

DISCLAIMER: The content of this presentation may not accurately reflect current legal or regulatory requirements, industry standards, or professional best practices. ISMPP is providing access to this presentation as a member service only, and does not recommend or condone the use of this presentation in whole or in part to support legal or professional decisions or practices.

ISMPP U Lunchtime Series:
Product Life Cycle
Considerations in Publication
Planning
September 14, 2005

Robert A. Norris

Complete Healthcare Communications, Inc.

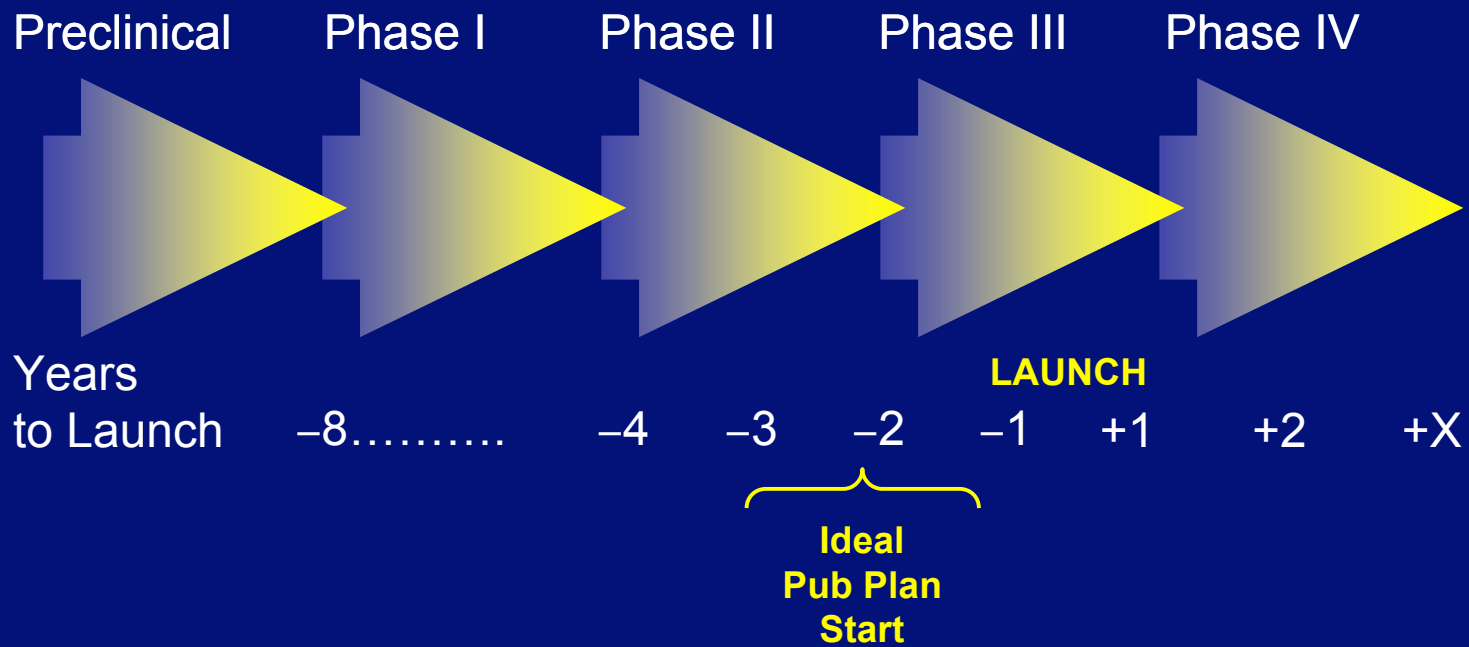


Product Life Cycle Considerations in Publication Planning

Topics:

- Stages of a publication plan
- Life cycle considerations

Stages of a Publication Plan



Stages of a Publication Plan

Corporate Philosophy

Science Driven

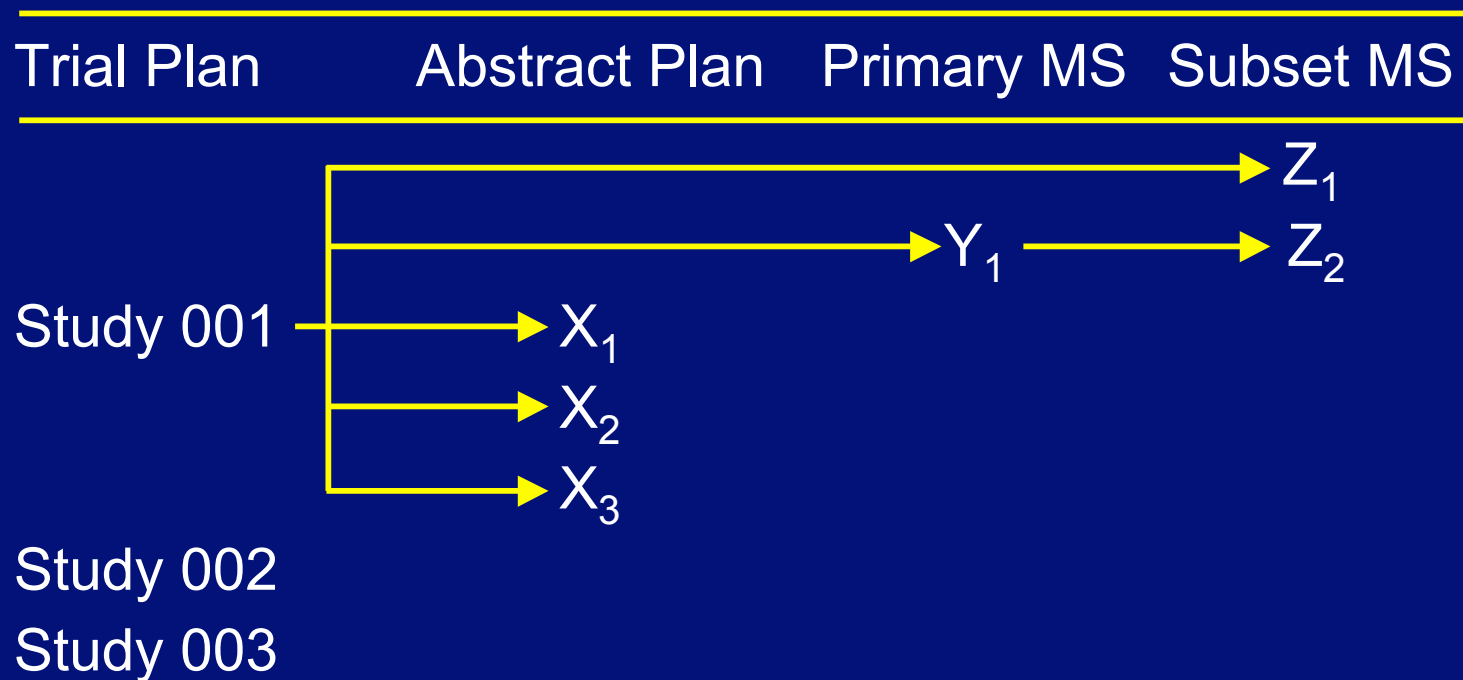
- Smaller Biotech
- Science Speaks for Itself
- One Publication/Study
- Budget Constraints

Marketing Driven

- Large Pharma
- Market Needs/Market Research
- Multiple Publications
- People Constraints

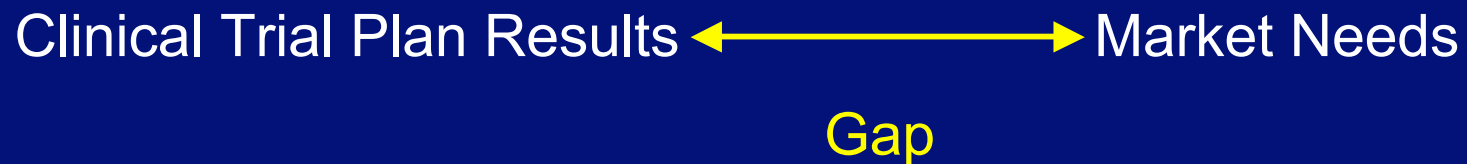
Stages of a Publication Plan

Science Driven



Stages of a Publication Plan

Market Driven



Target Audience

Clinical Results: Messages

Market Preparation

Share of Voice

Competitive Response

Stages of a Publication Plan

Stage I – Scientific Rationale

Preclinical

Publication Objectives:

- Disease State Awareness
- Unmet Medical Needs
- Demographics
- Pathogenesis
- Epidemiology
- Therapeutic Targets
- Diagnosis/Markers

Audience:

- Academic KOL
- Basic Research

Stages of a Publication Plan

Stage 2 – Proof of Concept

Phase I

Publication Objectives:

- MOA
- Early Clinical Rationale
- Nomenclature
- Product Characteristics
- PK/PD

Audience:

- Academic KOL
- Therapeutic KOL

Stages of a Publication Plan

Prelaunch Considerations

- Entry in Class
 - First in Class
 - Late Entrant
- Patent Issues
- Investment in
 - Therapeutic Area
 - Creating Need
 - Clinical Investment
 - Competitive Environment

Stages of a Publication Plan

Stage 3 – Clinical Benefit

Phase II/III

Publication Objectives:

- Efficacy
- Safety
- Clinical Significance

Audience:

- KOL
- Early Adopters

Stages of a Publication Plan

Stage 4 – Clinical Value

Phase IIIb/IV

Publication

Objectives:

- Long term Effect
- Pharmacoeconomics/Societal Effect
- Comparators
- Other Indications

Audience:

- All Potential Prescribers
- Extended Healthcare Providers
- MC/Government/Reimbursement

Stages of a Publication Plan

Postlaunch Considerations

- Patent Extension
- Internal Investment
 - IST Plan/Support
 - Reanalysis
 - Meta-analysis
- New Indications
- Follow on Compounds

Life Cycle Management of a Publication Plan

Considerations

- Competitive Environment
- Multiple Publications From the Same Study
- Use of Review Papers
- Data Availability and Gaps
- Delayed Launch
- Off-Label Publications
- Publication Team Makeup
- Agency Role
- Internal Resources
- ROI

Life Cycle Management of a Publication Plan

Competitive Environment

- Where Is Your Drug vs Competitor(s)
- Stage of Development
- Investment by Company
- Patent Status
- Importance to Portfolio
- Clinical Trial Support
- Where Is Science Going

Life Cycle Management of a Publication Plan

Competitive Environment

None

- Create Need
- Create Disease State
- Create Diagnosis
- Educate

2nd/3rd Entrant

- Super Drug
 - Be Aggressive
- Me Too/Inferior
 - Expand Market
 - Niche Out

Heavy Competition

- Focus at Launch and Postlaunch
- Don't Tip Hand
- Primary Data
- Reviews Postlaunch

Life Cycle Management of a Publication Plan

Multiple Publications From the Same Study

- Company Policy
- Industry Guidelines
- Congress Abstract Submission Criteria

Life Cycle Management of a Publication Plan

Industry Guidelines on Multiple Publications

ICJME

Overlapping Publications

- Duplicate Submissions – No Go
- Redundant Publications – No Go

“Overlays Substantially With One Already Published...”

Life Cycle Management of a Publication Plan

Industry Guidelines on Multiple Publications

ICJME

Acceptable Secondary Publications

- Intended for a Different Group of Readers
- Other Countries
- All Editors Agree
- Secondary Version Reflects the Data and Interpretations of the Primary
- Footnote on Title Page States Primary Reference
- Title Indicates
- Translation
- Competing Manuscripts Based on Same Study/Database
- Supplements

Life Cycle Management of a Publication Plan

Industry Guidelines on Multiple Publications

PhRMA

Related Publications for Multisite Clinical Trials

“Such reports should not precede and should always reference the primary presentation or paper of the entire study.”

Life Cycle Management of a Publication Plan

Multiple Publications From the Same Study

Congress Abstract Submission Criteria

- More Prestigious, More Selective
- Do not Define What Duplicate Means
- Author/Presenter Interest
- Company Policy

Life Cycle Management of a Publication Plan

Use of Review Papers

Disease State

- Build Anticipation
- Unmet Medical Needs
- Epidemiology
- Demographics
- Primary Prelaunch

Life Cycle Management of a Publication Plan

Use of Review Papers

Product Reviews

- Need Data to Generate
- Valued by Primary Care

Life Cycle Management of a Publication Plan

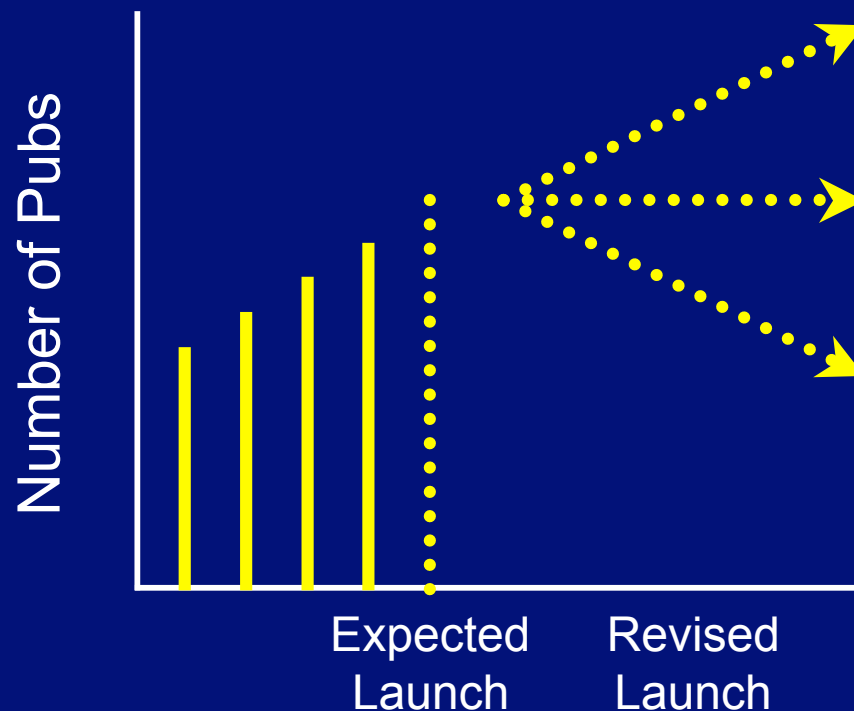
Use of Review Papers

“Conflicts of interest may be difficult to detect in the subset of articles and presentations sponsored by pharmaceutical companies that never mention the targeted drug, but focus on stimulating the perceived need for the targeted drug in highlighting problems with competing drugs.”

Life Cycle Management of a Publication Plan

Delayed Launch

- FDA/Regulatory
- Trial Delays



Life Cycle Management of a Publication Plan

Off-Label Publications

- Unapproved Drugs or Indications

FDA Excludes

- Peer-Reviewed Articles on Unapproved Uses of Approved Drugs (FDAMA Regulations/WLF Principles)
- Peer-Reviewed Articles Relating to Unapproved Products or Uses May Be Authored by Company Personnel or With Assistance of Company for Publication: Original or Review Papers

Line Between Promotion and Independent Education Is Important

Life Cycle Management of a Publication Plan

Publication Team Makeup

	Preclinical	Phase I–II	Phase II–III	Phase III–IV
Research/Discovery	X	X		
Clinical		X	X	X
Biostats			X	X
Marketing		X	X	X
Development	X	X	X	
Med Affairs			X	X
Regulatory	X	X	X	
Health Econ			X	X
Sales				X
Publication Mgmt	X	X	X	X
Vendor			X	X

Consider Global—US Responsibilities

Life Cycle Management of a Publication Plan

Agency Role

	PreClinical	Phase I-II	Phase II-III	Phase III-IV
Strategy			X	X
Editorial	X	X	X	X
Pub Mgmt		X	X	X
Database Mgmt			X	X

Life Cycle Management of a Publication Plan

Internal Resources

What Drives Strategy?

“Strategy Is Nice, but...”

Life Cycle Management of a Publication Plan

Internal Resources

- Hard Dates
 - Abstracts
 - Meeting Presentations
- Reviewer's Time
- Other Product Priorities
- Budgets

Life Cycle Management of a Publication Plan

Internal Resources

	<u>% Budget Spent</u>
2 Years Prelaunch	10
1 Year Prelaunch	25
Launch	40
Postlaunch	25

$P \gg 0.05$

Life Cycle Management of a Publication Plan

Use of Publication and the Sales Force

Prelaunch

No Sales Force

Publications Are
“Marketing”

Launch

Strong Sales Force

Support Sales
and Messaging

Postlaunch

Sales Force?

Support/Replace
Sales

Life Cycle Management of a Publication Plan

ROI Considerations

- Vehicles
- Audience
- Prestige
- Potential Impact

THANK YOU

Bob Norris, President
COMPLETE HEALTHCARE COMMUNICATIONS, INC.
One Dickinson Drive
Chadds Ford, PA 19317
Phone: 610-358-3600
Fax: 610-358-3636
Email: Robert.Norris@CHCinc.com
www.CHCinc.com

