# Policy on Development of Publications

## Background

Professional medical writers play an important role in publication development, and the profession has developed in response to the need for high-quality, timely publications. Time pressure on clinicians and researchers means that they cannot always prioritise publication development, and they may request medical writing or editorial support.

In the past, editors of medical journals have expressed unease about the role of professional medical writers in the development of publications. To maintain legitimacy of the profession, and to ensure quality and reliability of publications, it is important that medical writers follow recognised guidelines. Prime Global has, therefore, developed a well-defined procedure for our writers when working with authors on manuscripts.

There are several established guidelines for the development of peer-reviewed publications, including the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE)[1] and Consolidated Standards of Reporting Trials (CONSORT) developed specifically for publication of randomised clinical trials.[2] Many journals also have their own requirements. In addition, Good Publication Practice (GPP) guidelines were first published in 2003 to provide standards for the ethical and responsible communication of industry-sponsored research. As reporting requirements for medical research evolved, the guidelines were subsequently updated in 2009,[3] and again in 2015.[4] The GPP3 recommendations on authorship, contributorship, sponsorship, and the role of professional medical writers were designed to ensure publication integrity, transparency, accountability and responsibility. Additionally, the American Medical Writers Association (AMWA) has developed a code of ethics for medical writers.[5] The AMWA position statement concurs with similar statements, including ICMJE[1] and the Pharmaceutical Research and Manufacturers of America (PhRMA).[6] The European Medical Writers Association (EMWA) has developed clear and concise guidelines to ensure the legitimacy and integrity of the medical writing profession.[7]

Prime Global has developed a policy in keeping with these guidelines. In addition, we recognise that many of our clients have their own policies and such policies will be cross-referenced with our own policy and ensure that any differences are understood and, where necessary, resolved.

## Publication of Clinical Trials

In principle, all clinical trials should be published regardless of outcome. In addition, study identifiers should be used in every publication to ensure complete transparency in the reporting of clinical data. Prime Global aims to ensure that publication content is accurate, objective, well balanced and scientifically valid.

## Authorship and Acknowledgement of Medical Writers

Many journals have endorsed the Uniform Requirements,[1] which provide recommendation on how to determine who qualifies as an author, based on:

- substantial contribution to conception and design, acquisition of data, or analysis and interpretation of data; and
- drafting the article or revising it critically for important intellectual content; and
- final approval of the version to be published; and
- agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

To be listed as an author, an individual must fulfil all four criteria. Journals may also ask that an author is identified that will act as a ‘guarantor’, taking responsibility for the integrity of the whole work, from inception to publication, and acknowledge this information in the publication.

ICMJE and GPP3 state that all contributors to an article who do not qualify for authorship should appear by name in the Acknowledgements section. This includes anyone providing medical writing or editorial support, and their funding source.

Prime Medical Group’s recommended wording for the acknowledgement of medical writers is:

*Medical writing support was provided by [lead writer] at [state business organisation name within Prime Global] during the preparation of this paper, supported by [name of client company]. Responsibility for opinions, conclusions and interpretation of data lies with the authors.*

Clients may have their own preferred wording; this can be used PROVIDING it is at least as transparent as above.

## Medical Writer role

It is essential that authors are fully involved in the whole course of publication development, with the opportunity to make a substantial contribution at each stage. It is not acceptable to send an author a completed first draft for minor revisions and comments.

The medical writer is the facilitator in developing a manuscript but the named author(s) is/are responsible for the content. The named author(s) always have the final say on content.

Both the named author(s) and the medical writer must have full access to relevant study data, i.e. clinical trial report or statistical tables before starting work on the publication. Authors should never be expected to comment on a publication without access to the data and schedules must permit adequate time for authors to fully analyse the data and interpret their findings.

The medical writer will only work with approved data, supplied by the client or by the author(s), and published literature. Prime Global has adopted the following procedure for publication development:

1. Contact the lead author before starting an article. Discuss the overall focus of the article, its scientific objective and target journal.
2. Follow-up with a more detailed description of the intended article for his/her review and comment. The author should be encouraged to make a significant contribution at this stage, and the specification revised to reflect this feedback.
3. Discuss how to proceed next. Some authors may wish to write the article themselves, while others may require writing assistance.

4. Secondary authors, if not included in the original discussion should be contacted at this stage, explaining that the principal author has already agreed to participate with the agreed specification and process.

5. Assuming that the author would like writing assistance, an outline of the article should be produced, outlining in bullet point format the main points of the article and suggested figures and tables and appropriate references.

6. The lead author should be encouraged to comment extensively on the outline and asked to add his/her interpretation of the data based on clinical experience and knowledge of the literature. The author should comment on any journal suggestions and make the final recommendation.

7. A revised outline incorporating the input of the lead author will then be sent to the secondary authors. All authors must make a sufficient contribution to the work to meet authorship criteria and to take public responsibility for its content.

8. Once the outline has been agreed with all authors, writing of the full first draft will commence, assuming that the authors require writing assistance.

9. Review of the full draft will follow the same steps as for the outline.

10. All authors must provide written approval of the article before it is submitted for publication by the lead author. Prime Global may directly liaise with the journal if this is the preference of the lead author. The lead author should remain the primary point of contact with the journal.

11. Throughout the development and submission of the publication, we will ensure complete documentation of all author, client and journal/secretariat correspondence.

## Medical Writers' Professional and Ethical Responsibilities

Medical writers should maintain awareness of all relevant guidelines for the publications they are producing and are responsible for advising clients, colleagues and named authors if these guidelines are not being followed.

**Bibliography**


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