

The logo for Ziment, featuring the word "ziment" in a lowercase, sans-serif font. The letter "z" is green, while the letters "iment" are black. The text is centered within a white rectangular box that is superimposed on a larger green square background.

**ziment**

## **Importance of Strategic Research Early In Compound Development Process to Maximize Commercialization**

Pharmaceutical Marketing  
Research Group  
Fall 2004 Conference  
Tuesday, 9/21/04

## 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?
- Show you five tricks to help you conduct better research to help optimize the commercial chances of your compound.
- Talk to you about a case study where the results from early stage research were put into action.

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# Why Should All of This Matter to You?



## There are four 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 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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- Costs between \$300 and \$600 million to bring a drug to market.
- Remember the opportunity cost.

### 3. NDAs and INDs are not growing

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	INDs	NDAs
1999	498	139
2001	425	99
2003	426	119

In 1999 R&D spend: \$23 billion industry-wide. In 2003, \$33 billion

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

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- Have you ever been stuck with comparators that do not matter to your customers?
- Have you ever demonstrated efficacy or safety against endpoints that do not matter to your customers?

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## Five Tricks For Better Research....

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First, Let Me Assure You...

Researchers Cannot  
See the Future

## Five tricks for better research....

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- 1 Modeling allows you the flexibility you need
- 2 Use approach that can handle variability
- 3 Don't forget the competition
- 4 It is about breadth AND depth
- 5 Its about incremental, not the absolute value of the trial

# 1. Modeling = flexibility

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- **Concept testing vs. trade-off modeling**

- ▶ 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.

## 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

#### A Dosing Frequency

- 1 time/day
- 2 times/day
- 3 times/day
- 4 times/day

#### B Incidence of Hypoglycemia

- <1%
- 1% - 3%
- >3%

#### C Incidence of Headache

- <5%
- 5% - 10%

#### D Price

- Same as gold standard
- 10% less than gold standard
- 20% less than gold standard

### Clinical End Points

#### E Indication

- Monotherapy 1st Line
- Combination Therapy
- 2nd Line Only

#### F Safety in Patients with Renal Impairment

- Data available
- No data available

#### G Safety for Use with Nursing Mothers

- Data available
- No data available

#### H Effects on Cardiovascular Mortality

- Data available
- No data available

#### I Delaying of Cardiovascular Complications

- Data available
- No data available

## When setting these studies up, don't forget to "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%

### 3. 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.

## 4. It's About Breadth AND Depth

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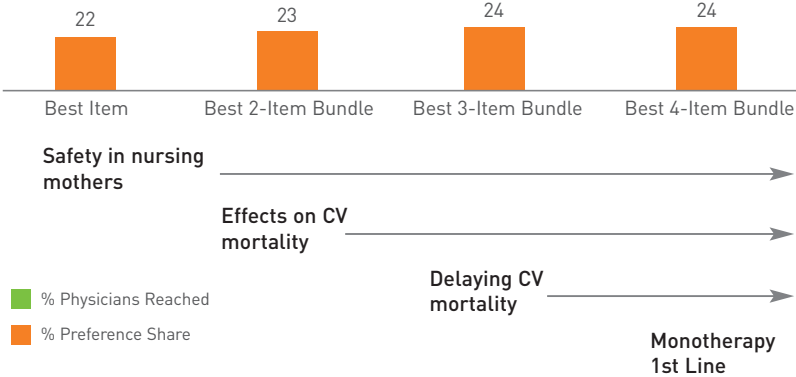
- Most work looks only at depth.
- Fine, but:
  - No measure as to overall customer penetration.
  - No insight into speed to peak share.
  - No clues as to the execution needed to accomplish given scenario.

## Problem is...

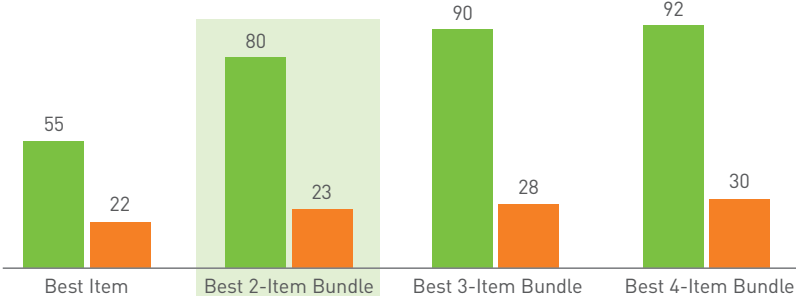
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- Easier to measure depth.
- Really hard to measure breadth, especially when measuring interactions between given potential trials, product attributes, etc.

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



# 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

## 5. 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 the optimal number of trials.

# 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%

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But in the end....

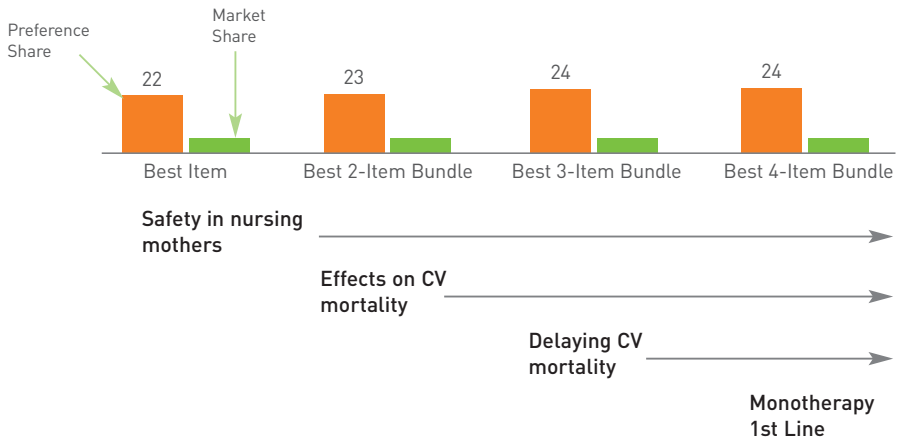
# It's the ability to put customer demand directly into forecast models that is crucial

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- Overstatement from primary research has made this problematic...until now.
- The key? To effectively correct for this overstatement, to “calibrate demand”.

# Preference Share Is Not Market Share

You Need to Calibrate  
To Feed Customer Demand Into Forecasts



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# How to Use The Results - A Case Study

# Gabitril, the first commercially available SGRI

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## What issues drove this research?

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- Poor GABA tone is implicated in a variety of patient disorders.
- SGRIs selectively inhibit reuptake of GABA and restore normal GABA tone.

### GABA A

Epilepsy  
Anxiety  
Panic  
Sleep

### GABA B

Analgesia  
Sleep  
Depression

## Why was this research important?

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### **There are many traps to avoid in the life-cycle planning process**

- 1 Determining market size by counting people who are prevalent/diagnosed/treated
- 2 Looking at world from univariate perspective – underestimating interaction phenomenon
- 3 Relying upon KOLs as proxies for clinicians
- 4 Understanding how much a benefit (or disadvantage) is meaningful vis-à-vis competition

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**These issues were all compounded by the presence internally of group think, individual biases, and the human tendency to draw far reaching conclusions from small sample sizes.**

# What research did we conduct?

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- **Explore!**

- Qualitative research with relevant physicians:
  - Identify which attributes are important in selection of a therapeutic option
  - Establish range of each variable
- Research appropriate epidemiological information each disease state
  - Prevalence, Diagnosis, Treatment Rates

- **Agree**

- Create product profiles with most likely attribute sets and identify possible ranges around each one
- Identify the costs for each clinical program

- **Quantify**

- Trade-off analysis
- Identify variables that “move the needle the most” and impact on preference share

- **Simulate**

- Run various scenarios of attribute bundles to determine potential market shares, market growth, penetration & NPV.

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**This research provided us a what we  
needed - a tool to facilitate objective,  
data-driven decisions!**

## What decisions did the research influence?

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- Life Cycle Management
- Audience Assessment/Targeting
- Pricing
- **Who delivered this tool?**
  - Ultimately, our customers crafted it

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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

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