Components of a Strategic & Tactical Publication Plan

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President and CEO, Thomson Scientific Connexions
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
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, hematologic toxicity
- Lack of cross resistance
- In vitro synergy with other agents
- Good single-agent activity in platinum-sensitive patients

**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

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

**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
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.
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)

- 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)

New antimicrobial agent for hospitalized pneumonia for US audience
### Analysis of Key Meetings/Journals (continued)

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

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

- New Product: 60
- Product A: 20
- Product B: 10
- Product C: 10
- Product D: 10
Journal supplements for new oncology agent

Year | No. of Supplements | Journal
--- | --- | ---
1998 | 1 | Br J Cancer
1999 | 2 | Oncology, Semin Oncol
2000 | 1 | Lung Cancer
2001 | 1 | Oncology
2002 | 2 | Semin Oncol, Lung Cancer
2003 | 1 | NSCLC NDA Filing 11/03
2004 | 2 | Oncology, Exp Rev Anticancer Ther
2005 | 1 | Lung Cancer
2006 | 1 | Ann Oncol

FDA Approval

Competitor Publication Analysis (continued)
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
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 (e.g., 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 (e.g., by study, chronology, key communication points)
<table>
<thead>
<tr>
<th>Study</th>
<th>Title/Study Design/Objective</th>
<th>Focus</th>
<th>Target Audience</th>
<th>Meeting/Journal Primary Author</th>
<th>Timing</th>
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</thead>
<tbody>
<tr>
<td>Study</td>
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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)

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Target Journal/Key Endpoints</th>
<th>Status</th>
<th>Clinical Trial Manuscripts/Abstracts/Posters/Review Articles/Supplments</th>
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<td>3022 DB</td>
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<td>3021/3025 OSA CDR Results</td>
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<td>3021/3025 CDR</td>
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<td>Meeting, Location, Date</td>
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</table>

- **Abstract deadline**
- **Prepare Abstract**
- **Meeting date**
- **Final CSR Available**
- **Manuscript start date**
- **Prepare Manuscript**
- **Submit/Peer Review/Resubmit**
- **Lead time to publication**
- **Product NDA**
- **Product FDA Approval**
- **Product NDA**
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)

<table>
<thead>
<tr>
<th>Society</th>
<th>Venues/Meeting Dates</th>
<th>No. Attendees</th>
<th>Abstract/Symposium Deadlines</th>
<th>Presentation Opportunities</th>
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<tbody>
<tr>
<td><strong>American Association for Cancer Research (AACR)</strong></td>
<td>April 1-5, 2006 Washington, DC</td>
<td>13,000–16,000</td>
<td>Abstract deadline: Nov 14, 2005 Late-breaker: Feb 1, 2006</td>
<td>Posters</td>
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<td></td>
<td>April 21-25, 2007 Boston, MA</td>
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<td>Abstract deadline: Mid Nov 2006</td>
<td>Oral presentations</td>
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<td><strong>American College of Clinical Pharmacy</strong></td>
<td>October 26-29, 2006 St. Louis, MO</td>
<td>1,500</td>
<td>Abstract deadline: late June 2006 Symposium deadline: early June 2006</td>
<td>Posters</td>
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<td>Commercial symposia</td>
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<tr>
<td>American College of Clinical Pharmacy</td>
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<td>Abstracts (published in Pharmacotherapy)</td>
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<tr>
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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)

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<th>Journal/Publisher/ Society Affiliation/ Editor</th>
<th>Focus</th>
<th>Frequency/ Circulation</th>
<th>SCI® Rank/ Impact Factor</th>
<th>Rejection Rate</th>
<th>Indexing</th>
<th>Publication Lead Time</th>
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<td><em>Journal of the American Medical Association</em></td>
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<td>Catherine D. DeAngelis, MD, MPH</td>
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Promotes the science and art of medicine and the betterment of public health

48/year
350,437
99% (US)
1% (ROW)

Internists, general practitioners, residents, students, physicians

2
General & Internal Medicine
24.831

94%

BIOSIS Previews
IDIS
IPA
CINAHL
MEDLINE
EMBASE
SciSearch /CC

Regular
†4 weeks
‡5 to 6 weeks
Fast Track
†2 weeks
‡2 weeks

Peer review

Editorials, unsolicited reviews, book reviews, original research, short communications, case reports, letters

Trial registration information (name, number, URL) to be listed at the end of the abstract

Contribution of each author and of all others involved (eg, editorial assistance) must be provided

Trial protocol must be submitted
## Key Journals Information (continued)

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Journal</th>
<th>ICMJE Uniform Requirements? (Y/N)</th>
<th>AMA style? (Y/N)</th>
<th>Other style (specify)</th>
<th>Clinical Trial Registration (&amp; dates)</th>
<th>CONSORT requirement for RCTs?</th>
<th>Disclosure/Acknowledgment requirements</th>
<th>Special requirements (written)</th>
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<tbody>
<tr>
<td>Allergy and Immunology</td>
<td>Allergy</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>No statement</td>
<td>Y</td>
<td>&quot;Any major sponsorship should be mentioned.&quot;</td>
<td>No more than 8 authors without justification.</td>
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<td></td>
<td>Allergy Asthma Proc</td>
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<td>N</td>
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<td>N</td>
<td>N</td>
<td>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.</td>
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<td>Ann Allergy Asthma Immunol</td>
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<td>N (except those in the ICMJE Uniform Requirements)</td>
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</tbody>
</table>

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**Notes:**
- For references only
-AMA style: American Medical Association
-ICMJE Uniform Requirements: International Committee of Medical Journal Editors
-CONSORT: Consolidated Standards of Reporting Trials
-AMA style? (Y/N): Yes/No
-Other style (specify): Specify other style if different from AMA
-Clinical Trial Registration: ClinicalTrials.gov registration number and dates
-Disclosure/Acknowledgment requirements: Specify any additional disclosure requirements
-Special requirements (written): Specify any additional special requirements (written)
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
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.