Publication plan development: variables affecting the timing and execution of a publication plan

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Abstract

Background: A Working Group (WG), formed under the Standards and Best Practices Committee, convened to review variables to be considered in publication plan (PP) development and execution, and to provide ISMPP members with a timing perspective in creating high-quality PPs.

Methods: The combined personal experience of the WG was used to identify variables that could affect initial timing of PP development or execution. The WG first constructed a 'typical' timeframe for PP development, then identified issues and circumstances that potentially require deviation from typical timelines.

Results: Typically, PP development begins 3-4 years prior to product launch (often prior to Phase III clinical development). Factors that suggest a need to start PP planning or execution earlier than this typical timeframe include first-in-class status, novel therapeutic indication, multiple indications, crowded therapeutic environment, need to increase disease awareness, new therapeutic area for the organization, or potential for expedited regulatory approval. Factors that would tend to indicate later initiation of publication planning than typical include lack of available resources, late go/no-go decision, short clinical trial duration, critical therapeutic need, questions about the compound, or an alliance or partnership situation.

Conclusions: Publication planning should begin 3-4 years prior to product launch. In some cases, publication planning begins in early product development and is completely integrated with clinical development plans. Several factors were identified that could influence decisions to follow typical timelines; these timing modification factors include clinical development timelines, therapeutic environment, and business/economic factors. The impact of PP timing and execution to overall publication development and product support will likely be a fertile area for further investigation.

Introduction

- Following the inaugural ISMPP meeting in April 2005, the Standards and Best Practices Committee (SBPC) was formed. Through discussions of the SBPC one area of concern identified for ISMPP members was understanding some of the variables that can influence the timing of the development of high-quality publication plans. Accordingly, a Working Group of the SBPC was convened to discuss and research this topic and provide guidance to ISMPP members.

Methods

- The combined personal experience of the Working Group was drawn on to define the variables affecting the timing and execution of a publication plan.
- A 'typical' timeframe for publication plan development was initially constructed to establish a baseline against which the variables could be considered.

Results

A typical timeframe

- The typical publication planning timeframe developed is shown in Figure 1. The x-abscissas show both the approximate time before and after launch and the phase of drug development to which this typically corresponds.
- As shown in Figure 1, the typical time point to start the formal process of publication planning is approximately 4 years before the initial launch of a compound. This often corresponds with the beginning of the Phase III trials for the compound.
- It should be noted, however, that Figure 1 provides only a framework for developing a publication plan. All publication plans are unique.
- Table 1 lists some of the steps that need to be included when developing a publication plan strategy and some of the elements involved in its execution.

Figure 1. Publication planning throughout the life cycle of a product.

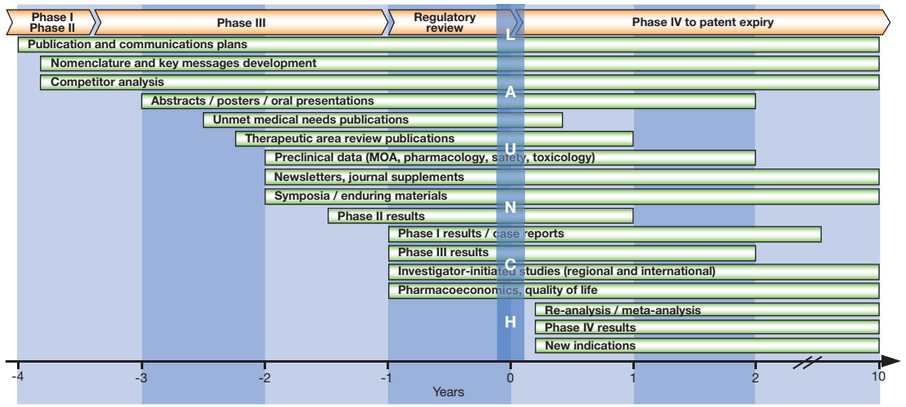


Table 1. Core steps involved in publication plan implementation.

Strategy development	Plan execution
• Therapeutic area knowledge	• Finalize publication plan - 'living/breathing document'
• Drug knowledge, including	• Review articles published
- Clinical development plan	• Preclinical and early phase clinical data (abstracts presented; manuscripts developed/published)
- Clinical data and study protocols	• Publication advisory board
- Analysis of existing publications	• Phase III clinical data (abstracts; manuscripts)
• Preliminary message development (target label)	• Reviews, monographs, additional studies/data, etc
• Competitive research	
• Congress research	
• Journal research	
• Investigator and author identification	
• Begin publication plan	

Variables leading to early execution

- Table 2 shows the factors that the Working Group considered could lead to early initiation of publication plan development.

Table 2. Potential reasons for executing publication plans early.

- First-in-class status
- Novel indication
- Long duration of clinical trials
- Multiple indications in simultaneous development
- A profundity of resources or budget
- Alliance or partnership situation
- Strategic decision to begin plan execution early
  - Crowded pharmacotherapeutic environment
  - Need to increase disease awareness
  - New therapy area for company
  - An educational need to communicate to physicians about a paradigm shift in a therapy area

- The potential factors listed in Table 2 include both clinical and economic factors.
- The clinical factors are first-in-class status, novel indication, long duration of clinical trials and situations in which there is an educational need to communicate to physicians about a paradigm shift in a therapy area. This latter point refers to the rare occasion where the introduction of a pharmacotherapeutic can radically change how a disease is treated or described.
- The economic factors are multiple indications in simultaneous development, a crowded pharmacotherapeutic environment, a need to increase disease awareness, a profundity of resources or budget, an alliance or partnership situation, and a new therapy area for the company.

Variables leading to later execution

- Table 3 shows the potential factors that the Working Group considered could lead to later than usual initiation of publication plan development.

Table 3. Potential reasons for executing publication plans late.

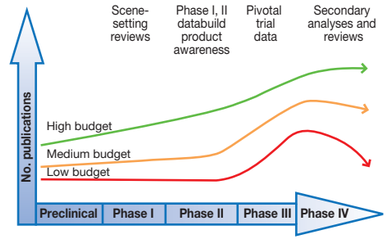
- Lack of resources or budget
- Late go/no-go decision
- Short clinical trial duration
- Strategic decision to begin plan execution late
  - Critical therapeutic need
  - Questions about the compound
  - A late alliance or partnership situation

- Again these include both clinical and economic factors.
- The clinical factors are a critical therapeutic need and short clinical trial duration. However, for the latter we would generally recommend following the typical timeline for strategy development although the publication plan execution may be delayed.
- The economic factors are lack of resources or budget, a late go/no-go decision, unresolved questions about the compound, and an alliance or partnership situation.

Effect of resources and budget on publication plan initiation

- As described above, the availability of resources or budget can affect when the publication plan development is initiated. Usually the availability of these corresponds to the anticipated revenue of the compound under development.
- Figure 2 shows the potential impact of budget on publication plan development.

Figure 2. The effect of budget on publication plan development.



Summary

- Typically publication plan development is initiated approximately 4 years before the launch of a compound.
- A number of clinical factors influence whether publication plan development is initiated earlier or later than usual.
- Economic factors can also influence the decision of when to start publication plan development.
- Gaining an understanding of the factors influencing publication plan development and execution, and applying this knowledge, is one of the many important requirements for publication planning professionals.

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