

Components of a Strategic & Tactical Publication Plan

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Presentation Agenda

- Based on ISMPP Publication Planning Workshop 101/102 presented in April 2006
 - Top-line overview on content
- Expectations for publication plans
- Typical components of a strategic & tactical publication plan
 - Description & purpose
 - Samples
- Questions & discussion

Introduction

Expectations for publication plans

- Can vary by pharma company and product
 - International vs US market
 - Focused on specific clinical indication(s)
 - Focused on specific physician or other healthcare practitioner audiences
 - Focused on pharmacoeconomics, outcomes, payor audiences
- Plan document needs to be “Good Publication Practice” compliant
 - Plan is basis for appropriate dissemination of scientific & clinical data, education/awareness, not a marketing communications plan

Introduction (continued)

Expectations for publication plans

- **Larger pharma companies with dedicated publication staff**
 - Often develop strategy, some components internally
 - May desire only selected, specific components from agency
 - May desire only agency review and input to existing plan based on expertise/experience
- **Small to medium pharma companies**
 - May not have publication-dedicated staff
 - May desire full strategy and/or tactical plan development

Components of a Publication Plan

Depending on need, may include:

- Executive summary
- Situation analysis and/or SWOT
- Target audience identification
- Key scientific & clinical communication points
- Analyses of key journals/medical meetings
- Competitor publication & gap analyses
- Publication strategy

Components of a Publication Plan (cont'd)

- Abstract & publication tactical recommendations
- Timing of abstracts/posters/publications
 - Gantt charts, other visual presentations
- Key meetings information
- Key journals information
- May include other communication/meeting activity recommendations

Executive Summary

Description & purpose

- ◆ Narrative synopsis to communicate the critical elements of the publication plan strategy in an abbreviated format
 - Summary of product clinical development status/plan
 - Competitive landscape, clinical issues, challenges, opportunities
 - May appear in more detail in association with SWOT analysis
 - Publication strategy & objectives
 - Key target audiences
 - Key scientific & clinical communication points
 - Critical tactics & timing

SWOT Analysis

Description & purpose

- Thorough analysis of product strengths, weaknesses, opportunities, and threats that provides a basis for developing publication strategy
- Based on multiple sources:
 - Available product preclinical & clinical data
 - Available market research data on product and competitors (existing & future)
 - Competitor publications analysis, medical or marketing communications
 - Key opinion leader interviews or advisory board feedback

SWOT Analysis (continued)

New cytotoxic agent for relapsed ovarian cancer

STRENGTHS

- Novel multicomponent MOA
- Favorable safety profile, hematol toxicity
- Lack of cross resistance
- In vitro synergy with other agents
- Good single-agent activity in platinum-sensitive patients

OPPORTUNITIES

- Unmet need for relapsed ovarian cancer; no SOC
- Potential in refractory disease due to novel MOA
- Potential in combination therapy (eg, platinum, liposomal doxorubicin)?
- Suitable for long-term therapy?

WEAKNESSES

- Minimal single-agent activity in platinum-resistant patients
- Optimal dosing TBD
- Limited published clinical data
- Only 1 active clinical trial, but key for ultimate positioning
- No QOL data

THREATS

- Older agents with more clinical data and/or physician experience (eg, platinum compounds, taxanes, liposomal doxorubicin, topotecan)
- Newer targeted agents, effective against platinum-resistant disease

SWOT Analysis (continued)

- May also include a literature gap analysis on publication plan product
 - What's missing in the literature?
 - Type of data, journal coverage, communication points, unaddressed issues or challenges
- May be part of “Situation Analysis” section that includes:
 - Product profile summary
 - Competitive landscape
 - Clinical development plan
 - Issues & challenges

Target Audience Identification

Description & purpose

- Identify healthcare professionals & other parties who will use or influence use of the product and its reimbursement
- Target audiences have data & product profile awareness needs to allow appropriate assessment of product and its clinical role
- Identification allows:
 - Proper planning in terms of where, when, and how the information is published to reach the specific audiences of interest
 - Resource priority decisions

Target Audience Identification (continued)



Typical audiences

- Physician specialists
- Primary care physicians
- Pharmacists

Other audiences may include:

- Physician assistants/nurse practitioners
- Nurses
- Manage care, payors, case managers
- Health economists, outcomes experts
- Employers

Key Communication Points

Description & purpose

- Primary scientific & clinical communication points about a product's preclinical & clinical profile in publications that will underscore a reader's basic understanding of the product
 - Based on data and evidence from the product's preclinical & clinical development program
 - Can take competitor profiles and clinical use into consideration
 - Can evolve as new findings emerge: may be contingent on data developments
 - May change over lifecycle of product
 - May vary by geography/country (US vs non-US)

Key Communication Points (continued)

Immunomodulating agent for pancreatic cancer

- Novel targeted immunotherapeutic for use in patients with cancer
- Differs from other therapies; not a traditional 'vaccine'
- New and effective second-line therapeutic option for patients with advanced pancreatic cancer who have received gemcitabine-containing chemotherapy
- Subcutaneous 'prime-boost' regimen in combination with GM-CSF
- Efficacy (increased survival) demonstrated in clinical trials in patients with advanced pancreatic cancer
- Improved safety profile for patients

Analyses of Key Meetings/Journals

Description & purpose

- Top-line assessment of key journals & scientific/medical meetings that are critical to communicating product data
 - Focuses the publication strategy
 - Provides guidance on where clinicians seek and obtain data
 - Helps prioritize resources
- Details on key journals and scientific/medical meetings are often provided as appendices to the publication plan

Analysis of Key Meetings/Journals (continued)

New antimicrobial agent for hospitalized pneumonia for US audience

- ◆ Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)
- ◆ Infectious Diseases Society of America (IDSA)
- ◆ American Thoracic Society International Conference (ATS)
- ◆ Annual Meeting of the American College of Chest Physicians (ACCP)
- ◆ Society of Critical Care Medicine (SCCM)

Analysis of Key Meetings/Journals (continued)

*New multiple sclerosis agent for global audience:
where do trials appear?*

Journal (Country)/Ranking	Number of Publications
1) <i>Neurology</i> (USA)	67
2) <i>Journal of Neuroimmunology</i> (The Netherlands)	32
3) <i>Multiple Sclerosis</i> (UK)	32
4) <i>Annals of Neurology</i> (USA)	31
5) <i>Archives of Neurology</i> (USA)	20
6) <i>Journal of Neurology Neurosurgery and Psychiatry</i> (UK)	17
7) <i>Lancet</i> (UK)	14
8) <i>European Journal of Neurology</i> (UK)	12
9) <i>Biodrugs</i> (UK)	11
10) <i>European Neurology</i> (Switzerland)	10
10) <i>Journal of Interferon and Cytokine Research</i> (USA)	10
12) <i>Journal of Neurology</i> (Germany)	9
13) <i>Journal of Neuroscience Nursing</i> (USA)	9

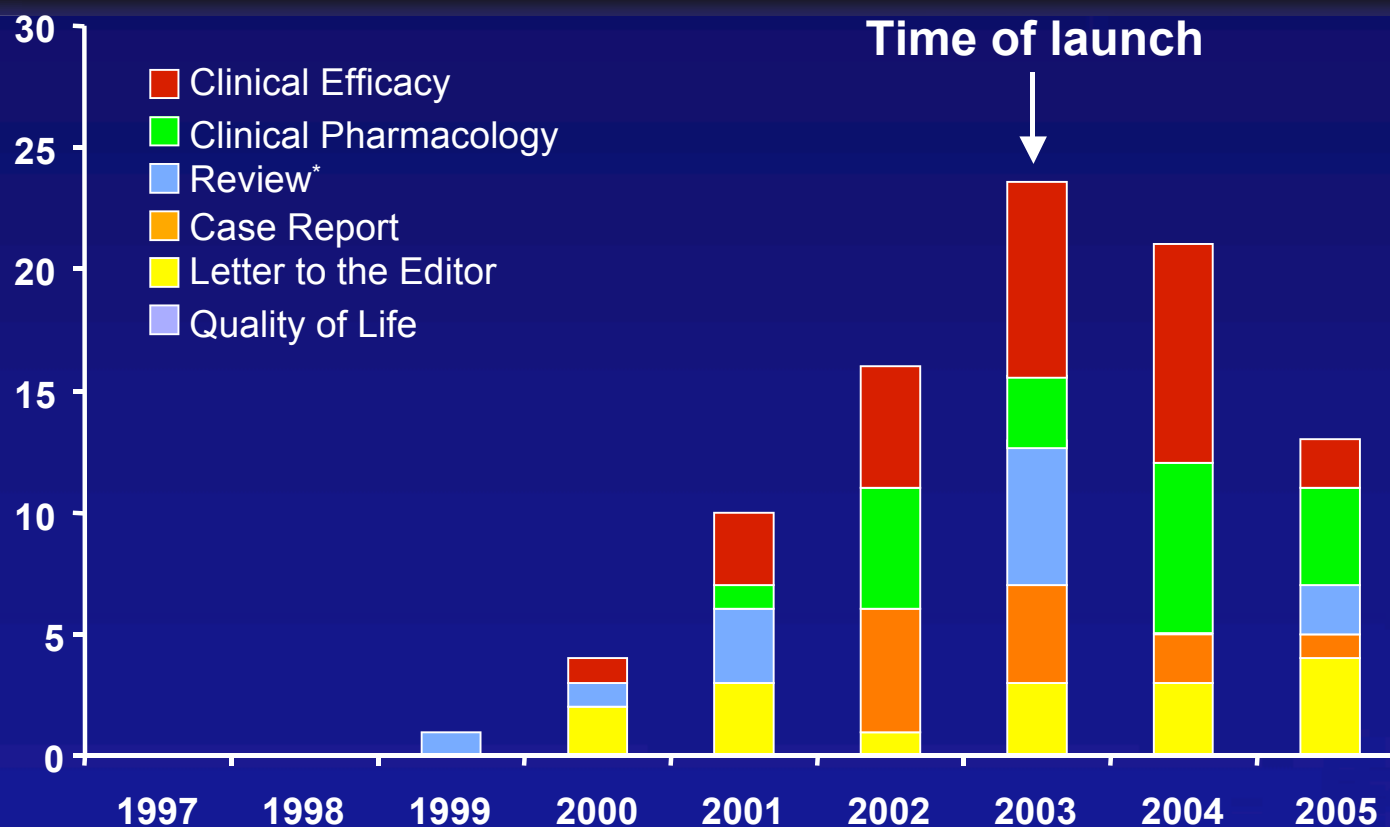
Competitor Publication Analysis

Description & purpose

- Narrative, interpretive evaluation of published literature (describe search strategy, sources) on one or more key competitors or future competitors to assess the following:
 - Numbers of publications
 - Types and focus of publications (eg, preclinical vs clinical, reviews, letters)
 - Timing of publications and publication types (vs lifecycle)
 - Journals (target audiences)
 - Geography (US vs non-US, specific countries)
 - Authors/investigators/research centers & study sites
 - Key scientific & clinical communication points
 - Strength of clinical data/evidence
- Metrics often presented graphically

Competitor Publication Analysis (continued)

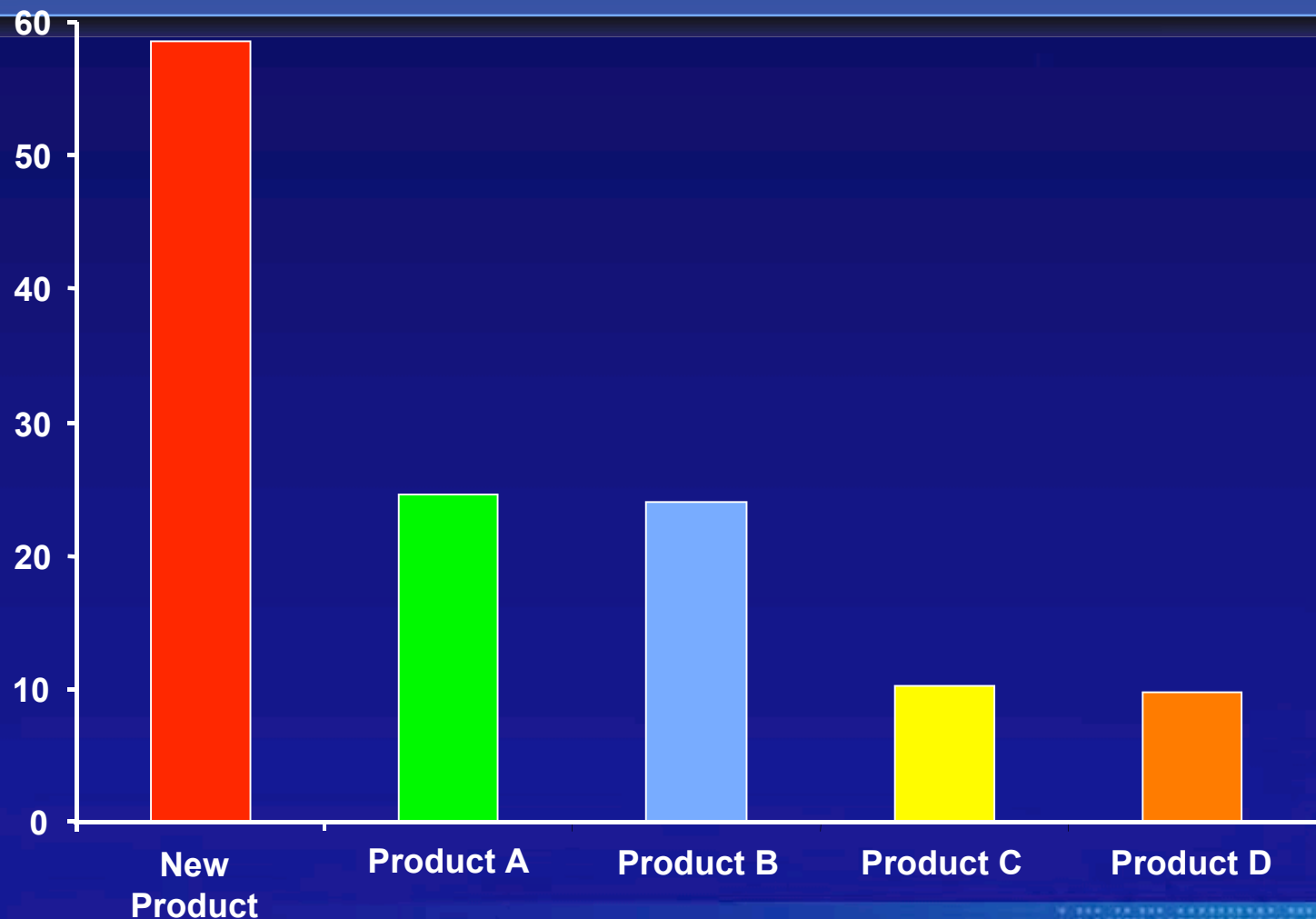
Number & type of publications per year for new product



*Includes only Product X-specific reviews

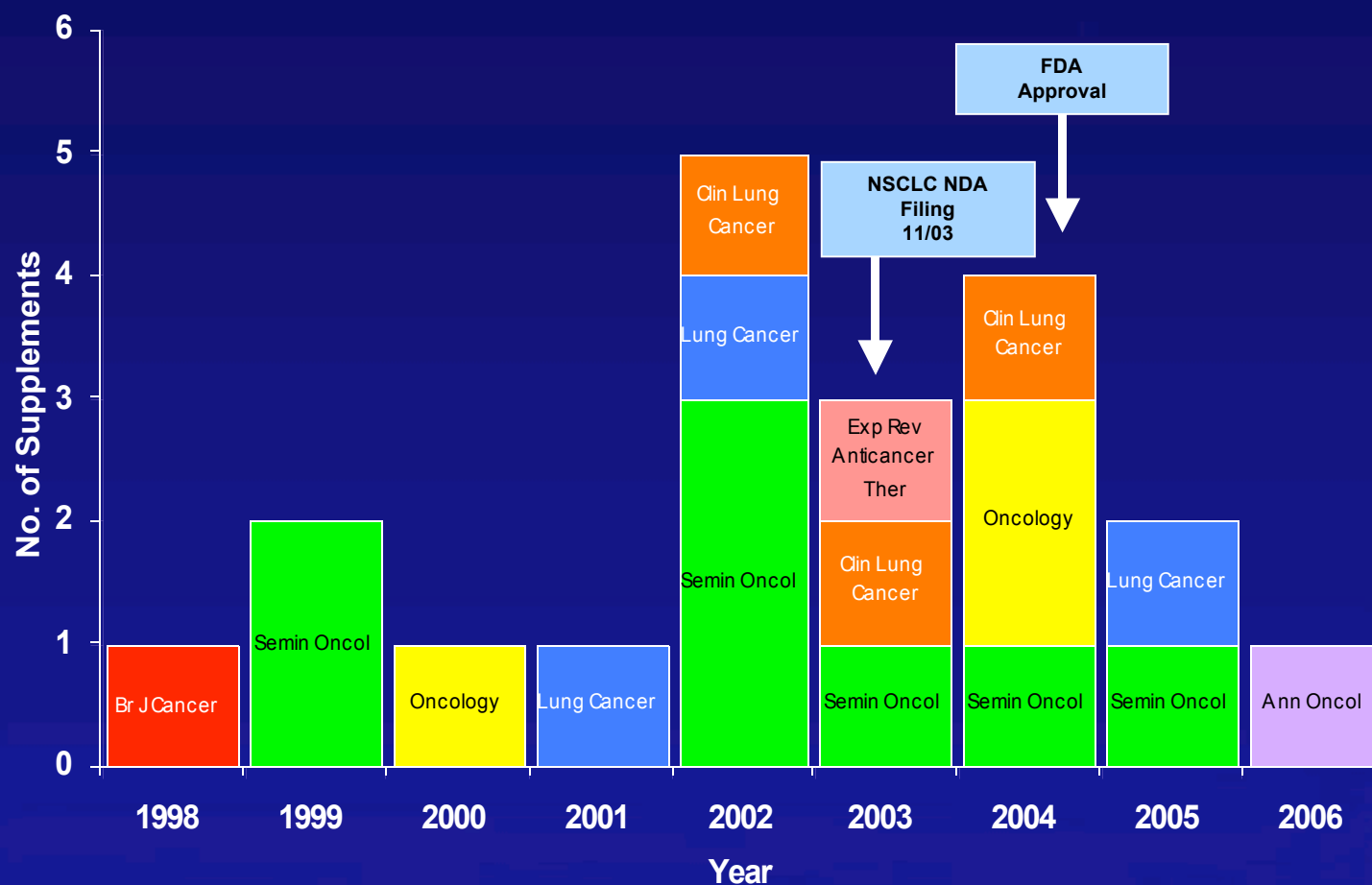
Competitor Publication Analysis (continued)

Total number of publications for new product & competitors at time of launch



Competitor Publication Analysis (continued)

Journal supplements for new oncology agent



Publication Strategy

Description & purpose

- Narrative summary that distills the essentials of the publication plan and execution of the plan into a “plan of action”
 - Strategic objectives
 - Key scientific & clinical communication points
 - Target audiences
 - Top-line tactics
 - Critical timing
- Typically appears near beginning of plan or following SWOT/Situation Analysis section
 - Includes previously discussed information

Publication Strategy (continued)

New agent to treat multiple sclerosis

Objectives:

- Increase awareness level among key target audiences during prelaunch, launch, & postlaunch periods
- Emphasize & reinforce novel features and unique MOA
- Present scientific rationale for a fixed-dose treatment regimen
- Communicate clinical trial results highlighting efficacy, safety, and tolerability to primary target audiences
- Extend data to secondary target audiences

Abstract/Publication Tactical Recommendations

Description & purpose

- Tactical recommendations for specific abstract submissions and publications (eg, clinical trial manuscripts, reviews, letters) that are based on:
 - Strategic considerations
 - Data considerations for target audiences based on one or more clinical indications
 - Meeting and journal considerations for target audiences
 - Timing & resource considerations
- Creating a “road map” for communications and data dissemination
 - Can be organized in variety of formats (eg, by study, chronology, key communication points)

Abstract/Publication Tactical Recommendations (continued)



AAN 2005					
Study	Title/Study Design/Objective	Focus	Target Audience	Meeting/Journal Primary Author	Timing
C-1701	Product A reduces annualized relapse rates compared with placebo in patients with relapsing- remitting multiple sclerosis	Clinical efficacy and safety data	Neurologists	AAN 2005 April 9-16, 2005 AU: Johnson C, et al.	Abstract deadline: November 1, 2004
C-1701	Product A attenuates lesion number and volume in patients with relapsing- remitting multiple sclerosis (RRMS)	MRI data	Neurologists	AAN 2005 April 9-16, 2005 AU: Smith A, et al	Abstract deadline: November 1, 2004
C-1702	Product A reduces disability progression in patients with relapsing-remitting multiple sclerosis.	Clinical efficacy and safety data	Neurologists	AAN 2005 April 9-16, 2005 AU: Doe J, et al.	Abstract deadline: November 1, 2004



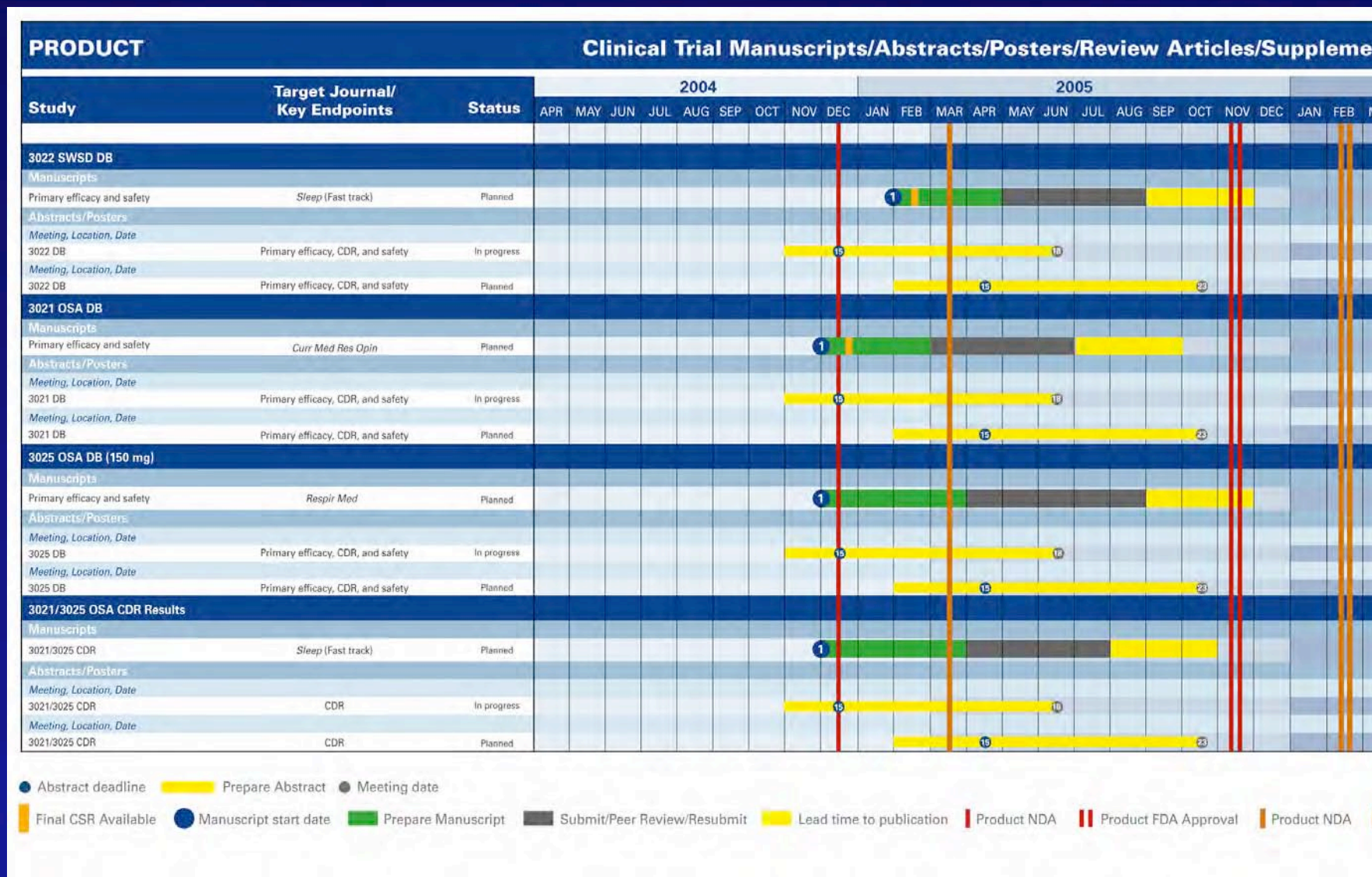
Timing of Abstracts, Posters, Publications



Description & purpose

- Summary of submission, presentation, and publication timing
 - Can be presented in a variety of formats (tabular, graphic) based on:
 - Meetings, target audiences, study number, specific data analyses, calendar dates
- Provides additional layers of detail for plan tactics, allows for resource planning and other time-related considerations

Timing of Abstracts, Posters, Publications (continued)



Key Meetings Information

Description & purpose

- In a publication plan document, this information provides key details on scientific and medical meetings relevant for target audiences for reference purposes
 - Typical information on:
 - Sponsor, affiliation & contact/website information
 - Date & location
 - Number and breakdown (if available) of attendees
 - Abstract deadline
 - Abstract notification date
 - Presentation opportunities (abstracts, posters, oral presentations, sponsored satellite symposia)
- Typically appears as an appendix to the plan
- May be supplemented by proprietary publication planning software, sponsor internet sites

Key Meetings Information (continued)



Society	Venues/Meeting Dates	No. Attendees	Abstract/Symposium Deadlines	Presentation Opportunities
American Association for Cancer Research (AACR) Tel: 215-440-9300 Fax: 215-440-7228 E-mail: aacr@aacr.org Website: www.aacr.org	April 1-5, 2006 Washington, DC April 21-25, 2007 Boston, MA April 12-16, 2008 San Diego, CA	13,000–16,000	Abstract deadline: Nov 14, 2005 Late-breaker: Feb 1, 2006 Abstract deadline: Mid Nov 2006 Abstract deadline: Mid Nov 2007	Posters Oral presentations Abstracts (published in <i>Proceedings of the AACR</i>) Educational sessions No commercial symposia Exhibit
American College of Clinical Pharmacy Meeting Organizer American College of Clinical Pharmacy 3101 Broadway, Suite 650 Kansas City, MO 64111 Tel: 816-531-2177 Fax: 816-531-4990 E-mail: accp@accp.com Website: www.accp.com	October 26-29, 2006 St. Louis, MO	1,500	Abstract deadline: late June 2006 Symposium deadline: early June 2006	Posters Commercial symposia Abstracts (published in <i>Pharmacotherapy</i>)

Key Journals Information

Description & purpose

- In a publication plan document, this information provides key details on journals relevant for target audiences for reference purposes
 - Typical information on:
 - Publisher, affiliation & editor/editorial board
 - Journal focus/content
 - Frequency/circulation
 - SCI rankings, Impact Factor
 - Online indexing
 - Rejection rates
 - Publication lead times
 - Notes on specific requirements
- Typically appears as an appendix to the plan
- May be supplemented by proprietary publication planning software, publisher/journal internet sites

Key Journals Information (continued)

Journal/Publisher/ Society Affiliation/ Editor	Focus	Frequency/ Circulation	SCI® Rank/ Impact Factor	Rejection Rate	Indexing	Publication Lead Time	Notes
<p>Journal of the American Medical Association American Medical Association PO Box 10946 Chicago, IL 60610 Tel: 800-262-2350 E-mail: ama-subs@ama-assn.org</p> <p>Society Affiliation: American Medical Association Website: http://jama.ama-assn.org</p> <p>Editor-in-Chief: Catherine D. DeAngelis, MD, MPH</p> <p>Editorial Office: address, phone number, website</p>	Promotes the science and art of medicine and the betterment of public health	<p>48/year</p> <p>350,437 99% (US) 1% (ROW)</p> <p>Internists, general practitioners, residents, students, physicians</p>	<p>2 General & Internal Medicine</p> <p>24.831</p>	94%	<p>BIOSIS Previews IDIS IPA CINAHL MEDLINE EMBASE SciSearch /CC</p>	<p><i>Regular</i> †4 weeks</p> <p>±5 to 6 weeks</p> <p>Fast Track †2 weeks</p> <p>±2 weeks</p>	<p>Peer review</p> <p>Editorials, unsolicited reviews, book reviews, original research, short communications, case reports, letters</p> <p>Trial registration information (name, number, URL) to be listed at the end of the abstract</p> <p>Contribution of each author and of all others involved (eg, editorial assistance) must be provided</p> <p>Trial protocol must be submitted</p>

Key Journals Information (continued)

Therapeutic Area	Journal	ICMJE Uniform Requirements? (Y/N)	AMA style? (Y/N)	Other style (specify)	Clinical Trial Registration (& dates)	CONSORT requirement for RCTs?	Disclosure/Acknowledgment requirements	Special requirements (written)
Allergy and Immunology	Allergy	For references only	N	N	No statement	Y	"Any major sponsorship should be mentioned."	No more than 8 authors without justification.
Allergy and Immunology	Allergy Asthma Proc	N	N	N	N	N	1. All funding sources and institutional or corporate affiliations. 2. Authors must submit a Conflict of Interest form stating specifically whether any commercial associations exist.	
Allergy and Immunology	Ann Allergy Asthma Immunol	Y	Y	N	N (except those in the ICMJE Uniform Requirements)	N (except those in the ICMJE Uniform Requirements)	N (except those in the ICMJE Uniform Requirements)	

Other Communication & Meeting Recommendations

- If desired, publication plan may contain other communication components & activities, such as:
 - Symposia/roundtables (journal supplement proceedings)
 - Advisory board meetings
 - Medical affairs monographs
 - Slide programs/slide resource program
 - Formulary kits/AMCP dossiers
 - Other communication vehicles & concepts

Questions & Discussion

Summary

- Publication plans vary in content and scope depending on what is desired
 - May vary in presentation by agency or pharma company style
- Publication plans need to be “Good Publication Practice” compliant
- Publication plan strategies & tactics are **dynamic** “road maps” that change as time progresses and new data, challenges, issues, and competitors arise