Effective management of multiple publication plans with overlapping timelines: A case study

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Abstract

Objective: The objective of this study was to identify strategies that allow for the effective management of multiple publication plans with a similar planning schedule.

Research design and methods: For this case study, we examined the strategies and tools employed by a Director of Global Medical Affairs and Publications at a major pharmaceutical company who successfully oversees 10 Global and US publication plans. Approaches used for financial, strategic, and tactical planning were analyzed.

Results: In this case study, a team of 3 people managing 1 product with 2 indications and 16 outputs (manuscripts, abstracts, presentations) in 2012 was reduced to 1 publication manager by 2016, who oversaw an increase in annual outputs, with 10 Global and US publication plans (7 Global and 3 US) across 4 products, 7 therapeutic areas, and multiple life cycles. Metrics achieved in fiscal year 2016 included 62 abstract submissions and 24 manuscript submissions with 46 additional manuscripts in varied stages of development across the publication plans. Effective execution of the publication plans relied on planning (financial, strategic, and tactical), implementation, financial management, international stakeholder consensus, and role clarity. A financial tracker (updated monthly) facilitated annual financial planning, quarterly reviews, and overall management. Annual integrated Global strategic plans were aided by gap analyses conducted monthly and yearly. Additionally, regular cross-functional monthly publication plan reviews were held with stakeholders across all regions, ensuring international stakeholder consensus on strategies, goals, and upcoming steps. These meetings also facilitated formal tactical planning meetings conducted biannually by the Global and US publication teams. Finally, the implementation of publication plans was facilitated by weekly update meetings with vendors.

Conclusions: A substantial increase in outputs can be successfully managed by an experienced publication manager by increasing stakeholder consensus and role clarity, and by developing and implementing effective planning and project management tools.

Background

- Publication directors and managers often face the challenge of managing several publication plans for multiple products with overlapping timelines
- This analysis represents a case in which one publication manager assumed responsibility for an increased number of publication plans and corresponding target outputs across multiple therapeutic areas
- The objective of this case study was to identify strategies that help to successfully develop and execute strategic publication plans and effectively manage the operational implementation of these plans

Research Design and Methods

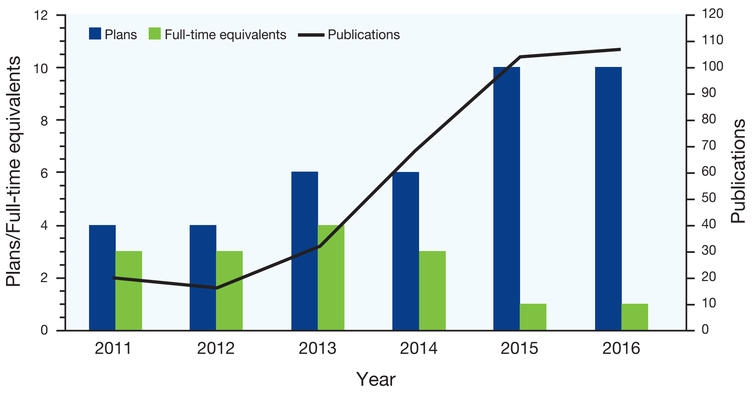
- Strategies and tools employed by a Director of Medical Affairs and Publications at a major pharmaceutical company were characterized
- Approaches for strategic, tactical, and financial planning were analyzed

Results

Publication outputs achieved

- In this case study, a team of 3 people managing 1 product with 2 indications with 16 outputs (manuscripts, abstracts, congress presentations) in 2012 was reduced to one publication manager, who oversaw an increase in annual outputs, with 10 Global and US publication plans (7 Global and 3 US) across 3 products, 7 therapeutic areas, and multiple life cycles

FIGURE 1. Publication goals achieved over time



- Publication output increased substantially, despite the reduction of publication managers involved
- In fiscal year 2016, 62 abstracts and 24 manuscripts were submitted, with 46 additional manuscripts in varied stages of development across the publication plans, resulting in a total of 107 publications (abstracts or manuscripts) achieved (**Figure 1**)
- Publications were achieved in high-tier journals, such as *New England Journal of Medicine* and *Lancet,* and at prestigious congresses, such as American Heart Association, European Society of Cardiology, American College of Cardiology, American College of Rheumatology, and American Diabetes Association

Overall approach

- A collaborative and integrated approach was taken in the development of global and regional strategic and tactical publication plans
- Annual planning involved presentation to all stakeholders to ensure early internal alignment/endorsement of global and regional plans
- Based upon the strategic product goals and yearly landscape and gap analyses, stakeholders worked together in a workshop setting to develop/refine the strategic publication plan and review the tactical publication plan
- All regions, all functional areas, and all stakeholders were at the table, ensuring collaboration and transparent alignment
- This approach eliminated redundancy in publications and provided an opportunity to educate on processes and policies

Stakeholders

- In order to successfully manage such a large volume of work, it was critical to ensure that there was alignment among the key stakeholders
- This was achieved by first defining the goals of the extended team and ensuring a significant level of commonality, and then defining the specific roles and responsibilities of each stakeholder (**Figure 2, Table**)

FIGURE 2. Stakeholders involved in publication planning and execution

HEOR, Health Economics and Outcomes Research; Med Comm, Medical Communications; R & D, Research and Development.
[a]Other key stakeholders included Legal, Intellectual Property, Regulatory, and Pharmacovigilance.

Goals, roles, and responsibilities

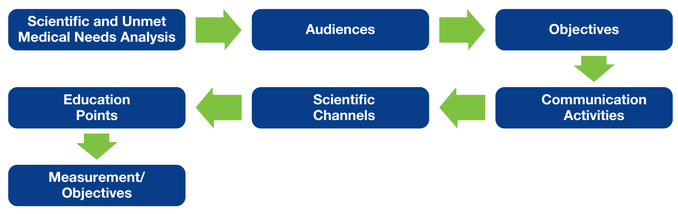
TABLE. Stakeholder alignment for the successful development and execution of a strategic publication plan

Shared goal across all stakeholders: successful development and execution of SPP		
Stakeholder	**Role**	**Responsibilities**
Internal/External Authors	Provide and direct content	• Substantial contribution to the conception or design of study; or acquisition, analysis, or interpretation of the data[a] • Write draft or revise critically for intellectual content[a] • Review and approve all drafts; final approval of version to be published[a] • Accountable for all aspects of the work[a]
Publications Director, Medical Affairs	Manage and oversee all aspects of plan development and execution (Global and Regional SPPs)	• GPP3 compliance[b] • Strategic planning • Tactical planning and execution • Financial management • Internal and external communication
Medical Lead, Medical Affairs	Integral part of the SPP development team to help ensure alignment of all publications with the SPP and overall Medical Communications strategy	• Provide input on and approve SPP • Review publications and make suggestions to ensure alignment to SPP
Clinical (R&D)	Provide insight into the clinical studies including content, context, and all planned timings	• Potential authorship • Liaison, if required, with external authors • Provide input into the strategic and tactical planning (particularly based upon their relationship with external authors) • Timely review of publications • Keep publication team apprised of all key timings
Biostatistics	To provide **prioritized** statistical support for the clinical studies and their associated publications	• Authorship, publication review and approval • Keep publication team apprised of the timing of availability of analyses
Clinical Pharmacology	Provide insight into the phase 1 studies including content, context, and all planned timings	• Potential authorship • Provide input into the strategic and tactical planning (usually in the earlier stages of product development) • Timely review of clinical pharmacology publication outputs • Keep publication team apprised of all key timings
Preclinical	Provide insight into the preclinical studies including content, context, and all planned timings	• Potential authorship • Liaison, if required, with external authors • Provide input into the early aspects of strategic and tactical planning (particularly based upon their relationship with external authors) • Timely review of publication outputs with which they are involved • Keep publication team apprised of all key timings
HEOR	To provide insight and planning to enable the integration of the HEOR publications into the SPP	• Authorship • Input into the SPP • Provide information about HEOR development plan for incorporation into the SPP • Keep the publication team apprised of timing of HEOR analyses
Legal	To approve publications from the legal perspective prior to submission for publication	• Review of all publications • Provide framework/advice to ensure that legal approval is as efficient as possible
Pharmacovigilance	Provide input into safety aspects of all publication content	• Provide input into the strategic and tactical planning (usually in the earlier stages of product development) • Timely review of publications
Regulatory	To approve all publications from a regulatory perspective prior to submission for publication and to provide insight into the regulatory process for consideration within the SPP	• Provide guidance on target indications, including insight from discussions with the regulatory bodies • Keep publication team apprised of key regulatory milestones • Timely review and approval of publications (this necessitates project management for regulatory milestones)
Intellectual Property	To approve all publications before submission from an intellectual property perspective	• Approve all publications in a timely and efficient manner • Provide a framework/advice to ensure that the approval of publications is an efficient process from their perspective
Medical Communications Agency	To support all stakeholders in the development of the SPP and all publications	• Under the direction of authors, provide medical writing and editorial support • Provide all project management support • Ensure that all relevant stakeholders are fully informed at every stage of every project

GPP3, Good Publication Practice guidelines version 3; HEOR, Health Economics and Outcomes Research; SPP, strategic publication plan.
[a]International Committee of Medical Journal Editors. 2016. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. http://www.icmje.org.
[b]Battisti WP, et al. Ann Intern Med. 2015; 163 (6): 461-4.

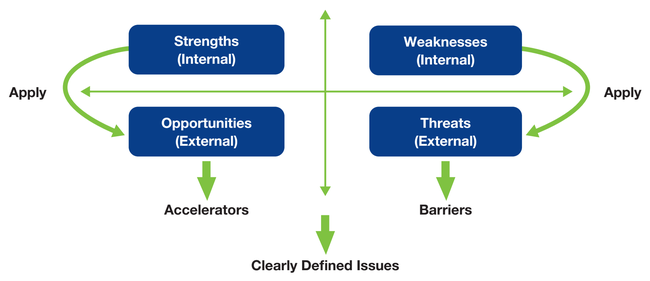
Strategic publication plan development

FIGURE 3. Strategic framework for the development of a strategic and tactical publication plan followed a disciplined, formalized process



1. Scientific and Unmet Medical Needs Analysis
   - The process commenced by developing an advanced Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis
     - This was based upon a deep dive into the data to fully understand it and all of its implications, an extensive search of the published literature, interrogation of the product profile and data package, and analysis of the marketplace and competitor landscape

FIGURE 4. Using SWOT analyses to identify barriers and accelerators

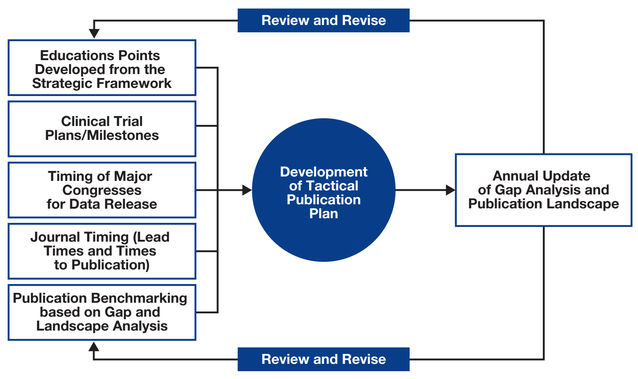


   - The strengths and weaknesses were then related to the opportunities and threats that exist in the competitive and regulatory environments
     - By applying the strengths (internal) to the opportunities (external), accelerators were derived
     - Similarly, by lining up the weaknesses with the threats, barriers were accurately identified
   - From this position, the stakeholders worked together to prioritize barriers and accelerators
2. Identification of Audience
   - A clear and prioritized understanding of the audiences to be educated was based upon an understanding of disease management, associated decision making, and the patient journey
   - Those involved included healthcare stakeholders (clinicians involved in the diagnosis and treatment), policy makers, allied healthcare professionals (non-MD prescribers), and patients
3. Education Objectives
   - The analysis conducted to identify the scientific and unmet medical needs and target audiences was combined with an understanding of the company goals to develop a list of the specific education objectives for each audience and/or indication
4. Education Points
   - Based on an in-depth review of the data, coupled with an intricate examination of the science, a list of education points to communicate, which would meet the education objectives, was developed
     - This formed the structure of the communication platform, which described the disease and the patient, the alternative therapies, and all aspects of the asset in question

Tactical publication plan

- From an intelligently designed strategic framework, targeted publication tactics were developed (**Figure 5**)

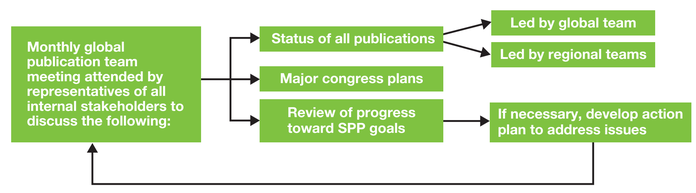
FIGURE 5. Publication activities and deliverables



   - The gap analysis and literature review used the following approach
     - Establish the search criteria
       - Timespan for search
       - Competitive agents
       - Parameters (eg, efficacy, safety, outcomes, HEOR, special populations, use in combination, patient management considerations)
     - Conduct a literature analysis
       - PubMed databases, congress databases, and internet searches were performed to identify potential outcomes and their associated publications
     - Prepare a gap analysis report to capture feedback and research results for each identified outcome
       - In order to inform the strategic framework, the gap analysis included detailed information and recommendations regarding the benchmarking of publication levels along with the following
         - Overall themes for each product or category that summarized the landscape and what was reported in the literature about the products (unmet medical needs, challenges, disease landscape) and related factors
         - Analyses of audiences, journals, and overall themes of statements

Effective stakeholder communication

FIGURE 6. Regular stakeholder communication and interaction



SPP, strategic publication plan.

- For each product, monthly meetings with global and regional stakeholders ensured consensus on strategies, goals, and next steps (**Figure 6**)
- An action plan was developed to address any issues identified
- Regular and rigorous project management ensured effective tactical execution
  - Weekly review of the status of each project
  - Next action required, by whom, and when
  - Priorities for the coming week based upon the strategic publication plan goals
- A financial report was produced by the medical communications agency to aid effective budget management and planning; it included the following:
  - Financial status of all projects
  - Items invoiced to date
  - Items to be invoiced, how much, and when
  - Provision of monthly, quarterly, and annual totals (in line with company financial reporting structure)

Conclusions

- The following are important tools and strategies that experienced publication managers should employ to successfully manage an increased number of publication plans
  - Goal alignment across all stakeholders
  - Effective strategic planning
  - Strong tactical execution
  - Regular and rigorous project management and financial management
- This case study shows the scope and volume of work that can be achieved by one publication manager who adopts a proactive approach to developing and implementing her publication plans
- Integral to this success was to gain all stakeholders' alignment to each plan, achieved by first gaining a consensus on common goals, and then defining each stakeholder's role and responsibilities in the development and the execution of the publication plan
  - This process established alignment to achieve a common goal
- The approach described here was further built upon by successfully creating a structure for regular effective communication
- In regular stakeholder meetings, the presentation and related discussions were focused on the progress made to achieve these common goals, making these meetings meaningful and pertinent for all attendees
- Because the communication was in real time, the discussion about and resolution of issues took place there and then, thereby, maximizing the efficiency of the process
- This case study is particularly important in today's environment of budget restrictions within the pharmaceutical industry, and can serve as a "blueprint" for how to effectively manage multiple publications with substantial numbers of outputs

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