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

- 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

**Publications by Brand & Competitor Agents by Year**

**Brand’s Publication Citations per 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

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
</table>
| - 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 | - 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 |

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
</table>
| - 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 | - 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
Discussion 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.
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