Strategic publication planning

Margaret Haugh
mediCom Consult
(mhaugh@medicom-consult.com)

Strategic Publication Planning – EUDIPHARM
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Strategies are not all good ...
Need for publications

• For academic research
  – Career advancement
  – Funding

• For the pharmaceutical industry
  – In any marketing material, every statement of fact must be referenced
    • Clinical trial data is essential for the delivery of product-related core messages
  – Before citation, the data must be published
    • Once published need to be made visible and accessible by all stakeholders in a timely manner
  – Lack of publication planning can lead to important delays and missed opportunities
Need for a publication plan

• For academic research
  – Organisational timetable and plan
  – Maximise results from research programme

• For the pharmaceutical industry
  – Process to release clinical, epidemiology, health-economics data into the biomedical literature
  – Supporting efficacy/effectiveness of the product
  – Increases disease awareness
  – Provides essential appropriate sources for other promotional or scientific communication
Driving Force Behind Publication Planning

• Maximise dissemination of research data
• Ensure research is clearly communicated and messages are consistent
• Differentiate product from competitors
• Increase product market share
• Single source describing all publication (non-CME) activities
Drug product life cycle

- Basic Research
- Preclinical Development
- Clinical Development (Phase 1, Phase 2, Phase 3)
- Market Authorisation/Launch
- Postmarketing Studies

Preclinical publications
Primary clinical publications
Secondary/tertiary publications
Market authorisation

Publication plan developed early and communicated
Publication plan amended as necessary over life cycle
Strategic Approach

• Consider both clinical and marketing initiatives
• Product life cycle
• Market and competitor activity
• Content and process
Anatomy of a Publication Plan

- **Situation Analysis**
  - Gap analysis
  - Message Testing
  - Advisory Board Findings

- **SWOT**
  - Market Research
  - Treatment Guidelines
  - Market Opportunities
  - Market Threats

- **Communication Imperatives**
  - WHAT ISSUES NEED TO BE ADDRESSED

- **Communication Messages**
  - MESSAGES TO ADDRESS THE ISSUES

**CLINICAL DATA**

**Product Strengths**

**Product Weaknesses**
Sample Table of Contents

1.0 EXECUTIVE SUMMARY

2.0 COMPETITOR PUBLICATION ANALYSIS (GAP) SUMMARY
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   3.4 Planned Clinical Studies
   3.5 XXXX Proposed Clinical Studies

4.0 SWOT ANALYSIS FOR PRODUCT
   4.1 Strengths
   4.2 Weaknesses
   4.3 Opportunities
   4.4 Threats

5.0 TARGET AUDIENCES, JOURNALS, AND MEETINGS

6.0 MARKET ANALYSIS

7.0 PRODUCT COMMUNICATION IMPERATIVES

8.0 KEY COMMUNICATION MESSAGES FOR PRODUCT

9.0 PRODUCT STRATEGIES AND TACTICS
Gap Analysis
Gap Analysis

• An assessment tool
• Two main questions:
  – Where are we now?
  – Where do we want to be
• Publication gap analysis
  – Identifies key topics related to a product and its competitor within a specific therapeutic area or indication
  – Analyses how these are addressed
    • Manuscripts
    • Congresses
    • Other communication vehicles
  – Identifies areas not covered or not sufficiently covered = GAP
Gap Analysis

• Regular gap analyses are crucial for evaluating strategy and tactics from early to late in a product’s lifecycle

• Identify areas where an increase in product-related or condition-related publication activity is required

• Measure the current publication performance for a drug against that for the competitors

• Evaluate gaps in a drug’s publication portfolio

• Determine whether maximal publication use has been made of available clinical data
Before Starting a Gap Analysis

• Rule #1— Make sure that there is agreement
  – Define search strings
  – Define timeframe
  – Define competitors
  – Define manuscript types
  – Define patient populations
  – Define study types
  – Define stakeholders
  – Identify key messages for analysis
  – Regroup, reassess, and confirm for consistency
Abstracts versus full manuscript review

• Review articles should be reviewed in full
  • Abstracts of review articles rarely cover all messages included in the review article

• Clinical/data-driven manuscripts
  • Abstracts can be informative
  • But preference is to review full manuscript
Information Generally Included in a Gap Analysis (1)

• Therapeutic indications
• Publication volume/quantity
• Audiences targeted:
  – General practitioners
  – Specialists
  – Nurses
  – Paramedical professions
• Types of publications:
  – Primary data
  – Reviews
  – Health-economics
  – Epidemiology
Information Generally Included in a Gap Analysis (2)

- Quality of data/strength of evidence
- Profile of publications/presentations over time
- Types of journals congresses:
  - Generalist topics
  - Specialist topics
  - Specific medical professions
- Ongoing clinical trials (clinicaltrials.gov)
- Key topics or communication points
Information Generally not Included in a Gap Analysis

- Marketing-related data and literature
- Advisory board input
  - But can be included if it gives guidance or suggests direction
How the gap can be assessed

• Qualitative
  – Examining major publications/presentations
  – Can be related to a specific indication/therapy area

• Quantitative
  – Numeric comparisons of publication activity

• Both qualitative and quantitative
  – Generally used
Types of Numeric Criteria in a Gap Analysis

• Number of publications per year
• Number of publications by target audience
• Number of publications by article type
• Number of publications by journal
• Number of publications by message
• Combinations of these
Key Message Usage

Number of mentions

- Novel agent: 70
- Dose/formulation: 20
- PK-PD drug: 10
- Efficacy: 60
- Safety/tolerability: 40
- Cost-effectiveness: 30
- Compliance/adherence: 20
- Key message X: 10
- Key message Y: 5
- Key message Z: 10

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### Analysis of Key Messages by Content

<table>
<thead>
<tr>
<th>Source</th>
<th>Type</th>
<th>Indications</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Paper</td>
<td>Abstract</td>
</tr>
<tr>
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</tr>
<tr>
<td>KM-5</td>
<td>11</td>
<td>3</td>
</tr>
</tbody>
</table>
Qualitative gap analysis criteria

- Major indication
- Key geographic population
- Specific sub-populations
  - Sub-population 1
  - Sub-population 2
- Patients with major comorbidity
- Long-term data
- Physician habits defined
Using Gap Analysis Results in the Publication Plan

• Create an overview of the therapeutic area from a scientific publications perspective

• Assessment of brand and competitors
  – Evidence base
  – Scientific/medical themes
  – Audience: width and depth

• Link with current and planned data (clinical, epidemiology, health-economics, etc).
Questions to answer

• Can the gap be filled by existing or forthcoming data
  – Studies take time to plan, fund, implement and analyse
  – Important to assess if new studies are needed or if a literature review (generally less labour-intensive and less expensive) could bridge the gap
Optimizing the Effectiveness of Publication Planning – Timing is important

- **Launch**: Strategy development, strategy refinement, and tactical development
- **Publication wind-down**: Tactical development and delivery with periodic strategic re-evaluation

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Timeline development for papers

2009 | 2010 | 2011 | 2012 | 2013
---|---|---|---|---
Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4

Primary papers:
- Paper 1
- Paper 2
- Paper 3
- Paper 4
- Paper 5
- Paper 6
- Paper 7

Secondary papers:
- Market authorisation
- Paper 1
- Paper 2
- Paper 3
- Paper 4
- Paper 5
- Paper 6
- Paper 7
Congress planning

Need to indicate deadlines for abstract submission!
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SWOT analysis
What is a SWOT analysis

• A SWOT analysis guides you in the identification of the positive and negative aspects of the product (S-W) and the opportunities and threats from the market (O-T)

• Developing a full awareness of your situation can help with both strategic planning and decision-making
SWOT analysis

Internal
- Strengths
- Weaknesses

External
- Opportunities
- Threats
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Target Audiences, Journals, and Congresses
Target Audiences

• Will impact on the choice of journal/congress
• Can have several target audiences
  – Need to adapt messages to audience
    • Specialist vs generalist
    • Administrative vs scientist
Journal Selection Process

Tier

Impact factor
Reach
Rejection rate

versus

Budget
Regulatory
Author influence

Timing

Timing to citability
Reprint availability
Other distribution
= Review articles
= Supplements
= Journal clubs
= Reprint carriers
Congresses

• Shorter time to ‘publication’
• Different audiences can be reached
• Possibility to have company-sponsored symposium
  (more marketing than scientific)
  – Can work with the presenters to summarise the
    symposium in a ‘scientific’ paper
• Abstracts can be used to support documents for one
  year
  – Abstract is accepted as an oral presentation or a poster
  – Increasingly, other opportunities are available:
    • e.g. preparation of four slides and four-minute talk which is
      recorded and available on congress website
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Key Communication Messages
Key Communication Messages

• **MUST** be based on clinical/scientific fact

• Small number of core messages with more detailed sub-messages as necessary

• Messages should be consistent across indications, formulations, and within franchises
Communicating the Right Messages to Ensure Strategic Success

• Define primary and secondary messages that will promote strategic imperatives

• Critically assess the data pool—align with messages

• Identify message gaps
  – Messages without supporting data
Type of messages

- Disease state/burden of disease
- Mechanism of action
- PK/PD/Metabolism/Drug-drug interactions
- Efficacy
  - Morbidity
  - Mortality
- Safety
- Health economic
- Quality of life
Summary
Strategic publication planning

• An important tool
  – To provide a framework for publication activities
  – To facilitate communication internally
  – To ensure all data is used as fully as possible

• Continually revised to adjust to changes in the internal and external environment
An idea without a plan is just a dream ...

Alice asked the Cheshire Cat: “which way ought I go to from here?”
“That depends a good deal on where you want to get to” replied the Cat
“I don’t much care where” said Alice
“Then it doesn’t matter which way you go” said the Cat