Publication Planning Overview

[abbreviated]

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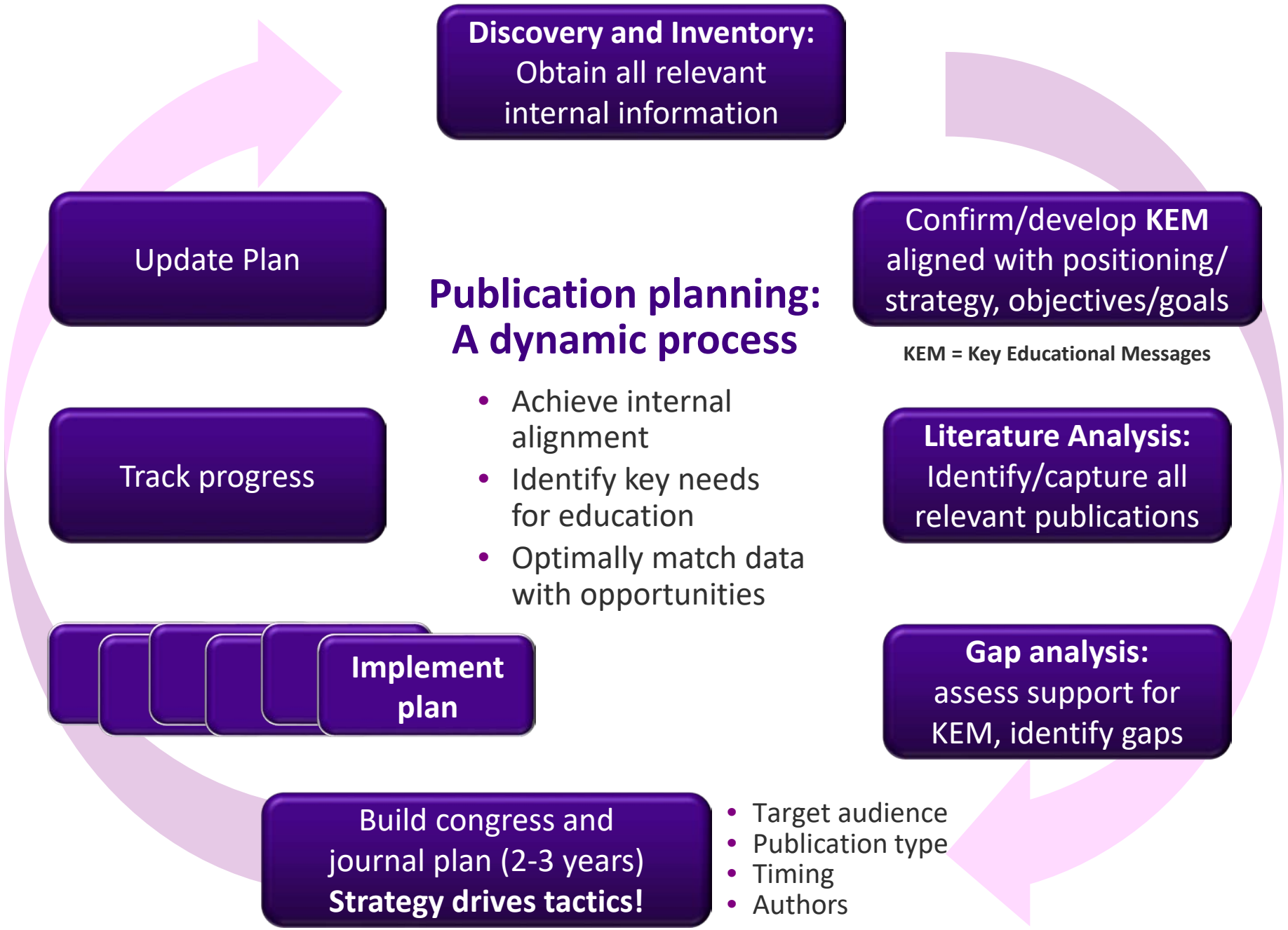
Why Do Publication Planning?

- More recently: drives increasingly *critical transparency (disclosure)* and *compliance* requirements/best practices through education and example/modeling (SOPs)
- Older, still very relevant: *accelerates ROI* by ***intentionally*** shaping/preparing market—and company—for product, and investing/empowering advocates
- Defines baseline and emerging *educational needs* through a rigorous and continuous assessment of market understanding
- *Maximizes impact of allocated resources* by focusing education on key areas identified as most relevant and important to achieving goals and objectives
- Promotes *consistent communications* by aligning stakeholders on agreed-upon educational messages and language
- Establishes a *proactive, compliant, and multifunctional team approach to process and resourcing* that facilitates timely data publication/disclosure and appropriate (and nimble) responses to emerging challenges/threats
- Helps resolve potential internal and external issues that can often impede building the foundation of peer-reviewed publications needed to strongly support compliant regulatory submissions and successful commercialization


Discovery and Inventory: Obtain all relevant internal information
Confirm/develop KEM aligned with positioning/ strategy, objectives/goals
KEM = Key Educational Messages
Literature Analysis: Identify/capture all relevant publications
Gap analysis: assess support for KEM, identify gaps
Target audience
Publication type
Timing
Authors
Build congress and journal plan (2-3 years) Strategy drives tactics!
Implement plan
Track progress
Update Plan
Publication planning: A dynamic process
Achieve internal alignment
Identify key needs for education
Optimally match data with opportunities

Publication Planning in 8 Steps

1) **Education and Alignment**
   - Transparency (disclosure) and compliance best practices
   - Establish SOPs and multifunctional publication team (all key stakeholders represented)
2) **Discovery and Inventory**
   - Obtain, review, and organize all relevant internal information
3) **Key Educational Messages (KEM)**
   - Identify/confirm "positioning" and KEM (no more than 6)
4) **Literature Analysis**
   - Assess relevant literature through searches of Congress proceedings and PubMed; perform quantitative and qualitative analyses
5) **Gap Analysis**
   - Measure existing publication support of KEM; recommend strategies and tactics to address identified gaps
6) **Publication Plan**
   - Recommend specific tactics and timing for congress activity and journal articles within 2–3-year timeframe
7) **Lexicon and Communications Platform**
   - Approved language and KEM-based "story" with supporting references
8) **Monitor and Update**
   - Regular status meetings to track/facilitate progress; updates as necessary

Step 1: Education and Alignment

- Understanding publication planning and its value
- Transparency (disclosure) and compliance requirements/best practices (FDAAA, ICMJE, GPP3)
- Establish SOPs and multifunctional publication team (all key stakeholders represented)

✓ **Provides a framework for accountability and support**

✓ **Adopting processes that work now builds a strong base for the future**

✓ **It's fine to start small based on current needs—it will make work easier now. Having it in place later? Critical!**

Compliant Publication Planning (Shire, 2012)

8 Publication planning at one pharmaceutical company: A guidance document creation to ensure compliance with industry best practices and laws

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Abstract

Objective: Provide practical guidance for the development process of a publication plan at Shire.

Research Design and Methods: The approach to publication planning and development can vary widely among publication professionals within the pharmaceutical industry. In early 2011, the publications group at Shire completed the development of a best practices guidance document to align the publication development process. A supplemental guidance document on the publication planning process was developed more recently to specifically address the development and updating of publication plans at Shire. The Shire Best Practices Publication Guidance Document, Shire policies, and standard operating procedures (SOPs) on publication development, a review of various pharmaceutical company corporate integrity agreements that addressed publication-related activities, and feedback from Shire publication leads were all used in the development of this current guidance document.

Results: The publication planning guidance document presents an overview of the publication planning process, including the initiation of a publication plan and publication tactics for different publication types. Additional sections included in this guidance document are: publication planning tools, gap analyses, needs assessments, and the role and responsibilities of publication service providers in the development of a publication plan. More detailed information on each of these areas will be outlined.

Conclusions: The Shire publication planning guidance document provides a practical, yet specific framework for how a publication professional at Shire should approach the development of, and update processes for, a publication plan.

Introduction/Background

- The number of Corporate Integrity Agreements (CIAs) aimed at pharmaceutical companies has increased over the past 5 years[1]
- Several of these CIAs include sections on pharmaceutical company publication practices, causing many companies to examine their current publication policies and procedures[2,3]
- In 2011, Shire completed a company best publication practices guidance document, which was presented at the 2011 International Society for Medical Publication Professionals (ISMPP) meeting[4]
- More recently, a new guidance document was developed to specifically address Shire's approach to publication planning

Objective

- The purpose of this guidance document is to explain the publication planning process at Shire, and to describe the tools that the Scientific Publication Team (SPT) uses to develop a publication plan

Process

Purpose of a publication plan

- To ensure that the results of Shire studies are published in a timely manner, regardless of whether the outcomes are perceived as positive, neutral, or negative
- The Shire Publication Lead (PL) and SPT will also consider unanswered scientific questions from the scientific/medical community and suggest publications that may be able to assist in answering those scientific questions
- Publication plans help to address unmet medical needs for a particular disease state or specialty

Contributors to the publication plan

- The PL collaborates with other SPT members as part of the initial and later stages of the publication planning process
- Core SPT members include:
  - PL
  - Biostatistics representative
  - Clinical development physician
  - Intellectual property (IP)
  - Medical affairs physician
  - Research and Development product strategy lead
- Extended SPT members may include:
  - Clinical programs
  - Medical communications
  - Pharmacokinetics and clinical pharmacology
  - Health economics and outcomes research (HEOR)
  - Legal
  - Native speaker scientifically qualified (NSSQ) for translations*
  - Medical science liaison (MSL)
  - Regulatory affairs
  - Pharmacovigilance and risk management
  - Representatives of commercial functions, including marketing

* Native speaker scientifically qualified (NSSQ) is a Shire medical affairs employee (eg, Local Operating Company [LOC] medical director) who is responsible for ensuring the accuracy of any publication translated into a particular language. (Source: Shire Policy SH-004.)

- Commercial representatives may attend SPT meetings as part of the extended SPT for:
  - Informational purposes to gain knowledge around publication activities
  - Providing general comments about product strategy
- Commercial representatives are not permitted to be reviewers or approvers on any Shire publication drafts prior to submission

Timelines

- Publication plans are first developed typically during Phase 2 of a clinical program:
  - They are generally revised and updated on an annual basis but can be updated more or less frequently if necessary
  - To begin the process, the PL assesses the data expected to be available over the next 12–18 months
  - Using various tools and input from other SPT members, a PL develops a preliminary publication plan (generally in Q1–Q2) (**Figure 1**)

Figure 1. Timeline of publication planning process*

* Timelines are approximate and may vary depending on the needs of the publication team.

- By mid-year (approximately June/July), the PL will meet with the SPT to fully develop the publication plan for the following year:
  - The preliminary plan will be updated with more current information at that time and team discussions will focus around finalizing the publication plan for the following year
- Publication steering committees (PSCs) are formed when appropriate and guide the publication planning process:
  - Recommendations from PSCs are brought back to the SPT for implementation
- The SPT will consider presentation of data to reach the educational needs of each of the intended countries
- The publication plan will include all of the publication tactics (eg, congress abstracts, congress posters, congress presentations, manuscripts, review articles) planned for the next 12–18 months

Publication planning tools

- A PL may collaborate with many SPT members to identify publication planning needs during the initial planning stage
- Other tools used to draft a publication plan include:
  - Clinical development plan
  - Long-range medical plan
  - Clinical study report (CSR) data
  - Statistical tables, figures, and listings
  - Study protocols
  - HEOR study data
  - Gap analyses
  - Needs assessments

Gap analyses

- As part of the publication planning process, the SPT may first identify information or data gaps within Shire's existing data sets as well as in the published literature regarding a particular product or disease state
- Gaps must represent bona fide scientific or medical needs supported by adequate data that when addressed, advance the field of medical knowledge
- A gap analysis may be completed every 12–24 months to determine if any new informational gaps exist. The following gap analysis methods should be conducted to identify any new potential information gaps:

1. External Gap Analysis:
   - Used to identify informational or data gaps within the existing published literature for a particular product and its competitors, therapeutic drug class, or general disease state
   - May provide additional insight to unanswered scientific questions regarding a product or disease state
2. Internal Gap Analysis:
   - Used to identify gaps in Shire's current body of data that would be helpful to answer any identified unanswered scientific questions regarding a product or disease state
   - SPT will examine Shire's data to determine if there are any completed analyses or potential post hoc analyses that may be helpful for identifying further insights to unanswered scientific questions

Needs assessments

- A needs assessment is performed to identify the medical/scientific need for publication activities:
  - Provides a reason for each publication tactic that is listed on the publication plan
  - Each publication included in the publication plan is associated with an identified need to ensure the scientific validity of the publication activities
- The needs assessment should:
  1. State the source of information for a publication
  2. Describe the proposed publication type to be generated (eg, manuscript, abstract)
  3. Describe the reason for the publication
- Each publication identified on a publication plan should include one or more of the following 8 needs:

Table 1. Identified needs for publications

Need	Key Points
1. Conclusion of a Clinical Trial	• Shire will endeavor to submit a manuscript from qualifying, applicable, and covered clinical studies for publication whenever possible
2. Inquiries to Shire Medical Information Group	• PL and/or SPT may become aware of inquiries received by Shire's medical information group regarding a topic for a particular product through dialogue with medical information colleagues and call center reports • SPT may use this information to determine if a publication may be appropriate to address the unmet medical need on the topic
3. Gap Analyses	• Internal and/or external gap analyses may identify a need for publication on a particular topic
4. External Subject Matter Expert (SME) Inquiries	• SMEs external to Shire may express a need for further information on a topic or body of data through communications with Shire Medical Affairs staff
5. Long-range Medical Plan	• May provide information on potential studies, post hoc analyses, and educational needs for different regions where the drug is being developed or marketed
6. Publication Steering Committee (PSC)	• Noncommercial body that advises and/or decides upon the most appropriate approach to dissemination of clinical study data to the scientific community[5] (Source: Shire Policy SH-004) • Individuals who participate in a PSC may be internal or external to Shire
7. MSL Interactions	• Through interactions with health care professionals, the MSL may be informed of unanswered scientific questions regarding a particular topic
8. Shire SMEs	• Often intimately involved with the development of Shire clinical studies, and the data analyses following the close of those studies. • May become aware of additional unanswered questions or educational needs that may require post hoc analyses

- Needs assessments performed for the publication tactics on an individual publication plan should be documented:
  - Shire's publication management tools (eg, Pubs Hub), spreadsheets, or slide decks are some examples of how to document the completion of a needs assessment
  - **Table 2** provides an example of information that should be captured from a needs assessment for a publication plan

Global publication planning tools

- For global publication plans, the PL and SPT will examine the medical goals for each country where data will be presented or published for a particular product
- The medical goals of different countries may vary depending on a number of factors such as:
  - Stage of clinical development
  - Lifecycle of the product in that country
  - Educational needs of a particular country or region
- The development of a local or country-specific publication plan will be focused on the medical goals of one particular country but should take into account publications that may already be covered by a global plan to avoid duplication

Table 2. Sample needs assessment documentation

Short Title Description	Publication Type	Potential Journal or Congress	Reason for Publication
Study 300 Primary endpoint	Manuscript and abstract	JAACAP journal; APA 2012 congress	Clinical trial concluded
Study 302 Post hoc analyses	Poster	American Association of Child and Adolescent Psychiatry (AACAP) 2012	Medical information inquiries/dialogue
Study 300 Secondary endpoints	Presentation at a congress	AACAP 2012	Gap analysis of existing data
Integrated/meta-analysis	Manuscript/ abstract	Pediatrics; CHADD 2012 congress	External subject matter expert inquiries
Post hoc data analysis	Manuscript	*J Clin Psych*	Long-range medical plan
Study 315 Secondary Analysis	Manuscript	*Am J Transplant*	Publication steering committee

Prioritization of publications within a publication plan

- The prioritization of publications is based on a number of factors, including:
  - Timing of data release
  - Congress submission deadlines
  - PSC input
- Although a comprehensive plan will be developed, it is important to note that publication tactics may be added or deleted depending on changing timelines, data availability, or other business reasons as the year progresses

Publication agencies

- Throughout the publication planning process, publication service providers may:
  - Assist the PL and the SPT in developing a publication plan and in the development of individual publications
  - Conduct literature searches and gap analyses
  - Research potential congresses and journals
  - Assist with the development of materials such as spreadsheets and slide decks which reflect the current state of the publication plan
- Publication agencies work under the explicit direction of the PL and publication team, but may provide ideas to the team for consideration during the publication planning process

Conclusions

- A guidance document has been created to describe in detail the process for global scientific publication planning at Shire
- This guidance document details the publication lead ownership of the publication plan and its development
- The PL role is a Research and Development function at Shire
- A needs assessment was identified by both examination of CIAs and internal Shire PL input as a vital component in the development of a publication plan
- Documentation of the needs assessment will now be required

References

1. Rodino F, Rose L. "Corporate Integrity Agreements". Slides presented at ISMPP U, February 18, 2011.
2. Office of the Inspector General, US Department of Health and Human Services. 2012. http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp. Accessed 02 March 2012.
3. Baronick T, Kendall J, Keene C. Corporate Integrity Agreements 2007-2011. 8th Annual Meeting of the International Society for Medical Publication Professionals, Baltimore, MD, April 28-29, 2012.
4. Scheckner B, Baronick T, Young-A Chae J. Create a scientific publications Guidance Document to ensure continued awareness and compliance with industry best practices, regulations, guidelines, and laws. 7th Annual Meeting of the International Society for Medical Publication Professionals, Arlington, VA, April 4-6, 2011.
5. Graf C, Battisti WP, Bridges D, et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ*. 2009;339:b4330.

Poster presented at the International Society for Medical Publication Professionals, 8th Annual Meeting, Baltimore, Maryland, 28–28 April 2012

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

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This updated Good Publication Practice (GPP) guideline, known as GPP3, builds on earlier versions and provides recommendations for individuals and organizations that contribute to the publication of research results sponsored or supported by pharmaceutical, medical device, diagnostics, and biotechnology companies. The recommendations are designed to help individuals and organizations maintain ethical and transparent publication practices and comply with legal and regulatory requirements. These recommendations cover publications in peer-reviewed journals and presentations (oral or poster) at scientific congresses. The International Society for Medical Publication Professionals invited more than 3000 professionals worldwide to apply for a position on the steering committee, or as a reviewer, for this guideline. The GPP2 authors reviewed all applications ($n = 241$) and assembled an 18-member steering committee that represented 7 countries and a diversity of publication professions and institutions. From the 174 selected reviewers, 94 sent comments on the second draft, which steering committee members incorporated after discussion and consensus.

The resulting guideline includes new sections (Principles of Good Publication Practice for Company-Sponsored Medical Research, Data Sharing, Studies That Should Be Published, and Plagiarism), expands guidance on the International Committee of Medical Journal Editors' authorship criteria and common authorship issues, improves clarity on appropriate author payment and reimbursement, and expands information on the role of medical writers. By following good publication practices (including GPP3), individuals and organizations will show integrity; accountability; and responsibility for accurate, complete, and transparent reporting in their publications and presentations.

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For author affiliations, see end of text.
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GPP3

Step 2: Discovery and Inventory

- Obtain, review, and organize all relevant internal information

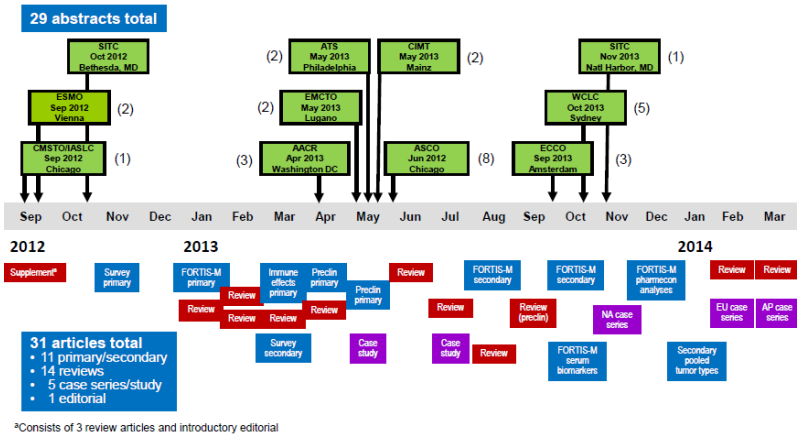
Publication Planning "Wish-List"

- Current internal strategic thinking
  - For each indication, if separate
  - Positioning and potential strategies for differentiation
  - Existing slide decks that present strategy
    - Eg, Long-range Medical Plan
  - Identification of key competitors (and any relevant competitive intelligence)
  - Results of any relevant research performed to date to inform strategy
- Any existing communication planning information/documents
  - Identification of key audiences
  - Scientific platform and/or key educational messages
  - Existing slide decks that present scientific rationale/MOA
  - Assess to any bibliography or digital library of publications relevant to product development in indications of interest

- All product publications to date
  - Includes published, submitted, in progress, and planned
  - Congress abstracts and associated presentations (poster pdf and ppt files)
  - Primary and secondary articles, reviews (pdf files)
  - Current draft files of manuscripts in progress
- Preclinical study and clinical trial information
  - Clinical Development Plan
  - Investigator brochure (if separate, for each indication)
  - Details/timelines for studies/trials completed, in progress, and planned, including investigator-sponsored studies/trials
    - All study protocols and CSRs
- Potential author information
  - List of and contact information for external investigators
  - List of and contact information for clinical advisors/advocates (advocacy plan if available)

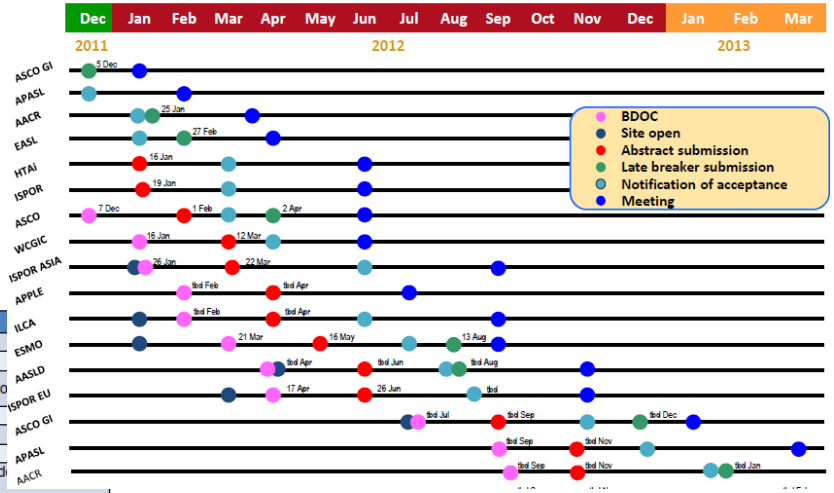
Sample Deliverables

Recommended 2012–2013 Publication Plan



[a]Consists of 3 review articles and introductory editorial

2012 Liver Congresses at a Glance



Lexicon: Granix™ (tbo-filgrastim)

Category	Term(s)
Chemical name	Recombinant methionyl human granulocyte-colony stimulating factor (r-metHuG-CSF)
Synonyms	XM02, filgrastim, Neutroval™, TevaGrastim®, Biograstim®, Ratiograstim®
General descriptors	Recombinant human G-CSF (rG-CSF), leukocyte growth factor, hematopoietic growth factor, immunostimulant, cytokine, bio
Modifiers	Daily, nonglycosylated
Structural components	Chemically and pharmacologically similar to filgrastim
	Protein composed of 175 amino acids with molecular weight of approximately 18.8 kDa
	Differs from endogenous human G-CSF due to *E coli*-based production, which yields nonglycosylated protein that has an ad methionine amino acid residue at its NH_2 terminal end
Mechanism of action	Binds to G-CSF receptors and stimulates proliferation and activation of neutrophils, resulting in increased neutrophil counts and activity
Safety	Well tolerated
	Safety profile comparable to filgrastim and similar to that of other rG-CSF products
	Bone pain is the most common treatment-emergent adverse reaction; generally low grade and manageable with standard analgesics
	Low immunogenicity
Disease/patient descriptors	Chemotherapy-induced neutropenia (CIN)
	Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia (FN)[1]
	Patients with individual factors, such as advanced age, that can increase the risk of neutropenic complications
Endpoints	Primary • Duration of severe neutropenia (DSN)[2] in cycle 1
	Secondary • Incidence of FN[3]; incidence of protocol-defined FN (administration of antibiotics) by cycle and across all cycles; DSN in cycles 2–4; depth of absolute neutrophil count (ANC) nadir and time to ANC recovery in cycles 1–4
Efficacy	Reduces DSN
	Superior to placebo
	Equivalent to filgrastim
Pharmaco-economics	Lower cost alternative to Neupogen®
	Improved value compared with Neupogen®

1. Same day ANC <0.5×10^9/L and oral body temperature >38.5°C for at least 1 hour.
2. Number of days with grade 4 neutropenia (ANC <0.5 ×10^9/L).
3. Strict definition of FN was one of: (a) Oral body temperature >38.5°C for ≥1 hour at 2 consecutive measurements on the same day ≥1 hour apart, and observed severe neutropenia (ANC <0.5 x10^9/L) the day before, the same day, or the day after the elevated temperature; (2) Neutropenic sepsis, ie, sepsis in combination with ANC <0.5 x10^9/L, or (3) Serious or life-threatening neutropenic infection, ie, a life-threatening infection in combination with ANC <0.5 x10^9/L.