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

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ABSTRACT

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

Research Design and Methods: The approach to publication planning and development at one pharmaceutical company is described. A needs assessment was performed to gain knowledge about an industry publication plan. A subsequent publication planning process was developed more recently to specifically address the educational needs of a particular country or region.

Prioritization of publications within a publication plan

• The prioritization of publications is based on a number of factors, including
  – Manuscript/pathway
  – Gap analyses
  – Other factors

• 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.

Publications agencies

• Provided an example of information that should be captured from a needs assessment for a publication plan.

Conclusions

• A needs assessment is performed for the publication tactics on an individual publication plan.

• Needs assessments performed for the publication tactics on an individual publication plan should be documented:
  – Shire’s publication management tool (eg, PubIS, Publish) spreadsheet, or slide deck is some examples of how to document the completion of a needs assessment.

Table 1. Identified needs for publications

<table>
<thead>
<tr>
<th>Need</th>
<th>Key Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs assessment</td>
<td></td>
</tr>
<tr>
<td>State the source of information</td>
<td></td>
</tr>
<tr>
<td>for a publication or publication</td>
<td></td>
</tr>
<tr>
<td>tactic that may already be covered by a global plan to avoid duplication</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Sample needs assessment documentation

<table>
<thead>
<tr>
<th>Description</th>
<th>Type</th>
<th>Source of Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs assessment</td>
<td>needs assessment</td>
<td>cited in the body of the document or elsewhere</td>
</tr>
<tr>
<td>Source of information for a publication or publication tactic</td>
<td>needs assessment</td>
<td>documented within the body of the document or elsewhere</td>
</tr>
<tr>
<td>Needs assessment for a publication or publication tactic</td>
<td>needs assessment</td>
<td>documented within theSlide deck or elsewhere</td>
</tr>
</tbody>
</table>

Figure 1. Timeline of publication planning process

- By mid-year (approximately June/July), the PL will meet with the SPT to fully develop the publication plan for the following year.
- The SPT members, once the publication plan is finalized, will be informed of the completed plan.
- The publication plan will be updated as changes occur.
- The publication plan will be updated at least once or more per year if necessary.

- The Shire publication planning guidance document provides a practical approach to 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.
- Several of these CIAs include violations on their companion corporate compliance programs and procedures.
- In 2011, Shire completed a company-wide best practices publication guideline, which was presented at the 2011 International Society for Medical Publication Professionals (ISMPP) meeting.
- More recently, a new guideline 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, and to show that the tools for a scientific publication (Publication Plan (SPP)) can be developed.

Process

- Purpose of a publication plan
  - To ensure that the results of Shire studies are published in a timely manner, regardless of whether the outcome is positive, neutral, or negative.
  - The Shire Publication Lead (PL) and SPT will also consider unanswered scientific questions from other medical/clinical communications and publications that may be useful in answering those scientific questions.

Figure 1. Timeline of publication planning process

- Manuscript submissions to other journals, PL develops a preliminary publication plan (generally in Q1-Q2) (Figure 1)

Checklist

- Does the Shire publication planning guidance document provide a practical approach to the development of, and update processes for, a publication plan? Yes

- Does the Shire publication planning guidance document provide a practical approach to the development of, and update processes for, a publication plan? No

- Does the Shire publication planning guidance document provide a practical approach to the development of, and update processes for, a publication plan? Uncertain

- The Shire’s commitment to the development of, and update processes for, a publication plan is documented.

- The Shire’s commitment to the development of, and update processes for, a publication plan is not documented.

- The Shire’s commitment to the development of, and update processes for, a publication plan is uncertain.

References