

# 7 Publication steering committee development at a pharmaceutical company: Experience one-year post-departmental guidance document development

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## ABSTRACT

**Objective:** Provide practical guidance for the development of publication steering committees based on experience from one pharmaceutical company.

**Research Design and Methods:** In February 2011, the publication group at Shire introduced a publication best practice guidance document, which included the creation of steering committees. Shire publication leads were surveyed in January 2012 to assess their experience with steering committee creation over the past year.

**Results:** Eight steering committees were convened in 2011 relating to 8 clinical studies and 1 non-clinical survey. Seven were developed with the single goal of supporting publication development specific to the study that the steering committee members were participating in, while one utilized an older model of including publications as part of an agenda of an overall clinical trial steering committee meeting. Overall, 79 Shire and external steering committee members were engaged through this process over the year, and ideas were generated for 75 publications through the steering committee process. Practical matters regarding the steering committee process at Shire will be described.

**Conclusions:** The steering committee model was successfully implemented at Shire and was consistent with Shire and Good Publication Practice updated (GPP2) guidelines. Full participation in the publication planning process by external advisors has become the standard for studies with steering committees. These guidelines may prove useful for other publication planners.

## INTRODUCTION

- GPP2 recommends that the formation of steering committees be considered<sup>1</sup>
- In February 2011, in an effort to increase publication leader understanding and interpretation of the GPP2 guidelines (and other publication topics), a company best publication practice guidance document was issued. This guidance document was written to supplement the existing company publication policy and standard operating procedure:
  - The summary of this guidance document was presented at the International Society for Medical Publication Professionals (ISMPP) 2011 annual meeting<sup>2</sup>
  - This current poster reflects on the 1-year experience of a company's publication leaders since the issuance of the company guidance document with regards to development of publication steering committees

## OBJECTIVE

- Provide practical guidance for development of publication steering committees based on experience from one pharmaceutical company

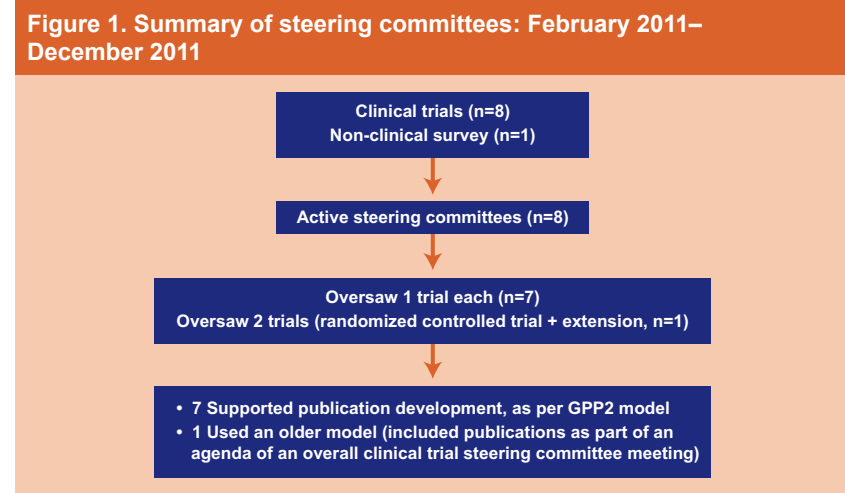
## RESEARCH DESIGN AND METHODS

- Shire publication leads were surveyed in January 2012 to assess their experience with steering committee creation over the past year (postavailability of the company publication guidance document)
- The following questions and discussion topics were included:
  - Number of steering committees
  - Number of studies
  - Description of steering committees, and whether the steering committees followed the model issued by GPP2 and the Shire publication guidance document
  - Confirmation of the role of the steering committee
  - Number of steering committee members (internal and external to company)
  - Number of publications added to the publication plan poststeering committee creation

- General timing of the steering committee creation
- Description of author make-up of publications derived from the steering committee
- Characterization of studies that have and have not used steering committees

## RESULTS

- Out of 8 Shire Specialty Pharmaceuticals and Shire Movetis publication leads, 5 indicated that they had active steering committees from the period of February 2011 to December 2011
- Figure 1** summarizes the steering committees during this time period:



### Criteria for contemplating the creation of steering committees

- The company guidance on whether to consider creating a steering committee is shown in **Table 1**:

Table 1. Guidance related to steering committees	
Recommended	Examples
<ul style="list-style-type: none"> <li>Phase II, III, or IV studies</li> <li>Multicenter studies</li> <li>Studies with many endpoints</li> </ul>	<ul style="list-style-type: none"> <li>Steering committees were created for multicenter Phase II studies for a product:                             <ul style="list-style-type: none"> <li>There were many secondary efficacy measures and safety measures to these studies, leading to a need for scientific dialog regarding the optimal data presentation</li> </ul> </li> </ul>
Not recommended	Examples
<ul style="list-style-type: none"> <li>Phase I or preclinical studies</li> <li>Single-center studies</li> <li>Studies with few endpoints</li> </ul>	<ul style="list-style-type: none"> <li>Steering committees were not created for single-center, Phase I pharmacokinetic studies or a single-center Phase II study:                             <ul style="list-style-type: none"> <li>There were a limited number of efficacy measures and relatively basic protocols, giving the studies easily identifiable publication targets that company publication planners/scientists could identify without external validation</li> <li>External and internal company authors for these studies made decisions related to the publications without a steering committee</li> </ul> </li> </ul>

### Timing of steering committee creation

- Some steering committees (3) were created before data availability, while the remainder (5) were created immediately after data availability (final tables issued)
- Table 2** shows advantages and disadvantages of earlier and later steering committee creation:

Table 2. Advantages and disadvantages based on timing of steering committee creation	
Earlier steering committee creation	Later steering committee creation
<b>Advantages</b> <ol style="list-style-type: none"> <li>Early and clear communication to steering committee members regarding the obligation and commitment to publish the primary study results</li> <li>Enthusiasm for publication process generated</li> <li>Proactive publication planning completed prior to data availability</li> </ol>	<b>Advantages</b> <ol style="list-style-type: none"> <li>Understanding the data fully before completing the publication planning process, which allows for a more in-depth discussion of definitive secondary and post hoc analyses of scientific interest</li> <li>Avoids unnecessary commitments and discussion of secondary publications that may not take place</li> </ol>
<b>Disadvantages</b> <ol style="list-style-type: none"> <li>Uncertainty regarding purpose of meeting formation at an early stage before data availability</li> <li>Beyond commitment to publish the primary data regardless of outcome, hesitancy in some cases to plan for additional publications without viewing the data, particularly post hoc analyses</li> </ol>	<b>Disadvantages</b> <ol style="list-style-type: none"> <li>Omits the public transparency role of the steering committee's obligation to publish the primary study results regardless of the outcome</li> </ol>

### Responsibilities of the steering committees

- Table 3** presents the remit of the Shire steering committees:

Table 3. Shire steering committee responsibilities	
Commit to publishing the key primary and secondary results of the trial in an objective and timely manner	
Provide input into the initial publication plan for each individual study (eg, congress presentations and manuscript planning)	
Provide input into discussions of educational needs in the therapeutic area	
Identify, based on robust medical hypotheses, and publish subanalyses or exploratory endpoints that would be of interest to the scientific/medical community	
Provide input into authorship, contributors, and journal and congress choices	

### Authorship topics related to steering committees

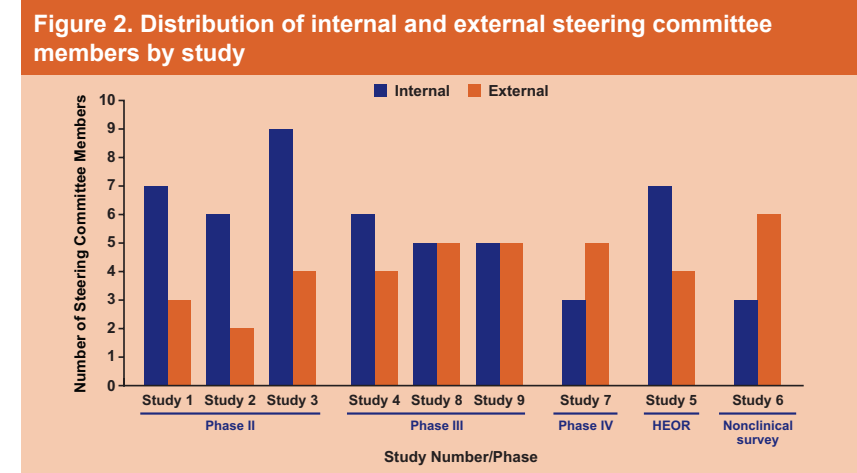
- Table 4** describes the authorship criteria described to steering committee members:

Table 4. Authorship guidelines for publications derived from steering committees	
Membership on the publications steering committee may or may not include authorship responsibilities	
Authorship is determined by the level of intellectual contribution to the publication of an individual	
ICMJE criteria <sup>3</sup> are utilized to determine authorship eligibility	

- One year of experience with the publication leads has shown a mix of authorship (both steering committee authors and nonsteering committee authors) of publications derived from steering committees:
  - Publications have generally included steering committee members as authors, as they most often qualify for authorship based on International Committee of Medical Journal Editors (ICMJE) criteria<sup>3</sup>
  - Some steering committees were diligent about recommending additional nonsteering committee members for publications, particularly related to publication reviews or post hoc analyses
- Pre- or poststeering committee work by the publication team (eg, conducting literature searches to identify other subject matter experts to recommend to the steering committee) sometimes lead to an increase in qualified nonsteering committee authors for appropriate publication topics

### Steering committee composition

- Overall, 79 company internal and external steering committee members were engaged over the last year:
  - Of these, 46 were company internal steering committee members and 33 were steering committee members external to the company
- Figure 2** shows the distribution of internal and external committee members by study:

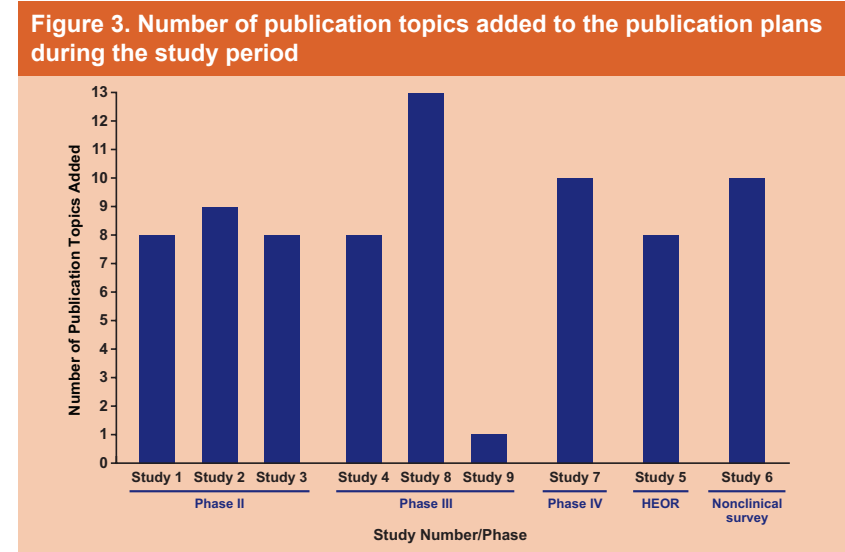


- There was variability across the steering committees in terms of the ratio of company to external steering committee members
- Typical company steering committee members consisted of members from the company research and development organization, including the publication lead (steering committee leader or co-leader), clinical research lead, clinical operations, medical affairs physician, statistician, health economics and outcomes research, and product strategy lead:
  - There was some variation among teams as to which company team members participated
- Typical steering committee members external to the company consisted of the coordinating principal investigator and other identified study investigators

### Publication output

- In total, 75 publication topics (abstracts for posters and podium presentations, data manuscripts, and review articles) were added to the 8 publication plans through the steering committee process:
  - The company publication leader ensures that publication topics are appropriate, novel, and are not duplicative or redundant with other work in the publication plan

- Figure 3** shows the publication topics that were added to the publication plan during the study period:



### Limitations and potential 'road-blocks' of the steering committee

- Some potential limitations and concerns were discussed during the survey and research process:
  - Steering committee members' potential aims for self-publishing, attainment of a desired author line position, or presenter of research
    - Overall, however, the steering committee members' aims were deemed by the publication leads to be appropriate (see authorship guidelines discussion above)
  - Potential lack of consensus between steering committee members

## CONCLUSIONS

- The steering committee model, as described in GPP2, has been implemented across publication teams at Shire:
  - Steering committee creation has become the standard of practice at Shire for Phase III and larger Phase II studies
- External input into the company publication planning process was deemed to be helpful in confirming the scientific and clinical utility of the publication topics and lead to the creation of externally validated publication plans
- There are many other avenues of potential research that may be useful to optimize steering committee creation:
  - Confirmation of industry best practice regarding the timing of steering committees
  - Confirmation of ideal steering committee composition
  - Measurement of metrics (acceptance rates, etc) pre- and poststeering committee creation across companies

## References

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