

# Validating Your Medical or Life Science New-Product Opportunity

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Center for Business Intelligence

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# Occasions for assessment

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- A start-up's success depends on its first product
- A notion for a new product emerges from within
- A product's sales revenues are disappointing
- A technology is being considered for in-licensing
- A product is being considered for distribution
- A product line is being considered for acquisition
- A venture investment is being contemplated
- A corporate acquisition or merger is in the works
- Others ...?

# What's the worst that can happen?

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## **Consider a start-up example:**

- A. You don't get funded, so you can't get started
- B. Your investors are SOB's that pull you in all the "wrong" directions
- C. Product development takes much longer than expected, so you miss the market window
- D. Your investors cannot exit at a fair valuation
- E. None of the above

# None of the above!

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- The real worst-case scenario:
  - Your team does a bang-up job developing a great product and gets it to market quickly with a world-class distribution partner!
  - Nobody buys your product because it's the wrong product for its target market!!
- You simply must do a reasonable (and reasoned) job assessing the business opportunity before the hard work starts.

# Why validate?

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- Correctly sets expectations of company execs, investors, 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
- Curtails a development and commercialization program destined to fail

# The elements of opportunity assessment

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- Who are your customers – present and future?
- What's your market, how big is it, and what are its growth prospects?
- Who or what is your competition – present and future?
- What will motivate and discourage adoption, and why? How long will it take?



# What is validation?

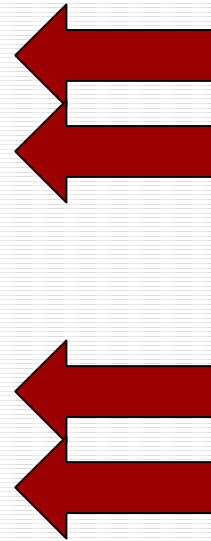
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- Deciding what business you're really in
- Assessing market potential
- Analyzing options and selecting the best business model
- Assessing resource requirements to determine what's really possible and what initiatives to kill
  - Will you enjoy sustainable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

# When to validate?

Consider a drug development example:

Therapeutic indication  
Disease model  
Target identification  
Target validation  
Compound synthesis  
Screen development  
Compound library screening  
Lead compound optimization  
Preclinical studies  
Phase I  
Phase II  
Phase III  
Post-market surveillance



**Validate early and often!**



# Agenda

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- What's the product?
- Who's the customer?
- What's the market?
- What's the competition?
- Why/when will customers buy?
- When should you seek help?
- What are the seven deadly sins of opportunity assessment?



# What's the product?

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- 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 — exactly?
- Does it significantly save healthcare \$\$ overall?

# Who's the customer?

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- First, define the product as best you can
- Then identify the customers: Who must be satisfied in order to achieve success?
  1. User
  2. Purchase influencer (specifying clinician)
  3. Clinical thought leaders
  4. Payer
- Iterate to properly match product to customers



# What's the market?

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- With the product and customers defined, attempt to characterize the market and its segmentation
- It's almost never the market characterized in an off-the-shelf report; usually a subset
- Need an educated guess at latent demand in the market available to you at maturity
- Secondary research is a start, but discussions with prospective customers are usually essential
- Oh...and you must also predict the future!

# Market access

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- You will almost certainly overestimate your ability to access customers
- Most medtech and biotech firms should not consider directly accessing clinical customers ... unless access to a small cadre of specialist physicians is sufficient and feasible
- In any case, regional marketing partners and distributors are likely to be needed

# What's the competition?

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- In the biomedical arena, the most important competition is often the status quo (medical inertia)
- First consider alternative methods and procedures
- Existing suppliers of similar products are easy to discover and research, especially if public
- Finally, imagine which other firms could enter your space; consider patent literature and hard-science publications

# Why/when will customers buy?

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- 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

# Customer attitudes

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- Prospective customers lie!
  - When not asked the right questions by experienced analysts who know 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?



# When should you seek help?

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- Total objectivity is required by your stakeholders (investors, partners, employees, etc.)
- You lack the time or skills to do a credible job
- You're just not sure, and the consequences of a bad decision are dire



# Working with advisors and consultants

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- Make the assessment's objectives and your personal aspirations crystal clear
- Do at least some of the work yourself, then test your consultant's understanding and methodology; do they "feel" right?
- "Name brand" firms seldom work for start-up budgets
- Beware hiring for equity; will you get objectivity?

# What next?

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## **If all looks favorable:**

- Solidify your plans
- Document your findings and rationale
- Sell your validated ideas to company execs, 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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# Bad Advice: The Seven Deadly Sins of Opportunity Assessment

# Sin #7

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Keep your product concept fluid and your product description vague.....

.....that way you can readily deflect constructive criticism.

# Sin #6

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Tomorrow's competitors  
equals  
today's competitors.

# Sin #5

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You must always satisfy your stakeholders.....

.....so be sure your market “estimates” match the revenue projections.

# Sin #4

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Just use the data in that 5-year-old F&S report.....

.....it's not exactly your market, but it's close enough.



# Sin #3

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Customer enthusiasm  
equals  
customer orders.

# Sin #2

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Never speak to prospective customers.....

..... they will derail your carefully formulated product plans.

# Sin #1

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Don't waste your resources doing  
market research .....

.....just ask your Scientific Advisory  
Board.



# Inquiries welcome:

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