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ISMPP U today!**

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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**

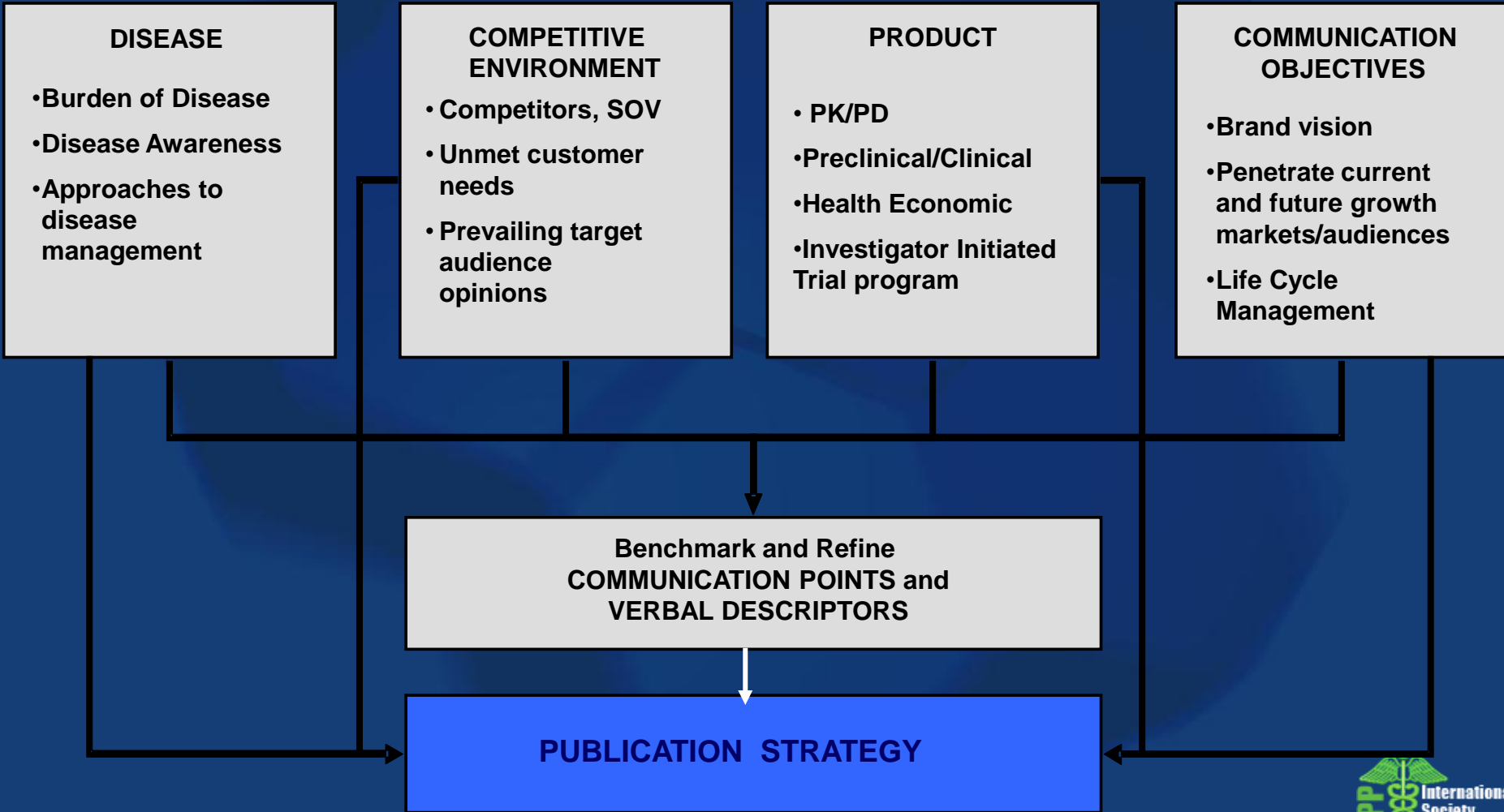
SPP Fundamentals

- 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



From Strategy to Publication Plan Development

Publication Strategy

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

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.)

Communication Points / Vocabulary

Publication Plan

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

Abstracts

Posters

Publications

Presentations

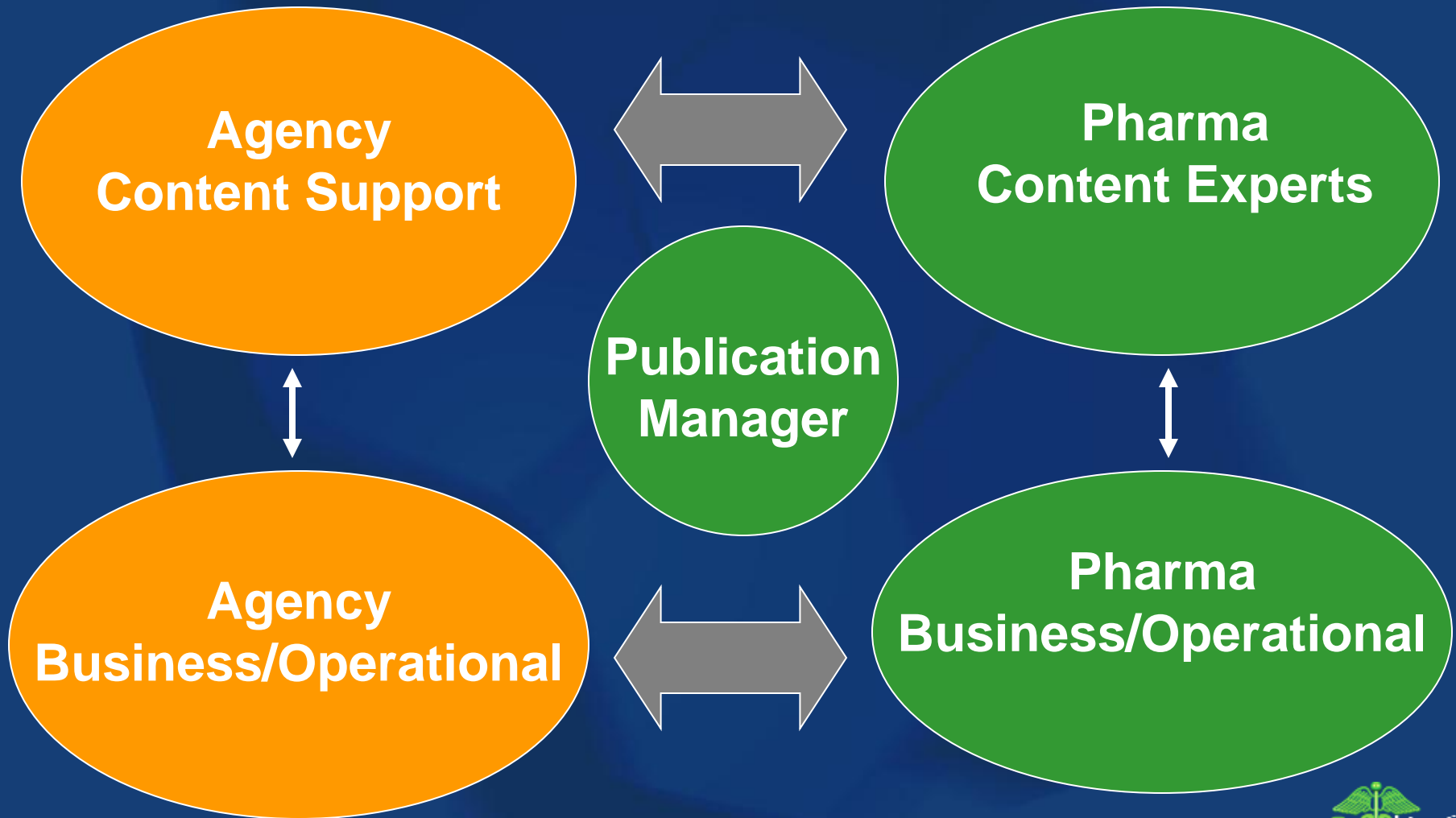
**Lit Analyses and
Publication Alerts**

**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



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

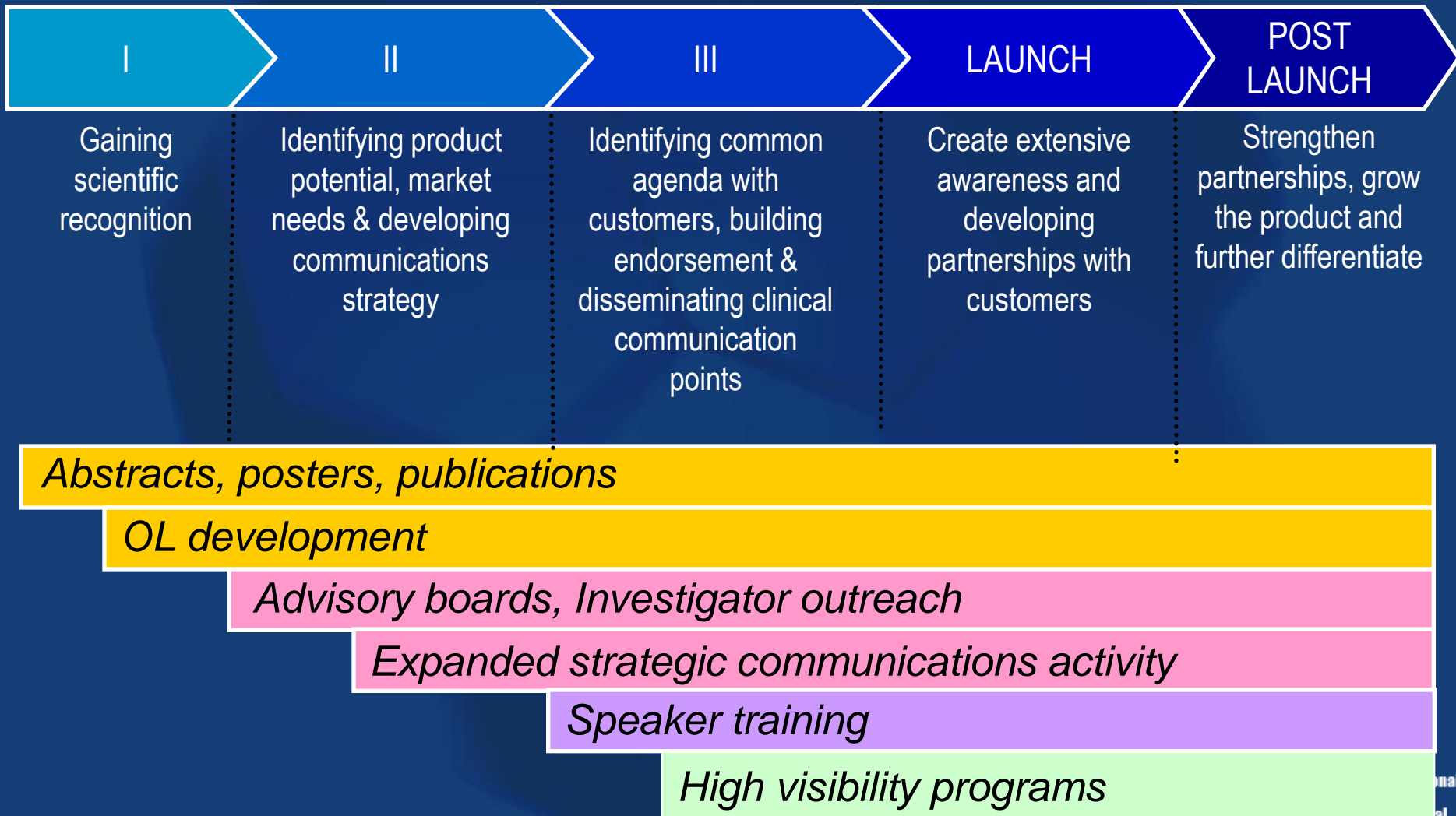
Metrics

- 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



Agenda

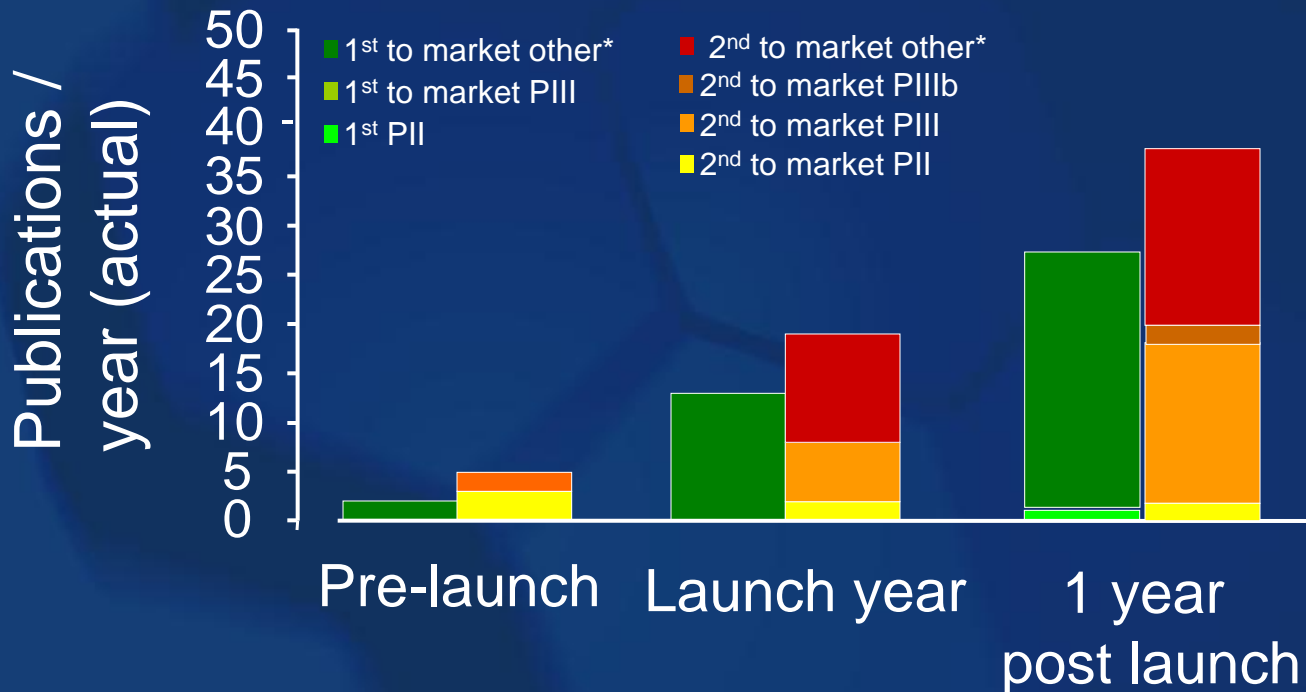
- Strategic Publication Planning Fundamentals
- **Addressing the Challenges**
 - Early Phases (I/IIa)
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Addressing the Challenges:

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

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For Authors

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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.

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[Full guidelines for authors of The Lancet](#) (PDF - 146Kb)

Writing for The Lancet Infectious Diseases

The aim of *The Lancet Infectious Diseases* is to publish important and informative evidence on subjects associated with infectious diseases. Manuscripts must be

Addressing the Challenges: Pre-launch Phases (IIb/IIIa)

- 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

Core Evidence clinical impact summary for Product X in hypertension

Outcome measure	Evidence	Implications
<u>Patient-oriented evidence</u>		
Improvement in cardiovascular morbidity and mortality	Clear (for each agent alone)	Trials on both drugs as monotherapy have shown either direct protection against cardiovascular events or surrogate benefit by reducing blood pressure
Reduced atrial fibrillation	Moderate	Reduced recurrent atrial fibrillation
Patient acceptability	Limited	Low rate of adverse events
Improvement in quality of life	Moderate	Less edema, better tolerability
<u>Disease-oriented evidence</u>		
Effective control of blood pressure	Clear	Combination more effective than monotherapy
<u>Economic evidence</u>		
Cost Effectiveness as antihypertensive therapy	Limited	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

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)
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Open Discussion/Audience Q&A

Next ISMPP U

- **Topic:** TDB
- **Date:** March 18
- **Time:** 12 Noon EST

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