



DISCLAIMER: The content of this presentation may not accurately reflect current legal or regulatory requirements, industry standards, or professional best practices. ISMPP is providing access to this presentation as a member service only, and does not recommend or condone the use of this presentation in whole or in part to support legal or professional decisions or practices.

Thank you for joining
ISMPP U today!

**Today's program will begin promptly at
12:00 noon EST**

**For optimal viewing, please utilize
the 'Full Screen' button at the
top left of your screen**



Developing Strategic Gap Analyses: Practical Considerations

July 16, 2008

Gap Analyses Overview

Gap Analysis: Definition

- An analysis of published literature, congress abstracts, and other communications for a product and selected competitors to identify pertinent topics or ideas that are not covered or are covered inadequately

Gap Analysis: Purpose

- Purpose
 - Identify communications gaps in currently available publications/communications vs internal objectives, competitor activity, and/or educational need
 - Maximize impact of publications
 - Provide background or foundation for new publication team
 - Develop or update publication plans
 - Situational analyses
 - Identify unmet educational need(s) in literature

What Can Be Analyzed?

- Volume of publications
- Indications
- Audiences
- Types of articles
- Quality of data/strength of evidence
- Timing
- Journal/meeting selection
- Ongoing clinical trials (clinicaltrials.gov)
- Key communications
 - What was said
 - How it was said (tonality)

Getting Started

- Identify areas of focus
- Determine a meaningful timeframe for analysis
- Identify scope of research (publications, meeting abstracts, other)
- Determine parameters for search (drug name(s), keyword, limits)

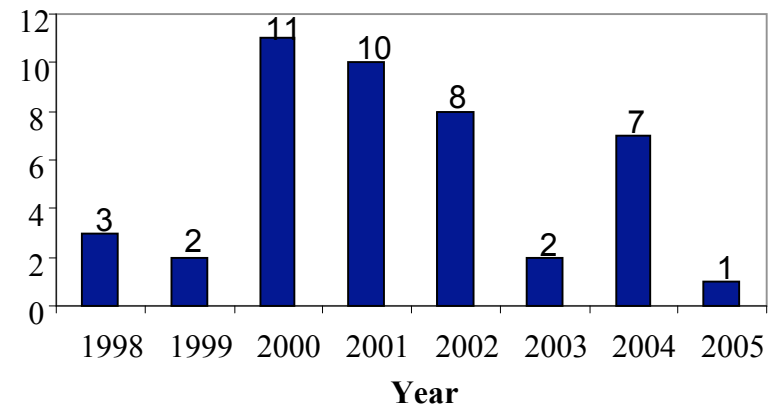
Determining a Meaningful Timeframe

- Analysis of current activity (eg, ~1 year)
 - What is relevant now
 - Allows for in-depth evaluation
- Milestone snapshot
 - Determine period of interest for competitive products (pre-launch, peri-launch, post-launch)
 - Look for trends
- Historical analysis (eg, 5+ years)
 - Benchmark vs competitor activity across multiple product milestones
 - Look for trends

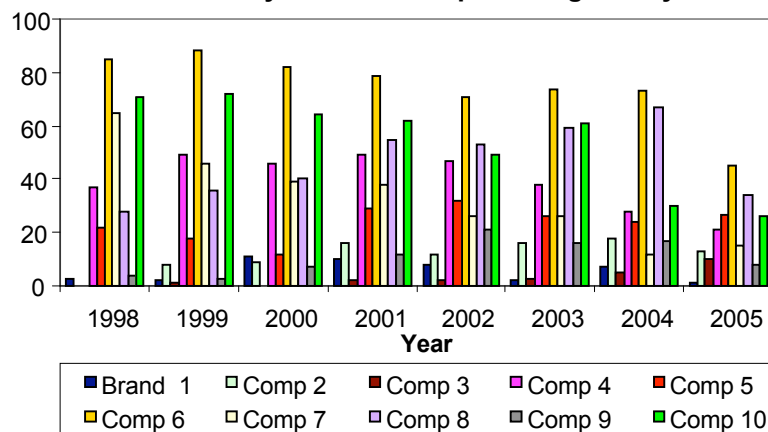
Tonality of the Evidence

- Numbers tell *part* of the story
- Numbers drive . . . numbers
- Remaining unanswered are:
 - Tone: positive/negative/neutral
 - Frequency of key evidence
 - Readership focus

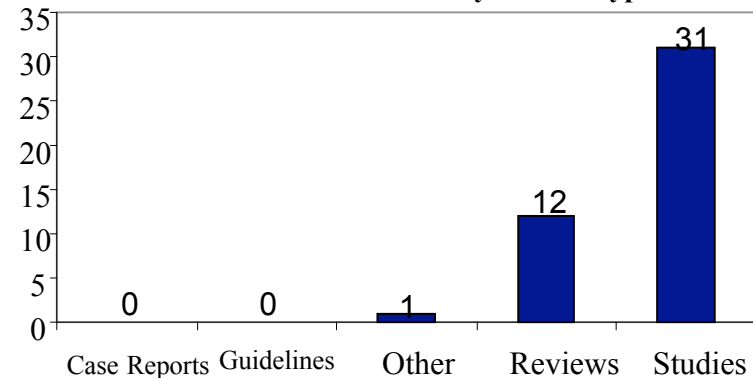
Brand's Publication Citations per Year



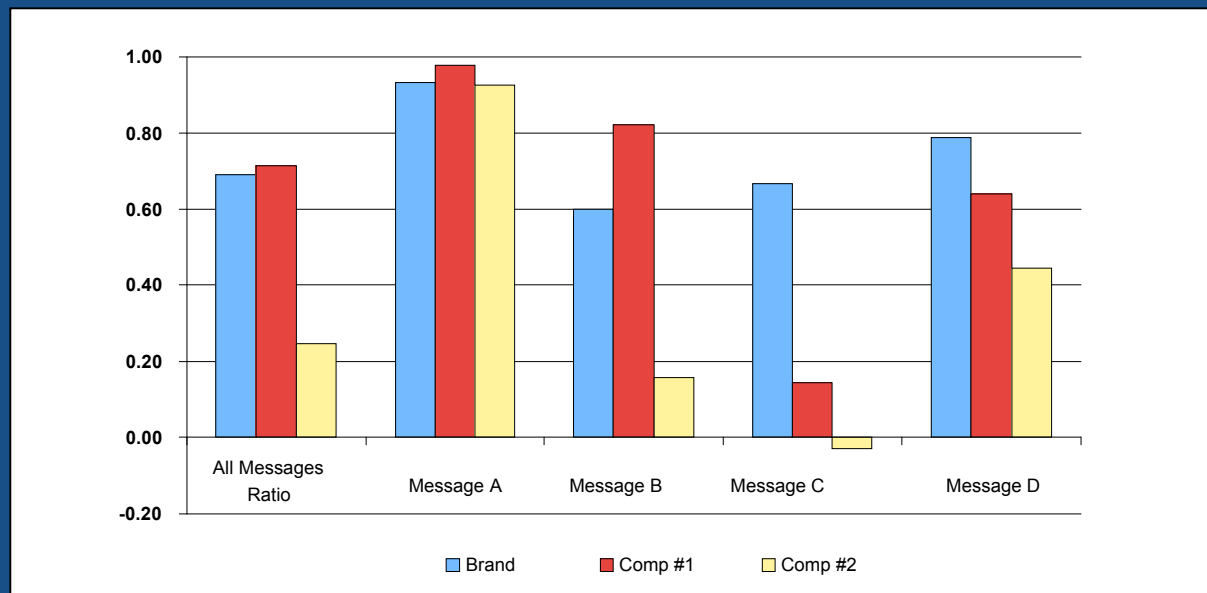
Publications by Brand & Competitor Agents by Year



Brand's # Publications by Article Type



Tonality of the Evidence



- Determining if the published evidence is positive/negative/neutral
- Comparing the evidences' tone to similar evidence of the competitors
- Knowing your evidence strengths and opportunities

Output of Gap Analysis (1)

- Internal audit (ie, where are we now?)
 - Inventory current publications
 - Identify common themes
 - Determine penetrance of theme (ie, venues, journals, audiences)
- Considerations
 - Align goals of audit with brand plan
 - Status of ongoing and planned trials

Output of Gap Analysis (2)

- External comparison (ie, what have others done?)
 - Inventory competitor communications over time
 - Determine reach of competitor communications
 - Determine strength of competitor communications
 - Construct SWOT for each compound to identify potential gaps

Example SWOT

Strengths	Weaknesses
<ul style="list-style-type: none">• More favorable phase 2 clinical data than competitor compounds• No adverse effect on QT interval• General tolerability proven in phase 2 trials• Intravenous formulation will be first in class	<ul style="list-style-type: none">• Development of oral formulation trails competitors• No long-term safety and tolerability data to support chronic use• Very little background on medication class• Issues with intravenous formulation• Optimal dosing not well defined
Opportunities	Threats
<ul style="list-style-type: none">• Meets unmet need for alternative to XXX with XXX properties for patients with XXX• Likely to become the first XXX with indications in XXX and XXX• Novel MOA• Many options for follow-on indications	<ul style="list-style-type: none">• Potential for long-term adverse effects caused by XXX• Risk of XXX recognized as a class effect• Earlier availability of oral formulations by competitors

Output of Gap Analysis (3)

- Internal comparison (ie, where do we want to be?)
 - Review results of internal audit/competitor activity and compare with desired target brand profile
 - Identify overlap and gaps
 - For overlap, determine strength of communications vs desired
 - For gaps, break out by feasibility to address
 - Existing data, easily addressed
 - Existing data, would require additional analyses
 - No existing data, would require additional studies

Output of Gap Analysis (4)

- Summary
 - Develop working communications SWOT
 - Summarize and prioritize gaps and feasibility of addressing each
 - Propose action plan to address gaps identified
- Potential Formats for Analyses
 - Word document
 - PowerPoint presentation
 - Others

Pitfalls

Pitfalls: Timeframes

- Pitfall: Using a too broad or too narrow timeframe for analysis
 - Too broad:
 - Very large volume of material to review
 - Lose focus of analysis objectives
 - Too narrow:
 - Miss a meaningful result
- Pitfall: Underestimating time for conducting gap analysis

Pitfalls

Analysis Paralysis

Problems

- A. Cutting the data, eg, all articles with 3 or more messages AND published in 2006 AND by an US-based author AND



Possible Solutions

- A. Answer the big picture questions. Start by listing the questions that are pertinent first. Clear analysis objectives must be written first.

Crystal Ball Syndrome

- B. Projecting incomplete data, eg, 8 of 15 ongoing clinical trials are more than 5 months behind schedule – projecting when all 15 trials will be completed for and ready for publications



- B. This example is alerting the publication team that most trials encounter delays. Therefore, avoid including this information in a Gap Analysis.

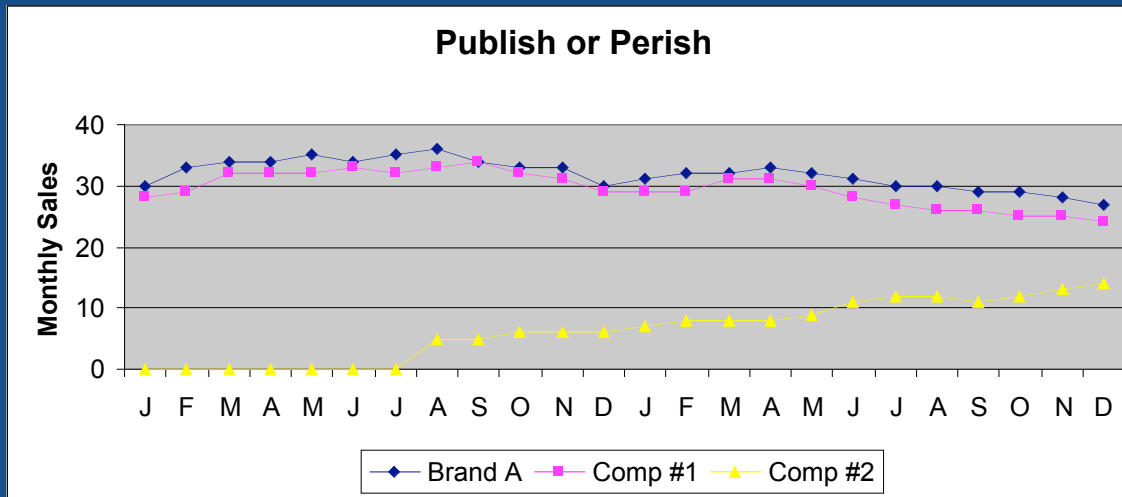
Pitfall: Losing Sight of the Ball

- Do not understand scope of analysis
 - Quick top-line vs. in-depth comprehensive analyses
 - Can result in reviewing too much or too little
- Change direction mid-stream
 - Add parameters or completely change scope
 - Can result in:
 - Confusing outcome
 - Additional time/cost



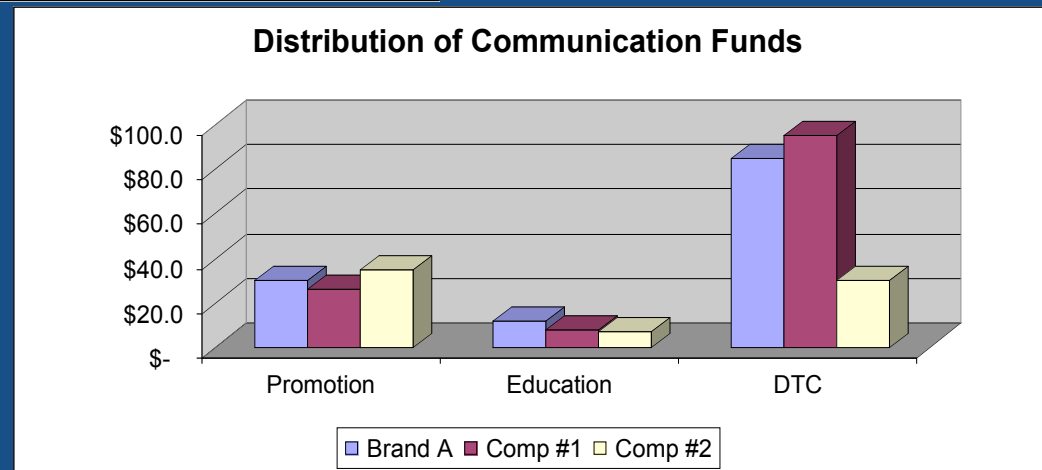
Case Studies

Case Study #1: “Who are those guys?”

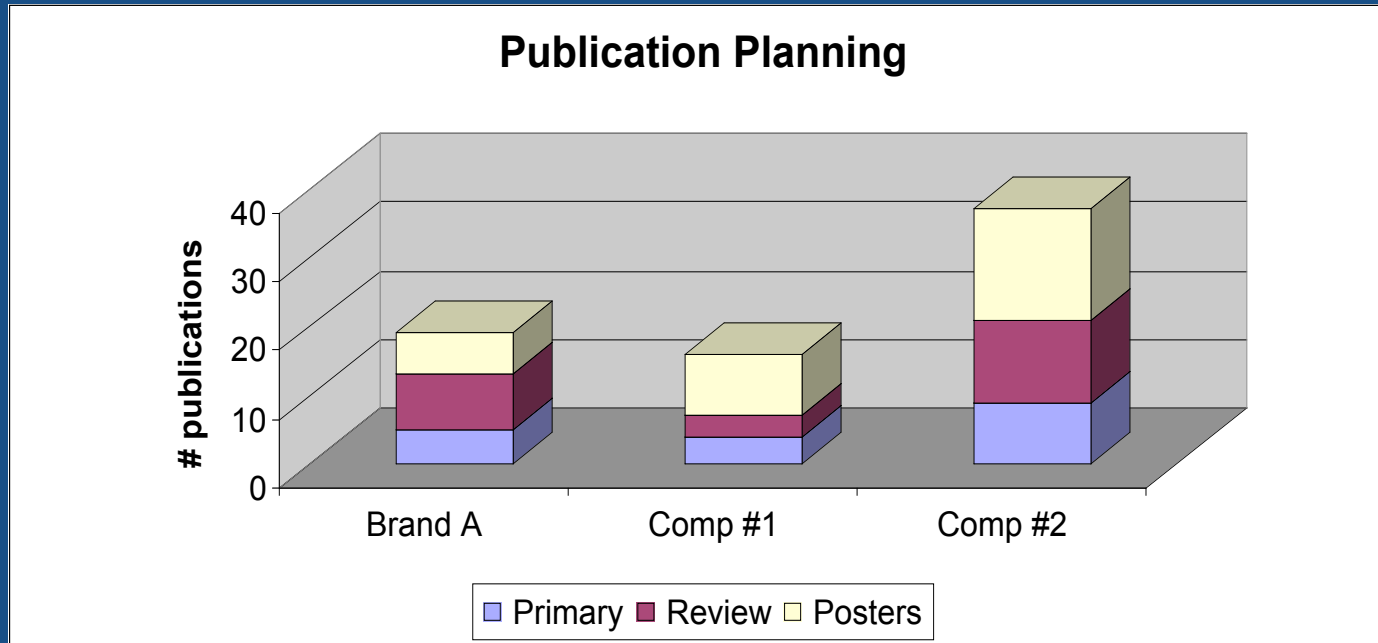


The “Brand A” Team has been the leader in their TA. The new “Comp #2” suddenly has started capturing share!

Analysis of the market shows that “Comp #2” is spending about the same in the traditional areas and significantly less DTC, which always had been a successful investment for this type of therapy.



Case Study #1: Evidence = Success



A gap analysis of the literature during this period discovered that the new competitor (Comp #2), was aggressively publishing the evidence to the right audience with positive, scientific messaging.

Brand A reallocated budget to its scientific publication initiative overnight!

Case 2: Finding the Golden Lining

Need: Identify potential in other audiences

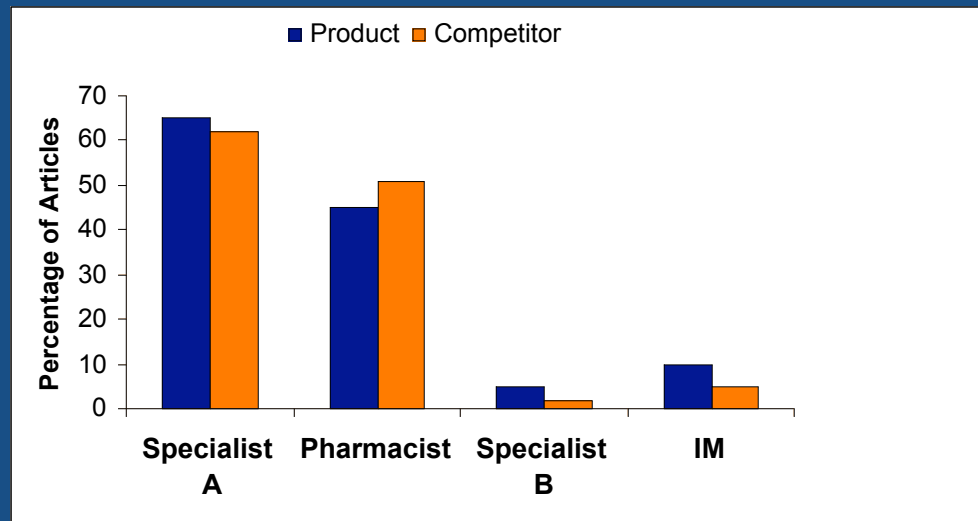
Scenario:

- Product has been marketed for 3 years
- All publications have been focused on ID and pharmacists
- Marketing research indicates that other specialists and IMs may use product

Case 2: Finding the Golden Lining

What was done:

- Gap analysis stratified by audience



Result:

- Identified potential “unclaimed” territory
- Manuscripts submitted to journals targeting “new” audiences

Developing Strategic Gap Analyses: Practical Considerations

Open Discussion/Audience Q&A

Next ISMPP U

- **Topic:** Certification Exam – Where Are We?
- **Date:** September 17
- **Time:** 12 Noon EST

**Thank you for joining
ISMPP U today!**

Your feedback is important....

Before logging off, please fill out
the brief evaluation that will appear
on your screen as you exit