Create a scientific publications Guidance Document to ensure continued awareness and compliance with industry best practices, regulations, guidances, and laws

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Objective: Provide guidance for publication leaders and teams to use for publication planning, processes and daily tactical operations. Supplement existing SOPs to include relevant provisions from GPP2 Guidelines, industry best practices, current laws and/or regulations, including industry government investigative trends. Provide additional guidance to publication leaders, teams, and agencies to continue to ensure consistency and compliance across publication teams.
Research design and methods: Publication department stakeholders and compliance and legal representatives provided guidance on relevant provisions of GPP2 Guidelines, regulations, and laws. US and ex-US departmental employees also provided feedback to ensure global applicability of the Guidance Document.
Results: A comprehensive Guidance Document was created and endorsed by key company stakeholders which included best practices provisions related to written authorship agreements, confidentiality agreements, author access to data, publication steering committees, authorship criteria and selection process, acknowledgments, disclosures and/or competing interests, author approvals, timelines, and local affiliate publication projects. Additionally, four written authorship agreement templates were created to cover various scenarios (agreements with external authors of primary and secondary publications, and of review publications; and agreements with internal authors). A standard consulting agreement template was also created for poster presenters.
Conclusion: A comprehensive Guidance Document provides publication team standardization and is an example of an effective proactive compliance measure to help companies continue to navigate through ever-changing industry guidances and regulations.

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 have written publication policies and standard operating procedures (SOPs) that reflect their publication best practice for publication teams.[3–5]
- Some companies also have government-mandated corporate integrity agreements relating to publication practice.[6]
- Publication teams at Shire follow a company Scientific Disclosures Policy, along with the Review and Approval of Scientific Disclosures R&D SOP. Shire also follows best publication practices as outlined in the Good Publication Practices version 2 (GPP2) Guidelines.[1]
- 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 teams for planning and daily tactical operations for scientific publications at Shire.
- To supplement and clarify 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 and SOPs 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 drafts followed by discussion with all publication leaders ensured consensus about best practice.
  - Review by compliance and legal representatives provided input regarding company policies and SOPs, and how to implement particularly in areas such as author agreements and consultant agreements for poster or podium presenters.

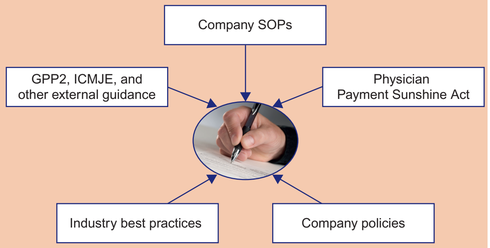
Results

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

Written author agreement

- A written author agreement should be executed so that authors and Shire know what is expected.
- A verbal or written communication with any prospective author should take place in advance of execution of the author agreement.

Figure 1. Writing process



GPP2, Good Publication Practice version 2; ICMJE, International Committee of Medical Journal Editors; SOPs, standard operating procedures.

- Authors are required to meet authorship criteria, as per Shire, GPP2, and International Committee of Medical Journal Editors (ICMJE) guidelines.[7]
- In accordance with GPP2, authors are advised that there is no payment for being an author and, to ensure transparency, full disclosure of competing interests is expected.
  - Authors are advised concerning provisions of the Physician Payment Sunshine Act.
- GPP2 recommends that written agreements should be executed at the earliest opportunity (e.g. when the protocol is finalized for primary publications or before work begins on other publications).
  - For practical purposes, Shire recommends that author agreements be sent out for execution within 3 months of the start of the study.
- Appendices have been created with sample author written agreements (including for internal company authors) for various publication types (primary publications, secondary publications and review articles).

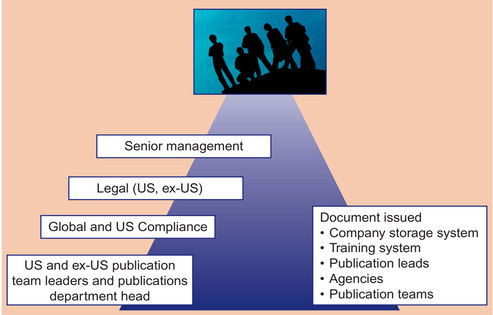
Confidentiality agreements

- Confidentiality agreements are to be completed and signed prior to providing any confidential information (such as clinical trial documents) and/or information to authors.

Author access to data and data sources

- Authors should be provided with full access to study data before the writing process begins.
  - Study documents (including protocols, statistical analysis plans, clinical study reports [CSRs], and final tables, figures, and listings) are typically used as data sources for publications.
- Sufficient time should be allowed for authors and contributors to review and interpret the data.
- For purposes of review, in the case of non-English language data, all original data sources are translated into English.

Figure 2. Review process



Reimbursement

- Shire may reimburse presenters for reasonable travel expenses related to presentation of Shire data at scientific congresses.
- A sample consulting agreement and logistics letter outlines the scope of reasonable expenses.
- Authors are not paid for their authorship, nor are they paid for time out of the office (e.g. honoraria) to present at scientific congresses.

Publications Steering Committee

- Shire complies with recommendations in GPP2 regarding the use of a steering committee to oversee and produce publications from larger studies.
- Shire recommends that a steering committee be formed within 3 months of the start of the study, in accordance with the recommendation for early steering committee development in GPP2.
- The Guidance Document contains a sample steering committee written agreement.
- The Publications Steering Committee is a small working group that may comprise the following, as appropriate:
  - the study principal investigator
  - other selected clinical investigators or individuals who have expertise in the area
  - the publications lead from Shire
  - Shire CDMA Medical Director for the study
  - other company employees or contractors, including, but not limited to, clinicians and biostatisticians.
- The Publications Steering Committee may:
  - propose a publication plan for each individual study (e.g. congress presentations and manuscript planning)
  - commit to publishing the key primary and secondary results of the trial in an objective and timely manner
  - propose additional publications to meet educational needs in the therapeutic area
  - based on robust medical hypotheses, identify and publish sub-analyses or exploratory endpoints that would be of interest to the scientific/medical community.

Authorship criteria

- The term "author" has been defined by the ICMJE.[7]
- As noted in GPP2, authorship criteria are applied to all authors, regardless of affiliation (external author, Shire author, medical communications writer/medical director).
- Contributors not meeting full authorship criteria are acknowledged.
- Roles of the lead author and guarantor are described as in GPP2.

Authorship selection process

- Authors must meet the Shire/ICMJE criteria, as noted in the above *Authorship criteria* section.[7]
- Determination of authors for publications from Shire studies is based on a number of criteria. These include, but are not limited to:
  - principal investigator of the study (will typically be lead author of the publication)
  - participation in the study design
  - investigator in the study who has a significant interest in presenting and publishing the data
  - nomination from the Publication Steering Committee, if applicable
  - a subject matter expert for a specific secondary or *post hoc* analysis.
- Authors for review articles should generally include those who have publications experience in the given topic and therapeutic area, as documented by literature searches.
- Authors should not be restricted from conducting research by their local governments. Websites to check author debarment were referenced.

Acknowledgments

- The list of acknowledgments ensures transparency regarding any contribution to the publication beyond authorship. All contributors to manuscript development are acknowledged in accordance with the GPP2 guidelines.
- Sample acknowledgment text for different types of publications is listed in Figure 3. The exact acknowledgment text in a publication may vary based on journal or congress requirements. Sample text is included for acknowledging Shire review and editing, to be added at the publication leader's discretion when appropriate, based on substantial contributions.

Figure 3. Sample acknowledgment 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, [writer name(s)], employees of [agency name], provided writing assistance for this publication. Editorial assistance in formatting, proofreading, copy editing, and fact checking was also provided by [agency name]. [Name(s)] from [company name] also reviewed and edited the manuscript for scientific accuracy. [Company name] provided funding to [agency name] for support in writing and editing this manuscript. Although the sponsor was involved in the design, collection, analysis, interpretation, and fact checking of information, the content of this manuscript, the ultimate interpretation, and the decision to submit it for publication in [journal name] was made by the authors independently.

Primary or secondary posters or podium presentations*
Clinical research was funded by the sponsor, [company name]. Under the direction of the authors, [writer name(s)], employees of [agency name], provided writing assistance for this publication. Editorial assistance in formatting, proofreading, copy editing, and fact checking was also provided by [agency name]. [Name(s)] from [company name] also reviewed and edited the manuscript for scientific accuracy. [Company name] provided funding to [agency name] for support in writing and editing this poster.

Review manuscripts or review posters
[Company name] provided funding to [agency name] for support in writing and editing this manuscript. (If the medical writer is not an author, include: Under the direction of the authors, [writer name(s)], employee(s) of [agency name], provided writing assistance for this publication.) Editorial assistance in formatting, proofreading, copy editing, and fact checking was also provided by [agency name]. [Name(s)] from [company name] also reviewed and edited the manuscript for scientific accuracy. Although [company name] was involved in the topic concept and fact checking of information, the content of this manuscript, the ultimate interpretation, and the decision to submit it for publication in [journal name] was made by the authors independently.

*Podium presentation disclosure can be made along with other author disclosures or acknowledgments.

Figure 4. Sample disclosure statements

Company author disclosure
[Author] is an employee of [company name] and holds stock [and/or] stock options in [company name].

Company contractor or consultant disclosure
[Author] is a contractor (or consultant) for [company name].

External author disclosure
[Author name] is a consultant for [company names]; is on the speakers' bureau of [company names]; has received grant/research support from [company names]; and holds stock in [company names].

Agency author disclosure
[Author name] is an employee of [agency name]. [Agency name] was funded by [company name] for support in writing and editing this manuscript.

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 the initial manuscript submission, and in poster and podium presentations.
  - 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 journal policy.
- Some sample disclosure statements are shown in Figure 4.

Documentation

- Subject matter noted in GPP2 (such as author agreements, reviews of publication drafts, literature searches, and approval of final publications) should be maintained by Shire and agencies in an electronic or hard copy repository designated for the storage of publications.

Checklist

- The GPP2 checklist for articles and presentations should be completed for all posters, podium presentations, and manuscripts.

Author approval

- As per ICMJE criteria, authors must agree to the final version of all publications before the publications are considered final.
- In the case of non-English language publication projects, Shire approval should be given based on the final version of the project translated into English, and in the local language if possible. The author approves the final version written in the language of the final publication. In the case of an encore publication, the author may approve a translated version of the final publication into their local language or English.

Literature searches

- Organized searches of the published literature (e.g. MEDLINE) are conducted by medical writers and/or authors in the process of identifying appropriate authors for reviews, and preparing for and writing publications.
- Search strategies and results are retained 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 follow the Shire Scientific Disclosures Policy, along with the Review and Approval of Scientific Disclosures SOP, and the CDMA Publications Guidance Document.
- Agencies should also have their own SOPs/policies for publication planning for the Shire accounts. These policies will supplement and not supersede Shire policies, and are created to provide details on internal agency processes for performing publication activities on behalf of Shire.
  - Agency SOPs/policies must be version controlled and 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 publication drafts.
- Suggested review times for publication drafts:
  - three business days for abstracts
  - five business days for posters and podium presentations
  - seven business days for manuscripts.
- Suggested review times for final sign-off of any publication:
  - ten business days for all original publications
  - five business days for encore abstracts or posters
  - three business days for approval of manuscript peer-reviewer comments (contingent on journal timelines).

Publication timelines and scope

- The Joint Position on the Publication of Clinical Trial Results in the Scientific Literature is followed.[8]
- Manuscripts reporting clinical studies should be submitted for publication whenever possible within 12 months and no later than 18 months of:
  - the completion of clinical trials (in the case of already marketed products)
  - the regulatory approval of the new product in a major market (in the case of investigational products)
  - the decision to discontinue development (in the case of investigational products).

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 publications leader to make local affiliates aware of the current CDMA Guidance Document and to assist the local affiliate in complying with the current document.

References

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3. Dowsett SA, Van Campen LE, Bednar LA. Developing good scientific publishing practices: one pharmaceutical company's perspective. *Curr Med Res Opin* 2010;26(6):1249–54.
4. Merck Guidelines for Publication of Clinical Trials and Related Works. Available from http://www.merck.com/research/discovery-and-development/clinical-development/Merck-Guidelines-for-Publication-of-Clinical-Trials-and-Related-Works.pdf (Accessed 11 February 2011).
5. Pfizer Public Disclosure and Authorship. Available from http://www.pfizer.com/research/research_clinical_trials/registration_disclosure_authorship.jsp (Accessed 11 February 2011).
6. Corporate Integrity Agreements Document List. Available from http://oig.hhs.gov/fraud/cia/cia_list.asp#p (Accessed 11 February 2011).
7. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. Available from www.icmje.org (Accessed 11 February 2011).
8. Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. Available from http://www.ifpma.org/fileadmin/webnews/2010/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf (Accessed 11 February 2011).

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