



## **Choosing Optimal Product Profiles and Clinical Trial Endpoints for Commercial Success**

Strategic Market Research for  
Pharmaceutical Practitioners  
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Philadelphia, PA

## Quiz To Test Your Knowledge About New Product Introductions

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- 1 The most important reason to measure commercial potential in early stages of product development is to:
- A Be ahead of the competition.
  - B Ensure that the right compound is being developed in the right way.
  - C Be able to buy your kid the latest Brittany Spears album next Christmas.

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**2** Compounds fail to reach their potential in the market most often because:

**A** Customer feedback was not incorporated into development process.

**B** Competition in most markets is very keen.

**C** Marketing lays out careful plans. Sales destroys them.

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### 3 Forecasting is the fine art of:

- A Structured input and experience to arrive upon a “best guess” as to what will occur.
- B Structured input and analogy modeling to arrive upon a “best guess” as to what will occur.
- C Supporting your WAG (“wild ass guess”) with an intricate Excel spreadsheet so complicated that no one can understand, much less question, the forecast.

ANOTHER TITLE FOR MY TALK TODAY COULD BE:

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“Customers Drive  
Your Commercial Success”

## Today I Will Tell You...

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- Why all of this should matter to you?
- Eight tricks to help you conduct better research to help optimize the commercial chances of your compound
- Five ways in which you can put the results from this research into action

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# Why Should All of This Matter to You?



## There are five reasons why it should matter...

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- 1 Intuition can and is often wrong.
- 2 The cost of getting it wrong is exorbitant.
- 3 NDAs/INDs are not growing.
- 4 R&D productivity is down.
- 5 Comparators\endpoints have to matter...to your customers!

# 1. Intuition - product introductions rarely go as expected...

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- Customers are unpredictable.
- The world changes - your intelligence needs to change with it.
- Corporate cultures demand consensus - but sometimes that consensus is counter to market desire.

## 2. The cost of getting it wrong is exorbitant

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- It is reported that it costs between \$300 and \$600 million to bring a drug to market.
- Remember the opportunity cost.
- And what % of new product/new indications become true successes?

### 3. NDAs and INDs are not growing

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	INDs	NDAs
1999	498	139
2001	425	99
2003	426	119

The pressure to make each opportunity “pay off” is increasing

## 4. R&D Productivity Is Down

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- In 1999, when NDA filings peaked, spend was \$23 billion industry-wide.
- In 2003, spend was \$33 billion for fewer NDAs and INDs.
- Less productivity = more pressure to commercialize the “winning” compounds

## 5. Endpoints and Comparators Have to Matter to Customers

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- How many times have you been stuck at launch with comparators that do not matter to your customers?
- How many times have you demonstrated efficacy or safety against an endpoint that does not matter to you customers?

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## Eight Tricks For Better Research....

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First, Let Me Assure You...

Researchers Cannot  
See the Future

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We Can Give You Tools To Best Know  
What Not to Do...

...and Several Good Options of  
What You Can or Should Do.

## Eight tricks for better research....

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- 1 Modeling allows you the flexibility you need
- 2 Use approach that can handle variability
- 3 Garbage in\garbage out
- 4 Stretch the rubber band
- 5 Don't forget the competition
- 6 It is about breadth AND depth
- 7 Its about incremental, not the absolute value of the trial
- 8 Put the cost of the trials into your analysis

# 1. Modeling = flexibility

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- Concept testing vs. trade-off modeling

- ▶ What are these?

- ▶ Concept testing is easier to understand but very limited.

- ▶ Modeling is the best way to allow you to look at many different product attributes combos.

## Why modeling?

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- You have uncertainty about your compound.
- Research must live on - you will get smarter about market.
- Ability to play “what if” games can influence analysis and give you direction.

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## GO TO SAMPLE SIMULATOR

Handle many attributes

“What if” games

How research can “live on”

## 2. Use a modeling approach that can handle a ton of variability

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- Most situations involve many variables and choices within variables.
- Tough to narrow down when doing this research.
- Makes it more believable internally.

## Example of product features that could be varied:

Product Benefits	Clinical End Points
<b>A Dosing Frequency</b> <ul style="list-style-type: none"><li>1 time/day</li><li>2 times/day</li><li>3 times/day</li><li>4 times/day</li></ul>	<b>E Indication</b> <ul style="list-style-type: none"><li>Monotherapy 1st Line</li><li>Combination Therapy</li><li>2nd Line Only</li></ul>
<b>B Incidence of Hypoglycemia</b> <ul style="list-style-type: none"><li>&lt;1%</li><li>1% - 3%</li><li>&gt;3%</li></ul>	<b>F Safety in Patients with Renal Impairment</b> <ul style="list-style-type: none"><li>Data available</li><li>No data available</li></ul>
<b>C Incidence of Headache</b> <ul style="list-style-type: none"><li>&lt;5%</li><li>5% - 10%</li></ul>	<b>G Safety for Use with Nursing Mothers</b> <ul style="list-style-type: none"><li>Data available</li><li>No data available</li></ul>
<b>D Price</b> <ul style="list-style-type: none"><li>Same as gold standard</li><li>10% less than gold standard</li><li>20% less than gold standard</li></ul>	<b>H Effects on Cardiovascular Mortality</b> <ul style="list-style-type: none"><li>Data available</li><li>No data available</li></ul>
	<b>I Delaying of Cardiovascular Complications</b> <ul style="list-style-type: none"><li>Data available</li><li>No data available</li></ul>

### 3. Garbage in\garbage out

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- Study is only as good as the stimuli.
- Thorough qualitative prior to set up.
- Qualitative should follow the 3 C's
  - Comprehensive
  - Concise
  - Consistent

## 4. “Stretch the Rubberband”

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- Very important perspective - we are measuring elasticity.
- We can generally model “the middle” - we can’t model outside “the ends”.
- Don’t test stimuli (i.e., endpoints) that are too alike

# Examples...

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- **Too similar** -  
Incidence of Hypoglycemia
  - 4%
  - 6%
  - 8%
  
- **Better** -  
Incidence of Hypoglycemia
  - 2%
  - 7%
  - 12%

## 5. Don't Forget Competition Is Developing Compounds, Too.

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- Sounds silly, but, happens frequently. So focused on own compound...
- Talking about ability to vary looks at competitive compounds as well so make sure your approach is flexible enough.
- Competitive intelligence is vital here.

## There are limitations...

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- Difficult to handle more than one to two other competitive compounds.
- Cannot simulate time.
- Can get a “feel” for order of entry impact.

## 6. It's About Breadth AND Depth

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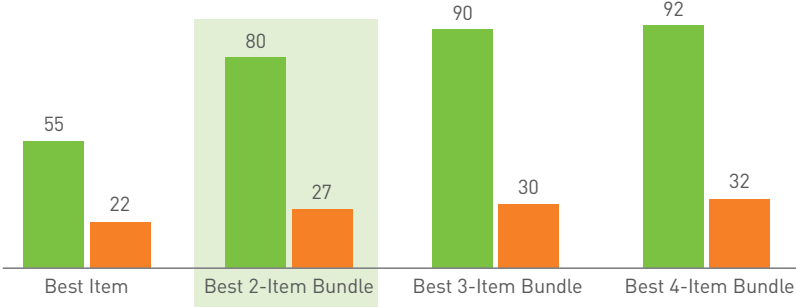
- Most work looks only at depth.
- Fine, but:
  - No measure as to overall customer penetration.
  - No insight into speed to peak share.
  - No clues as to the execution needed to accomplish given scenario.

## Problem is...

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- Easier to measure depth.
- Really hard to measure breadth, especially when measuring interactions between given potential trials, product attributes, etc.

# What is the trade off between preference share and reach?



Safety in nursing mothers



Effects on CV mortality



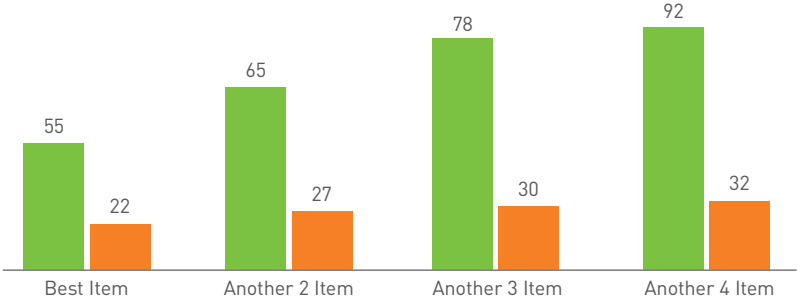
Delaying CV mortality



■ % Physicians Reached  
■ % Preference Share

Monotherapy 1st Line

# A second example....



Safety in nursing mothers



Delaying CV mortality



Effects on CV mortality



- % Physicians Reached
- % Preference Share

**Monotherapy  
1st Line**

## 7. Remember, it is about incremental, not absolute value of trials

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- Crucial, yet almost always overlooked.
- Key: what are the incremental values of adding different trials.
- Key: what is optimal number of trials, which ties directly into incremental value.

# What does “incremental” mean here?

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	Alone	Bundled
TRIAL “A”	20%	18%
TRIAL “B”	14%	4%
TRIAL “C”	12%	10%
TRIAL “D”	7%	7%
TRIAL “E”	5%	1%

## 8. Put the cost of trials into analysis

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- Often forgotten in this type of research.
- Never forgotten by clinical and upper management.
- Can significantly change your decisions when attached to incremental value.

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# Five Ways to Put Research Results Into Action...

# Five Ways to Put Research Into Action

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1. Focus clinical on the right product features to optimize.
2. Most obvious: conduct the right trials...
3. ...with the right endpoints.
4. Get first clues into “hot buttons” in market.
5. Understand the power of competitive compounds in development and resource accordingly

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# Who Will Win the Race?

He thinks he's #1, but in reality, he's not....

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With customer driven  
guidance, he can win

ziment

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**Thank You.**

**Strategic Market Research for  
Pharmaceutical Practitioners**

The logo features a large, solid green square. A white horizontal rectangle is positioned across the middle of the square, overlapping it. The word "ziment" is written in a lowercase, sans-serif font across this white rectangle. The letter "z" is green, while the remaining letters "iment" are black.

ziment