

The Prime Medical Group

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. The Prime Medical Group 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, first published in 2003 and subsequently updated in 2009,³ have been developed to provide standards for the ethical and responsible communication of industry-sponsored research. The GPP2 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.⁴ The AMWA position statement concurs with similar statements, including those from ICMJE¹ and the Pharmaceutical Research and Manufacturers of America (PhRMA).⁵ The European Medical Writers Association (EMWA) has also developed clear and concise guidelines to ensure the legitimacy and integrity of the medical writing profession.⁶

The Prime Medical Group 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 to ensure that any differences are understood and, where necessary, resolved.

Publication of clinical trials

The Prime Medical Group aims to ensure that publication content is accurate, objective, well balanced and scientifically valid. 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. Likewise, potential conflicts of interest should be disclosed.

Authorship and acknowledgement of medical writers

Many journals have endorsed the Uniform Requirements,¹ which provide recommendations 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.

To be listed as an author, an individual must fulfil all three 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.

ICMJE¹ and GPP2³ 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 should be provided.

Medical writer role

It is essential that authors are fully involved in the whole course of publication development. If medical writing support is required, the medical writer acts as a facilitator in developing a publication but the author(s) is/are responsible for and have the final say on the content. Authors must critically review and provide comments on the outline and drafts of the publication, making a substantial contribution at each stage. Schedules for manuscript development must permit adequate time for authors to analyse the data and interpret their findings.

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 authors if these guidelines are not being followed.

Bibliography

1. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. <http://www.icmje.org> [accessed 1 December 2011].
2. CONSORT statement. <http://www.consort-statement.org> [accessed 1 December 2011].
3. Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM, et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ*. 2009;339:b4330 doi: 10.1136/bmj.b4330. Also available from <http://www.gpp-guidelines.org>
4. American Medical Writers Association. Position Statement and Code of Ethics. <http://www.amwa.org> [accessed 1 December 2011].
5. Pharmaceutical Research and Manufacturers of America. Updated principles for conduct of clinical trials and communication of clinical trial results. http://www.phrma.org/sites/default/files/105/042009_clinical_trial_principles_final.pdf [accessed 1 December 2011].
6. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin*. 2005;21:317–321. Also available from <http://www.emwa.org/Mum/EMWAguidelines.pdf> [accessed 1 December 2011].