Gap Analysis

Neil Baker
Russell Traynor

Disclaimer

- The views expressed in this workshop are those of the facilitators and do not necessarily match those of ISMPP or UBC-Envision Group

Disclaimer

This presentation was developed to facilitate audience participation and the execution of this workshop.

•The content of this presentation was not developed to endorse, suggest, or imply, directly or indirectly, policies or procedures that should be followed when disseminating scientific information including the roles and interactions that cross-functional team members should have when developing or implementing a publication plan.

•When permissible, ambiguous language was used to foster audience participation and to encourage the evaluation of concepts from multiple viewpoints, some of which, may be contrary to accepted industry guidelines.

•It is the responsibility of each participant to this workshop to ensure that all applicable policies and procedures for his/her role are observed.

Learning Objectives

- To guide participants through the process of conducting a gap analysis
- To understand the appropriate source material
- To provide an overview of
  - The assessment of the findings
  - The discussions on how to apply the results effectively to build a strategic publication plan

Group survey: What is your experience level with Gap Analysis?

Publication-Specific Gap Analyses

What is a Publication Gap Analysis?

What is a Publication Gap Analysis?

1. Identifies key topics or educational areas related to a product within a specific therapeutic area or indication

   AND

2. Characterizes how these topics are addressed (published literature, congress proceedings, other communications), both in terms of breadth and depth.

   Gaps are those areas not covered or not covered sufficiently.

How can a Gap Analysis be used?

How can a Gap Analysis be used?

- Identify medical/scientific communication needs or deficiencies based on published/presented data or other communications
- Develop or update publication plans
- Use in presentations or updates to medical/publication team(s)
- Identify unaddressed issues in literature, which might represent educational opportunities/needs for the medical community

What type of information is generally included in a Gap Analysis?

What type of information is generally included in a Gap Analysis?

- Therapeutic indications
- Publications volume/quantity
- Audiences (primary care, nurse, pharmacist, etc)
- Types of articles (primary data, review, cases, etc)
- Quality of data/strength of evidence
- Profile of publication/presentations over time
- Types of journal or congresses
- Ongoing clinical trials (clinicaltrials.gov)
- Key medical communication points

Reminder:

- Analyses can be done in a number of ways

It is critical that the findings not be presented alone. They must be interpreted to provide salient recommendations for the improvement of the publication plan.

What Is Not Included in a Typical Gap Analysis?

- Marketing-related data, literature
- Advisory board input (though some information may give guidance or direction)
- Decision Resource Reports?
- ***What else?***

What Gaps are You Addressing?

What Gaps are You Addressing?

- Internal (self only)
  - How to improve your brand's publication plan based on previous performance
  - GAPS TO ADDRESS
- External (self vs others)
  - A comparison against competitor(s) to determine gaps between products
  - GAPS TO MAXIMIZE

How Will You Assess the Gaps?

How Will You Assess the Gaps?

- Qualitative
  - Examining major presentations/publications
  - These can examine specific part of an indication/therapy area
- Quantitative
  - Numeric comparison of publication activity
- Most analyses are hybrid
  - Clients tend to want both

Key First Steps

- Determine the scope of the analysis
- Considerations need to be given to
  - Therapy area
  - Historical timeline
  - Current publications activity
  - Phase/Maturity of the product
  - Competitor(s) of interest
  - Major internal/external milestones
  - Scope of analysis (content-, output-related…)

Example: Telaprevir

- Small molecule antiviral (protease inhibitor) for hepatitis C virus (HCV)
- High disease burden, long course of progression
- Challenge: establish efficacy role in setting of current standard of care (peg-interferon + ribavirin)
- Complex and emerging treatment algorithm: role of HCV genotype, host genetics, and other factors in therapeutic success rates
- Drug resistance: a new hurdle to clear
  - Small molecules are direct antiviral agents, so viral escape is possible via mutagenesis
  - Combination therapy w/ small molecules? (similar to HIV)

Do's and Don't(s)

Do

- Ask specific questions
- Define search strategy up front
- Go back to the original citations/sources

Don't

- Have vague needs
- Agree to/request everything
- "Cherry pick" source material

The difficult part: Only when you get into the details can you make a true decision on
1: How deep to go
2: When to stop digging

Organizing Information and Tips for Searching

Organizing information, ideas

- Take notes, summarize, categorize
- Identify key topic areas that distinguish this agent or are central/relevant to its role or identity in the therapeutic landscape
- Common themes: what is being said?
  - Positive, negative, neutral?
  - Focus on safety, efficacy, specific symptoms, special populations?
- Cluster related ideas or themes; eliminate redundancy
- Think of the "big picture" — identifying **gaps** in the literature where data or expert opinion may improve clinical understanding

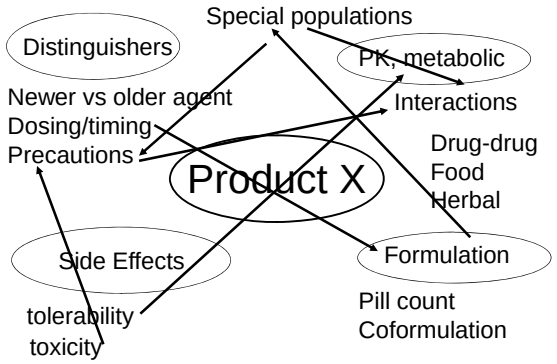
Random Topic Lists

Opportunities	**Challenges**
Newer agent	Product warnings or precautions
Side effect profile	Efficacy limitations
Improved dosing	Older agent
Tolerability	Side effect profile
Enhanced efficacy	Disease challenges
Cost/benefit analysis	(eg, viral or bacterial resistance)

Competitor(s)

Product lifecycle	Reformulation
Only agent shown to. . .	Indication, uptake
Current studies	Publication activity

Idea Clustering



Getting up to Speed

- Scan the literature and recent congresses for information on the therapeutic area, including the compound(s) of interest
- Review recent summary reports, CME modules, etc
- Corporate websites
- Product labels

Additional information sources

- State-of-the-art reviews in the literature – note sources/references)
- Congress updates (Medscape, others)
- Clinical guidelines (guideline.gov, medical societies, others)
- General sources (WebMD, MEDLINEplus)
- FirstWord
- Datamonitor
- Press releases
- Doctor’s Guide

Primary sources: Where to cast nets

- Public Databases
  - PubMed
  - Clinicaltrials.gov
  - Clinicaltrialresults.org
  - FDA.gov
  - Other
- Commercial Databases
  - ISI Web of Science
  - Ovid/SCOPUS
  - MD Consult
  - Other
- Congress literature (journal supplements, society/meeting sites, etc)

Using tools wisely

- Use advanced search features
  - Search engine example
    - Boolean, other criteria
    - Alternative search engines (meta, clustering, etc)
  - PubMed example
    - Limits
    - Parentheses, quotes, etc
    - My NCBI
- Identify keywords
  - Consider a controlled vocabulary ex: MeSH
  - Related articles, details tab

Gathering and Working with the Data

How deep to dig?

- Timeline Considerations
- How far "back" should you go?
- Historical vs current: *what is most critical to informing the analysis?*

Document the Search Methods

- Vary search strategies
  - Stay organized
  - Keep track of what works
  - Maintain consistent approach for related searches, information
- Define criteria for search parameters (keywords, limits, etc): what was included and what was not—and why?

Organizing the Information

- Build a reference "database"
  - Divide information into multiple fields (authors, journal/congress, type of publication, type of study/analysis, year, etc.)
  - Use predefined categories whenever possible
  - Allows for flexibility (sorting, grouping according to key characteristics)
- Tables and grids are helpful

Grid example

PMID	Publication type	Drug	Citation	Title	Endpoints (if applicable)	Key Summary Points	Relationship to Scientific Platforms
17352	Randomized, controlled clinical trial	A	NEJM, 109(8): 1250-60, 2008	Transient improvement in patients with mild to moderate impaired breathing in the STRATA study	Safety	• ADCD • EFGH • IJKLM	Improved safety profile with long-term treatment vs current standard of care

Beginning the Analysis

Product Arena

- Characteristics of products on market (unmet needs or new opportunities?)
- Characteristics of emerging therapies (“pipeline”)

Profiling the Product(s)

- Clinical trials
  - Size (patient numbers, enrollment sites, etc)
  - Endpoints
  - Findings
- Dosing and administration (differences?)
- PK profile, drug-drug interactions
- Efficacy
- Safety and tolerability
- Patient-reported outcomes

Set the Stage for the Plan/Proposal

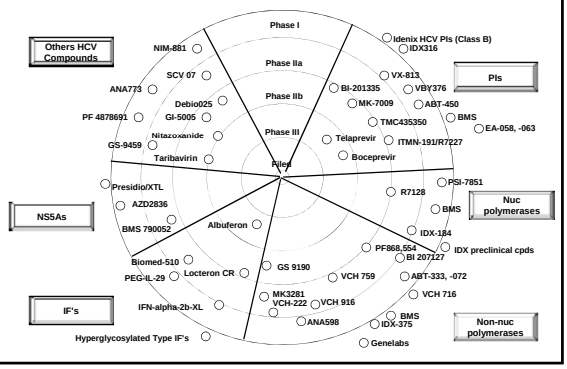
- Gaps
- Differentiators
- Challenges
- Trends

Keep in mind that such factors as clinical communication points, audiences, etc. may change over time for a single brand and may differ among various competitors.

Example: Telaprevir

GAPS	DIFFERENTIATORS
Genetic diversity of HCV & therapeutic response Optimal timing to treat, PEP? HIV co-infected patients	Small molecule (oral) Direct antiviral activity Mechanism of action
CHALLENGES	**TRENDS**
Viral resistance & clinical consequences Improve upon existing standard of care (SOC)	Combinations of agents Studies with and without either of the SOC agents "Treatment-experienced" patient population

HCV Compounds in Development



Refreshment Break

Question: Potential Analyses

For those with direct experience or knowledge of gap analysis, what are some potential types of analyses?

Potential Analyses

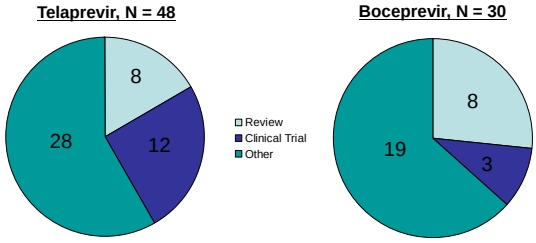
- publication volume
- publication type
- audiences
- geography
- indications
- key quotes
- type of studies
- journal/meetings
- agents studied
- scientific / medical communication points

Quantitative Analysis

Quantitative Analysis

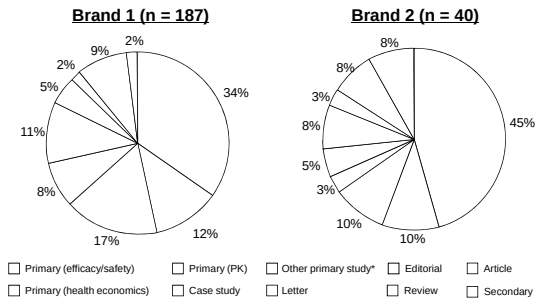
- Measurable statistics (numbers of publications by type, year, audience, topic or theme, etc.)
- “Graphable” and more directly comparable

Example: Telaprevir vs Boceprevir (simple pub type/volume)

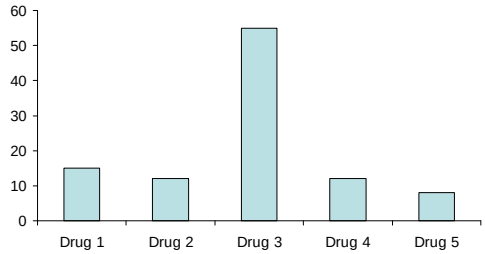


PubMed: Last 3 years, English, Title/Abstract fields

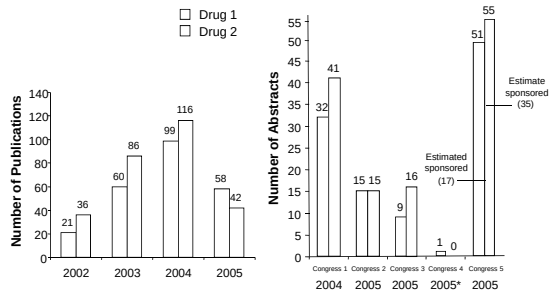
Types of Publications



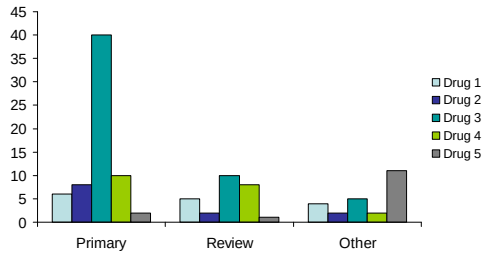
Quantity by <Year>: Competitor Publications



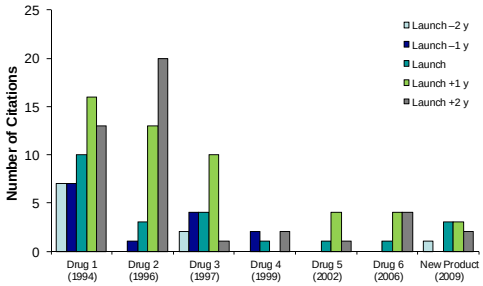
Quantity by Year: Important to Differentiate Abstract and Papers



<Year> Competitor Publications: Analysis of Papers by Type



Clinical Trial Publications: An Analysis Around Launch

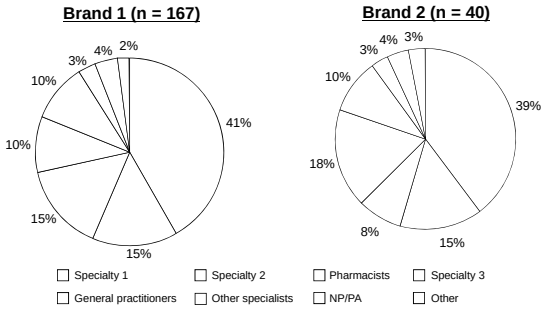


Phasing Publications for Target Audiences

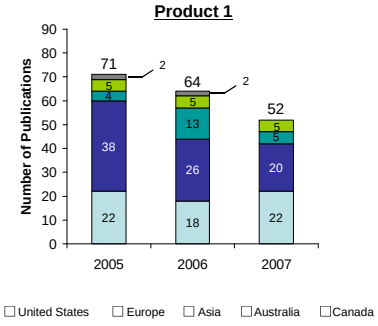
Key Target Audiences	2009	2010	2011
Virologists	****	****	****
Microbiologists	*	**	***
Dermatologists	***	***	****
STD physicians	***	****	****
Obstetricians	*	*	**
Paediatricians	*	**	***
Pain specialists	***	***	****

Asterisks signify relative importance (**** = highest importance, no star = no communications planned for given year)

Publications by Audience

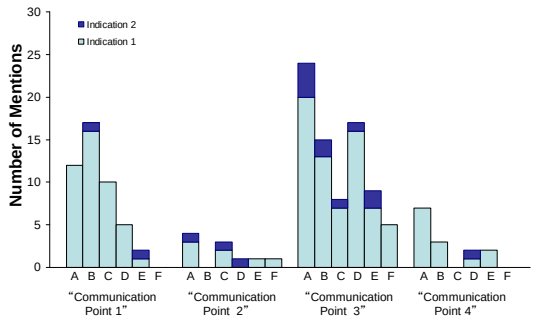


Number of Publications: Regional Analysis



Scientific / Medical Communication Themes

External Gap Analysis: by Communication Point



Internal Analysis

- Examining your publications for gaps
  - Use external and internal data
    - Are they consistent?
  - Look for gaps in both what is being communications and the audience

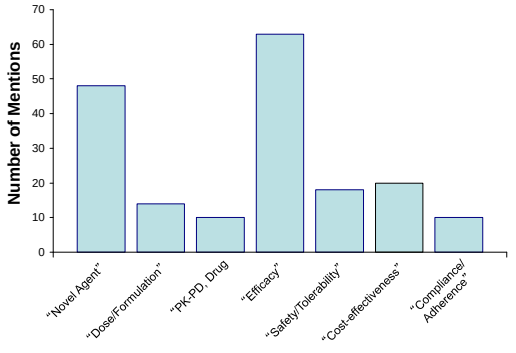
Internal Gap Analysis by Content

	Source		Type			Indications			
	Publication	Abstract	Primary	Review	Letter/ editorial	IN 1	IN 2	Both	IN 3
CP1	10	5	6	6	3	0	9	5	1
CP2	19	10	20	6	3	5	12	8	1
CP3	0	2	1	1	0	0	1	1	0
CP4	4	2	5	1	0	1	3	0	2
CP5	11	3	7	6	1	0	5	5	1

Internal Gap Analysis: Audience/Location

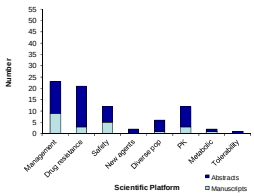
		Audience					Location				
	Total	PCP	Spec 1	Spec 2	Spec 3	NP/ PA	Eur	Asia	US	Can	Jap
CP1	14	4	2	5	2	1	0	0	14	0	0
CP2	18	3	1	8	2	4	7	1	10	0	0
CP3	36	9	2	17	5	3	0	0	33	1	1
CP4	6	2	0	2	0	2	1	0	5	0	0
CP5	33	5	1	20	4	3	4	0	27	0	2

Internal Gap Analysis: Communication Point Usage

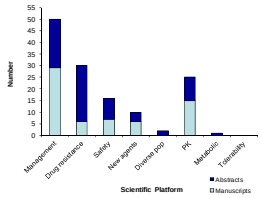


Overall Publications* by 2007 Scientific Platforms

Drug A



Drug B



* 2006/2007 conferences: ACOG, ICAAC, International Drug Therapy Workshop; manuscripts and publications in PubMed, Dec 2006 to Dec 2007

Qualitative Analysis

Qualitative Benchmarking

- Taken from only key papers (criteria-based)
- More selective
- Important to ensure relevance
  - How?

“Share of Voice” vs How Loudly

- Groundbreaking vs confirmatory results
- High-profile vs lower-profile venue or journal
- Clinical interest/uptake
  (including citations of published work)

Additional Key Details

- Leading congresses or meetings
- Key journals
- Clinical trials, sponsors
- Controversies or “hot topics”?
- Other sources of data
  - Physician/Provider surveys?
  - Consumer focus groups?
  - Other?

What is being said about _____?

- When reading the research on the products/therapy area, it is often useful to find key quotes regarding practices guidelines/ comprehensive reviews
- This provides external perceptions to be benchmarked
  - What is being said
- Care is needed to
  - Overly focus on supported publications
  - Ensure all quotes are from higher-end journals and top opinion leaders

Sample Qualitative Output

Product X: Core Communications

References in notes as citation

- MOA
  - It has been hypothesized that the MOA of XXXXXXX includes action1, action2 as well as action3, and mechanism1 effects[1,2]
  - XXXXXXX plus YYYYYYY provides a synergistic/additive? effect on typeA and typeB cell lines/animal models by ……[3,4]
  - In vitro studies suggest the XXXXX up/downregulates the expression of ……. which results in ……..[5,6]

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Product X: Core Communications

- Disease state/Unmet medical need
  - Indication 1
    - The natural history of disease state 1 has been improved in recent years with the advent of drug class1; however, a significant number of patients experience <unmet clinical need>[1]
      - Standard therapy statement
  - Indication 2 [3]
    - Disease state 2 is a characterized primarily by sign1 along with demonstration of symptom2

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Product X: Continued

- Continue with same theme of output
- Efficacy (main endpoints)
- Safety
- Health outcomes
- Comparison to other therapies/disease states
- Differentiation from other therapies
- Combination therapies
- Future development opportunities

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Remember

- Qualitative gap analysis can be very long and detailed
- Often important to include an executive summary on each product examined
  - Can be helpful to do a summary slide noting references between two products also

Qualitative Gap Analysis

- Major indication
- Key geographic population
- Special populations
  - Subpopulation 1
  - Subpopulation 2
- Patients with major comorbidity
- Major progressive disease?
- Long-term data?
- Minor comorbidity?
- Physician habits defined?

Brand	Competitor
List of key papers	Author 2004 Author 2005
Congress abstract 2009	Study NO/Acronym

Question

How do you avoid bias when doing a qualitative analysis of publications?

Where or When can a Gap Analysis Go Astray?

Too Little

- *No interpretation* – analysis not used to update plans/tactics
- *No depth* – a basic analysis of PubMed hits is not enough
- *Navel-gazing* – using the analysis to affirm the current strategy

Too Much

- *Going too Far* – analysis into minutiae: adding tactics on minor gaps that have no salient value to the overall strategy

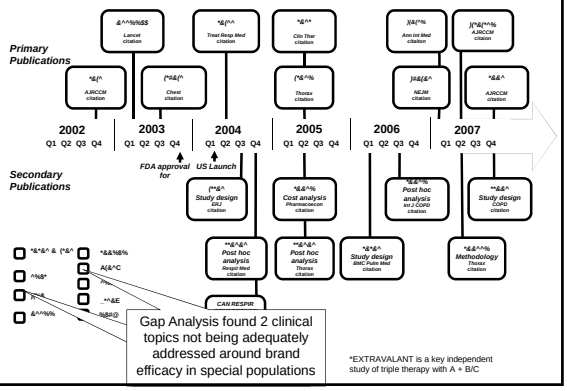
As with everything, it's all in the details…….

Harnessing the Gap Analysis for the Publications Plan

Harnessing the Gap Analysis

- Creating an overview of the therapeutic area from a scientific publications perspective
- Assessment of internal (client) and external (competitor)
  - Evidence base
  - Scientific/medical themes
  - Audience: breadth and depth
- Links with current or planned clinical data

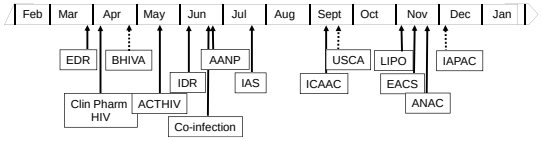
Harnessing the Gap Analysis: Timeline of publications of large clinical trials of Drug X for INDICATION



*EXTRAVALANT is a key independent study of triple therapy with A + B/C

Harnessing the Gap Analysis: Congress Planning

An analysis of publications by Audience found that clinical trial data for Brand A were not being submitted to nursing meetings, while Brand B had as much as 15% of its congress presence there. Thus, new targets were applied to the Brand A plan.



Using the Gap Analysis for Setting Goals in the Publications Plan

- Can the gaps be filled by existing or upcoming data?
- Quantitative and Qualitative analyses (ie, numbers vs interpretation): How to strike the right balance?

Gap Analysis Tools

Considerations for Tools and Technology

- Software suggestions: What is helpful?
  - Thomson Message Mapping System (TMMS)
  - Datavision, PubsHub, PubStrat
  - ISI Web of Science
  - Others?
- Online (free) resources?
  - Google Scholar
  - My NCBI (PubMed – saved searches and results)
  - Others?