Introduction

• Publication best practice guidance has been updated over the last few years, and has been helpful in evolving publication practice.1,2 Pharmaceutical companies and publishers have written publication guidelines and other standard operating procedures (SOPs) that reflect their publication best practices for publications.3

• Some companies also have government-mandated corporate integrity agreements (CIAs) with regulators that require them to properly fund publications.4

• Publication teams at Shire follow a company Scientific Disclosures SOP and R&D Shire also follows best publication practices outlined in the Good Publication Practice from 2008 (GPP2).5

• These company documents are useful for publication teams in providing high-level guidance, but lack the detail to guide day-to-day activities of publication teams.

Objectives

To create a Guidance Document that describes the process used by Clinical Development and Medical Affairs (CDMA) publication leaders and SOPs for the planning and drafting of scientific publications at Shire, and to ensure Shire’s interpretation of the GPP2 Guidelines for publication leaders and teams.

To include supplemental sections on topics not covered in GPP2.

Methods

• GPP2 guidelines, industry best practices, and Shire publication policy were considered in the writing of the Guidance Document (Figure 1).

• The Guidance Document was written by publication leaders, and vetted via a comprehensive internal review process (Figure 2).

• Peer review of draft followed by discussion with all publication leaders ensured consensus about best practices.

• Review by compliance and legal representatives provided input regarding company policies and SOPs, and how to implement in particular areas as such as author approval and consent for poster or podium presenters.

Results

• The comprehensive Guidance Document contains the sections described below. An abbreviated description of the guidance text is provided for each section.

Written author agreement

• Written author agreement should be executed so that authors and contributors to the publication have a mutual understanding as to their responsibilities and should take place in advance of the execution of the author agreement.

Figure 1. Writing process

Company SOPs
GPP, GJP, and other external guidance
Physician
Payment
Quality Assurance

Figure 2. Review process

GPP, Good Publication Practice version 2; ICMJE, International Committee of Medical Journal Editors; SOP, standard operating procedures.

Figure 3. Sample acknowledgement text for different types of publications

Primary or secondary manuscripts
Clinical research was funded by the sponsor, [company name]. Under the direction of the authors, [author name], [employee of [company name], provided writing assistance for this publication. [SOPs, standard operating procedures]. The preparation of this manuscript for scientific accuracy. [Company name] provided funding to support in writing and editing this paper. [Historical agency SOPs/policies should be archived.]

Primary or secondary posters or podium presentations
Clinical research was funded by the sponsor, [company name]. Under the direction of the authors, [author name], [employee of [company name], provided writing assistance for this publication. [SOPs, standard operating procedures]. The preparation of this manuscript for scientific accuracy. [Company name] provided funding to support in writing and editing this poster.

Company author disclosure

[Author name] is an employee of [agency name]. [Agency name] was funded by [company name] for research support in writing and editing this manuscript. [Agency name] provided writing assistance for this publication. [SOPs, standard operating procedures]. [Agency name] also reviewed and edited the manuscript and the final draft for [company name]. [Company name] funded the travel costs in [author name] for support in writing and editing this publication.

Company contract or consultant disclosure

[Author name] is a consultant for [company names]; is on the speakers’ bureau of [company name]; and was paid for a consultancy for [company name]. [Company name] provided writing assistance for this publication. [SOPs, standard operating procedures].

Figure 4. Sample disclosure statements

Company author disclosure

Company contract or consultant disclosure

Agency author disclosure

Disclosures/potential competing interests

• All authors, both internal and external to Shire, should disclose all potential competing interests to the journal at the time of initial manuscript submission, as noted in the authorship section.

• Disclosures should include, but are not limited to: employment, funding for research and/or promotional activities, and ownership of stock or stock options. The final level of disclosure is determined by the journal.

• Some sample disclosure statements are shown in Figure 4.

Author approval

• All authors, both internal and external to Shire, should acknowledge their contribution to the final version of all publications before the publications are considered final.

• The final version of each manuscript will be considered final when the authors have signed off on the final version of the manuscript. The author approval should be based on the final version of the project the translated into English for the local language of the publication. The author approval version will be the final version written into the local language or English.

Literature searches

• Documents related to the published literature (e.g. MEDLINE) are conducted by medical writers and/or authors in the process of identifying appropriate publications for the development of GPP2 publications.

• Search strategies and results are recorded as per the documentation section above, in order to document the rationale for the selection of articles and subsequent statements in the publication.

Agencies

• Agencies should follow the Shire Scientific Disclosures Policy, along with the Regulator’s Guidance Document on Scientific Disclosures SOP and the GPP2 Publication Guidance Document.

• Agencies should also have their own SOPs/policies for publication planning for the Shire agencies. These policies will supplement and not supersede Shire policies, and are created to provide additional agency processes for performing publication activities on behalf of Shire.

• Agency SOPs/policies must be followed in order for the publication to have an effective date.

• Historical agency SOPs/policies should be archived.

Review timelines

• Internal and external authors should, whenever possible, be given reasonable time to review manuscripts, and to provide comments either in writing or orally.

• Suggested review times for publication drafts:
  - Three business days for abstracts
  - Five business days for posters and podium presentations
  - Six to eight business days for manuscripts
  - Five business days for final sign-off of any publication
  - Five business days for abstracts or posters
  - Three business days for approval of manuscript peer-review comments (contingent on journal timeline)

Publication timelines and scope

• The timeframes shown in the example publication plan for the Trial Results in the Scientific Literature are followed.4

• The guidance text should be submitted for publication whenever possible within 12 months and no later than 18 months of the date of initial manuscript submission, as noted in the authorship section.

• The final version of the manuscript should be submitted for a manuscript peer-review comments (contingent on journal timeline). Publication for the Shire agencies should be submitted for approval by the journal for the final version.

Affiliate (LOC) publication projects

• Shire policies, SOPs, and the publications Guidance Document are all global in scope and apply to Shire local affiliates.

• It is the responsibility of the local affiliate to make local publications aware of the current CDMA Guidance Document and to assist and ensure compliance with the current document.

References


4. United States Department of Health and Human Services, Food and Drug Administration, Office of Communication, Research, and Medical Affairs. Clinical research was funded by the sponsor, [company name]. Under the direction of the authors, [author name], [employee of [company name], provided writing assistance for this publication. [SOPs, standard operating procedures]. The preparation of this manuscript for scientific accuracy. [Company name] provided funding to support in writing and editing this manuscript. [Company name] also reviewed the manuscript and edited the manuscript. [Company name] funded the travel costs in [author name] for support in writing and editing this publication.

5. Agency author disclosure

[Agency name] (Agency name) was funded by [company name] for research support in writing and editing this manuscript. [Agency name] also reviewed and edited the manuscript and the final draft for [company name]. [Company name] funded the travel costs in [author name] for support in writing and editing this publication.

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8. Journal Editor’s author disclosure

[Editor name] is an employee of [agency name]. [Agency name] was funded by [company name] for research support in writing and editing this manuscript. [Agency name] also reviewed and edited the manuscript and the final draft for [company name]. [Company name] funded the travel costs in [author name] for support in writing and editing this publication.

9. Identification of potential competing interests

• All authors should disclose any potential competing interests to the journal at the time of initial manuscript submission.

• Appropriate author disclosure should be included in the manuscript as provided by the corresponding author.

• Disclosures should include, but are not limited to: employment, funding for research and/or promotional activities, and ownership of stock or stock options. The final level of disclosure is determined by the journal.