Thank you for joining ISMPP U today!

Today’s program will begin promptly at 12:00 pm EST

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Strategic Publication Planning Through the Lifecycle

Presenter: Janet Shaw, Prime Medica
Moderator: Stephen Valerio, Roche
February 18, 2009
Strategic Publication Planning

- Strategic publication planning (SPP) is never the same for any two products.
- Different challenges exist at various stages in the product lifecycle.
- How you address them can be critical to the success of the SPP plan.
- However, there are common fundamentals that need to be underwritten in this increasingly regulated activity.
Agenda

• Strategic Publication Planning Fundamentals
• Addressing the Lifecycle Challenges
  – Early Phases (I/IIa)
  – Pre-launch (IIb/IIIa)
  – Launch
  – Post Launch
• Summary
• Discussion
SPP Fundamentals

• Creating the Plan – the SPP process
• Managing the Plan – is a team activity
• Metrics – using metrics to optimize activity
• Good Publication Practices (GPP) – need to be followed
SPP Fundamentals

- Creating the Plan
  - Publication Strategy
    - How key communication needs and data will be optimally communicated to target audiences through publications
  - Publication Plan
    - A timed, prospectively-planned series of outputs that deliver on the strategy

- Managing the Plan
  - A team approach
    - Teams change over time
  - Publication planning tools
  - Metrics
  - Competitive environment

- GPPs
  - The role of the publication manager
Publication Strategy

DISEASE
• Burden of Disease
• Disease Awareness
• Approaches to disease management

COMPETITIVE ENVIRONMENT
• Competitors, SOV
• Unmet customer needs
• Prevailing target audience opinions

PRODUCT
• PK/PD
• Preclinical/Clinical
• Health Economic
• Investigator Initiated Trial program

COMMUNICATION OBJECTIVES
• Brand vision
• Penetrate current and future growth markets/audiences
• Life Cycle Management

Benchmark and Refine
COMMUNICATION POINTS and VERBAL DESCRIPTORS

PUBLICATION STRATEGY
From Strategy to Publication Plan Development

**Publication Strategy**
*How key communication needs and data will be optimally communicated to target audiences through publications*

**Communication Points / Vocabulary**

**Publication Plan**
*A timed, prospectively-planned series of outputs that deliver on the strategy*

- Target audiences (Needs, timings)
- Product milestones (Launches, new indications, etc.)
- Trial details (Centers, size, endpoints, milestones, etc.)
- Journal info. (Readership, I.F., lead times, circulation, etc.)
- Congresses and Meetings (Submissions, audience, delegate numbers, etc.)
- KOLs / Advocates (Authors, presenters, investigators, etc.)

- Abstracts
- Posters
- Publications
- Presentations
- Lit Analyses and Publication Alerts
- Expert Panels
Managing the Plan: A Team Approach Achieves…

- Clear roles and responsibilities
- Engaged participants, leads to
  - A more collaborative approach
  - Strategic contributions of a higher quality
  - Ongoing needs assessment
  - Effective resource allocation
- Compliance with GPP
  - The role of the ISMPP Membership
  - External authors
- Open lines of communication based on job function to facilitate flow of information
  - Direct contact with team member that is best suited to complete the task
- Efficient transfer of information within team
Information Flow Between Members of Publication Team

- Agency Content Support
- Pharma Content Experts
- Agency Business/Operational
- Pharma Business/Operational
- Publication Manager
Managing the Plan: Publication Plan
Management Software

- Publications planning & management software
- Includes all components of the Publication Plan
  - Studies, Publications, Target Journals & Congresses, Resources
- Track/monitor, modify the plan
- Manage publication strategy, document development, and document review, according to GPP
  - From overall big picture to details
  - Improves compliance and workflow
Infinite number of metrics
Increasingly critical
- Time to publication
- Volume
- Quality
- Budget

Important to monitor schedules especially internal review times – use metrics to manage improvement

Publication acceptance rates – analyze and monitor
GPPs

- Pharma company GPPs
- Agency’s GPPs
- International Committee of Medical Journal Editors (ICMJE)
  - Uniform Requirements
  - Clinical Trial Registration Statement
- CONSORT (The Consolidated Standards of Reporting Trials)
- Specific journal/congress guidelines
- American Medical Writers Association (AMWA) position statement on contributions of medical writers
- European Medical Writers Association (EMWA) guidelines for medical writers
- World Association of Medical Editors (WAME) Policy statement on ghost writing
- International Society of Medical Publication Professionals (ISMPP)
Throughout the Lifecycle

I
- Gaining scientific recognition

II
- Identifying product potential, market needs & developing communications strategy

III
- Identifying common agenda with customers, building endorsement & disseminating clinical communication points

LAUNCH
- Create extensive awareness and developing partnerships with customers

POST LAUNCH
- Strengthen partnerships, grow the product and further differentiate

Abstracts, posters, publications

OL development
- Advisory boards, Investigator outreach
- Expanded strategic communications activity
- Speaker training
- High visibility programs
Agenda

- Strategic Publication Planning Fundamentals
- Addressing the Challenges
  - Early Phases (I/Ia)
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Addressing the Challenges: Early Phases (I/IIa) - Science driven phase

• When to start
  – SPP should begin as early as possible in the lifecycle of a product
  – Update annually

• Working as a team
  – Create team of key stakeholders; be inclusive, proactive and persistent

• Working independently and not within the plan

• Publication Share of Voice
  – Initiate and regularly update competitive literature audit
  – Utilize audit for decision making about noise level required to compete
    • Less is more? Match paper to paper? Science can drive SOV
Competitive SOV

*Other: includes reviews, scene-setting, preclinical and Phase I
Addressing the Challenges: Early Phases (I/IIa) Science driven phase cont’d

• Setting expectations – excitement about the product
  – Timelines
    • How long does it really take
  – Quality
    • Not to be compromised
  – Resource to get things done
  – Journal selection
    • Choose top tier and a back up;
    • Understand instructions to authors;
    • Objectively evaluate how important data is to clinical practice
    • Have authors assess journal interest early on
For Authors

Important notice

There are four Lancet journals (The Lancet, The Lancet Infectious Diseases, The Lancet Neurology, and The Lancet Oncology). Please ensure you submit your paper to the appropriate journal and use the correct electronic submission system. See below for further details on each journal.

- To submit to The Lancet, click on EES The Lancet
- To submit to The Lancet Infectious Diseases, click on EES The Lancet Infectious Diseases
- To submit to The Lancet Neurology, click on EES The Lancet Neurology
- To submit to The Lancet Oncology, click on EES The Lancet Oncology

Writing for The Lancet

The Lancet is an international general medical journal that will consider any original contribution that advances or illuminates medical science or practice, or that educates or entertains the journal's readers. Manuscripts must be solely the work of the author(s) stated, must not have been previously published elsewhere, and must not be under consideration by another journal.

For papers, which will usually be primary research, judged to warrant fast dissemination, The Lancet will publish a peer-reviewed manuscript within 4 weeks of receipt. If you wish to discuss your proposed submission with an editor, please call one of the editorial offices in London (+44 (0) 20 7424 4943) or New York (+1 212 633 3667).

How to submit your paper

The Lancet has an online submission and peer review website, known as EES The Lancet. Simply log onto EES and follow the onscreen instructions for all submissions. If you have not used EES before, you will need to register first. In EES, the corresponding author is the person who enters the manuscript details and uploads the submission files. Inclusion of illustrations (photographs, graphs, diagrams etc) is a prerequisite for publication. Digital photography files should have a resolution of at least 300 dpi and be at least 75 mm wide. In almost all cases, if you have a finished manuscript, you should submit it, rather than contacting The Lancet to enquire whether an unseen manuscript is likely to be accepted. Unless you have been asked by The Editor to submit by email, you should use the online system for all types of submission, including Correspondence.

Full guidelines for authors of The Lancet (PDF - 145KB)

Writing for The Lancet Infectious Diseases

The aim of The Lancet Infectious Diseases is to publish interesting and informative articles on topics related with infectious diseases. Manuscripts must be...
Addressing the Challenges: Pre-launch Phases (IIb/IIla)

• Growing team
  – Reevaluate key stakeholders; be inclusive, proactive and persistent

• Authorship
  – Authorship strategy needs to be developed
    • Have processes in place for agreements with Investigators, policy on company authorship, reduce overdependence on limited group of authors
    • ICJME guidelines

• Ensure publications support future launch(es); regulatory requirements; availability of data; expanding audience reach
  – Gap analysis
  – Agree acceptable terms & terminology

• Support key claims and label with appropriate level of clinical evidence
  – Perform evidence audit; quality of evidence
<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Evidence</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient-oriented evidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improvement in cardiovascular morbidity and mortality</td>
<td>Clear (for each agent alone)</td>
<td>Trials on both drugs as monotherapy have shown either direct protection against cardiovascular events or surrogate benefit by reducing blood pressure</td>
</tr>
<tr>
<td>Reduced atrial fibrillation</td>
<td>Moderate</td>
<td>Reduced recurrent atrial fibrillation</td>
</tr>
<tr>
<td>Patient acceptability</td>
<td>Limited</td>
<td>Low rate of adverse events</td>
</tr>
<tr>
<td>Improvement in quality of life</td>
<td>Moderate</td>
<td>Less edema, better tolerability</td>
</tr>
<tr>
<td><strong>Disease-oriented evidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective control of blood pressure</td>
<td>Clear</td>
<td>Combination more effective than monotherapy</td>
</tr>
<tr>
<td><strong>Economic evidence</strong></td>
<td>Limited</td>
<td>No studies to show the long term efficacy for lowering blood pressure and decreasing morbidity or mortality in spite of higher cost of the fixed combination</td>
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Addressing the Challenges: Launch

- Adapt SPP based on outcome of clinical trials
  - Utilize advisors to evaluate data and clinical evidence
- Resource in short supply at time of Launch
  - Streamline processes and procedures
  - Core team; critical sign off
  - Access to senior management as needed
  - Delayed TTP especially internal review
- Managing plan
- Different market needs – to support launch
Addressing the Challenges: Post Launch

- Maintaining momentum
  - Team approach
- Broaden evidence and reach with minimum data
  - Re-analysis
  - Pooling
- Investigator initiated trial responsibility
  - Track
- Communicate place in therapy
  - Safety
  - Use monitoring
  - Support use in clinical practice
SPP Through the Lifecycle

- SPP supports all stages of lifecycle
- Important to cover fundamentals on an ongoing basis in all phases
  - Creating the Plan
  - Managing the Plan
  - Metrics
  - GPPs
- Managing evidence to support claims at key stages in lifecycle
- SPP can be used to support advocacy and is the cornerstone to all communications
Agenda

• Strategic Publication Planning Basics
• Addressing the Challenges
  – Early Phases (I/IIa)
  – Pre-launch (IIb/IIIa)
  – Launch
  – Post Launch
• Summary
• Discussion
Open Discussion/Audience Q&A
Next ISMPP U

- **Topic:** TDB
- **Date:** March 18
- **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.