieve success?
  1. Clearly, the product's user must be satisfied
  2. The purchase influencer (specifying clinician) must be satisfied
  3. Clinical thought leaders must be satisfied, too
  4. Finally, a payer usually must be satisfied

**Is your venture allotting adequate consideration to all 4 of these customers?**

# Market research

- Market research is a tool for opportunity assessment:


1. Define your product and its various customers
2. Characterize its available markets
3. Quantify those markets (not the one described in the report on your shelf)
4. Methods are well known: published data, competitor interviews, customer interviews, focus groups, industry experts, etc.



- Always talk to prospective users and buying influencers

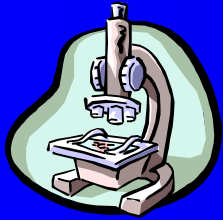
**Poorly executed research is a waste of time & \$!**

# Testing customer attitudes

- Prospective customers lie! 
  - When not asked the right questions by an experienced interviewer who knows the territory
  - When not expertly led to disclose their real attitudes
  - Because they're human and wish to please
- Must work through respondent attitudes and biases to answer the essential question:
  - What will it take for this prospective customer to choose, champion and routinely use your new product?

# Adoption dynamics

- You can almost always make quick sales to early adopters, but these sales will not sustain a business
- You must convince the larger body of mainstream users to adopt your new product, and that requires application knowledge, resources and time
- The opinions and rationales you hear during customer dialogs will establish the basis of your sales projection and the resources required to achieve it



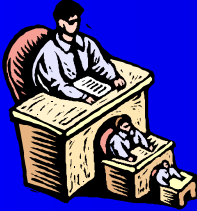
# Accuracy of estimates

- Absurd obsession with accuracy of market-size estimates
- \$102 M or \$152 M? It doesn't matter! It won't change decisions or behavior.
- Uncertainty for existing markets is  $\pm 20\%$ ; much greater (perhaps  $\pm 300\%$ ) for new markets

**What really matters are the analysis, the insights, and the credibility conveyed by your research!**

# Market access

- You will almost certainly overestimate your ability to access customers
- Most med tech firms should not consider directly accessing clinical customers
  - Unless access to a small cadre of specialist physicians is sufficient and feasible



# Distribution

- Objective: Engage a powerful ally to offset lower revenue per sale by achieving greater volume
- Customers often prefer dealing with a few powerful firms — more efficient and comfortable
- You must craft mutually beneficial relationships with your channel partners
- Don't let the distribution process de-emphasize or derail your marketing program; it's always needed

# What next?



## If all looks favorable:

- Solidify your plans
- Document your findings and rationale
- Sell your validated ideas to investors, colleagues and alliance partners



## If you find defects:

- Adjust your expectations and plans
- Consider redefining your product
- If necessary, alter your business model
- Re-validate

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