OXFORD PharmaGenesis™
The HealthScience Communicators

Ethical, accurate and timely publications

The Oxford PharmaGenesis publication policy

Background

- Effective communication of clinical research is important for advancing patient care. We believe that professional medical writing support can help to ensure ethical,[1] accurate[2-5] and timely[6] publication of research, whether supported by industry, academia or other bodies.[7]
- Our research with independent investigators has shown that professional medical writing support improves the reporting of clinical trials in peer-reviewed journals in terms of both compliance with reporting guidelines and the quality of writing.[3,8]
- When assisting authors with communication of the results of company-sponsored research, we will aim to:
  - follow the Joint Position Statement on the role of professional medical writers,[9] Good Publication Practice 3 (GPP3) guidelines[10] and International Committee of Medical Journal Editors (ICMJE) recommendations[11]
  - consult appropriate reporting guidelines (e.g. CONSORT[12] and others collated by the EQUATOR Network)[13]
  - ensure that the authors and sponsors are aware of their obligations under these guidelines[10-14]
  - keep up to date with advances in medical communications ethics and best practices.
- In line with the above guidelines and our company Conceptual Framework, the aim of the Oxford PharmaGenesis publication policy is to provide clear ethical guidance on our involvement in the preparation of:
  - articles and supplementary content for publication in peer-reviewed journals
  - abstracts, posters and oral presentations for scientific and medical congresses.

Acknowledging medical writing support

- Medical writing support will be acknowledged in manuscripts and congress presentations, including the:
  - nature of the support
  - name of the lead writer(s) involved and their highest relevant qualification(s) and, if appropriate, Certified Medical Publication Professional credentials
  - writers' affiliation with Oxford PharmaGenesis
  - source(s) of funding.
- We encourage transparency of contributions to publications through the use of tools such as the Open Researcher and Contributor ID (ORCID).[15]
- A draft acknowledgement statement is provided below, although the final version may be subject to specific journal/meeting or client requirements.

  The authors thank [name, ORCID identifier and qualifications] of Oxford PharmaGenesis [PharmaGenesis office name, city, country] for providing medical writing support funded by [sponsor name], in accordance with Good Publication Practice 3 (GPP3) guidelines (http://www.ismpp.org/gpp3).[10]

Acknowledging the contribution of patients

- The unique contribution of patients involved in clinical research will be acknowledged in manuscripts and congress presentations.[16,17]
- A draft acknowledgement statement is provided below, although the final version may be subject to specific journal/meeting or client requirements.

  "We thank all the patients [and their families] who kindly participated in this study."

Authorship

- In accordance with the ICMJE guidelines,[11] to qualify for authorship, contributors should meet all four of the following criteria:
  - making substantial contribution to the conception or design of the work, or to the acquisition, analysis or interpretation of data for the work
  - drafting or critically revising work for important intellectual content
  - giving final approval of the version to be published
  - taking accountability 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.
- ICMJE guidelines[11] state that authors should make a "substantial intellectual contribution" to the research and manuscript, therefore we encourage the use of "*on behalf of the [number of] study investigators*" when groups of more than 10 investigators are involved (as highlighted in GPP3).[10]
  - Exceptions may include clinical practice guidelines, expert consensus statements and meeting proceedings.
- In some circumstances, a professional medical writer may qualify for authorship.[18] When appropriate, this will be raised with the other authors as early as possible. Examples of such circumstances include:
  - writing of systematic reviews when the medical writer has also taken the lead in designing the review (e.g. development of search terms and inclusion/exclusion criteria plus conduct of the searches)
  - writing of primary manuscripts when the medical writer has also made a significant contribution to the conception or design of the study, or to the acquisition, analysis or interpretation of study data.

Accessibility

- To maximize the accessibility of published research, we recommend:
  - including clinical trials registration numbers in published abstracts for the purposes of indexing and disclosure tracking[19]
  - publishing in journals that enable their content to be made freely accessible, either immediately or after a delay of no more than 6 months
  - publishing in journals that are indexed in MEDLINE/ PubMed and/or Embase.

Above all, we aim to deliver the highest quality medical writing and project management support to provide the most value to our clients, healthcare professionals and patients.

References

1. Woolley KL, Lew RA, Stretton S *et al.* Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. *Curr Med Res Opin* 2011;27:1175–82.
2. Jacobs A. Adherence to the CONSORT guideline in papers written by professional medical writers. *The Write Stuff* 2010;19:196–9.
3. Gattrell WT, Hopewell S, Young K *et al.* Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. *BMJ Open* 2016;6:e010329.
4. Gattrell W, Maisonobe P, de Abada M. Outcome reporting, funding source and medical writing support in publications evaluated in the COMPare project. *Curr Med Res Opin* 2017;33(Suppl 1):27 [poster 9].
5. Mills I, Sheard C, Hays M *et al.* Professional medical writing support (PMWS) and the reporting quality of randomized controlled trial (RCT) abstracts among high-impact general medical journals. *Curr Med Res Opin* 2017;33(Suppl 1):18 [poster 7]. Available from: http://preview.parexel-mms.com/ISMPP-US-2017/index2.aspx (Accessed 2 May 2017).
6. Shah S, Nair S, Patil A *et al.* Role of medical publication professional in timely dissemination and transparent reporting of clinical data. *Curr Med Res Opin* 2016;32:S12 [poster 27].
7. Hamilton CW, Gertel A, Jacobs A *et al.* Mythbusting Medical Writing: Goodbye, Ghosts! Hello, Help! *Account Res* 2016;23:178–94.
8. Evuarherhe O, Gattrell W, White R, Winchester CC. Association between professional medical writing support and the quality, ethics and timeliness of clinical trial reporting: a systematic review [Poster]. Presented at the 2018 European Meeting of the International Society for Medical Publication Professionals (ISMPP), London, UK.
9. AMWA, EMWA, ISMPP. AMWA–EMWA–ISMPP Joint Position Statement on the role of professional medical writers, 2017. Available from: http://www.ismpp.org/assets/docs/Initiatives/amwa-emwa-ismpp%20joint%20position%20statement%20on%20the%20role%20of%20professional%20medical%20writers_january%202017.pdf (Accessed 24 January 2017).
10. Battisti WP, Wager E, Baltzer L *et al.* Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med* 2015;163:461–4.
11. ICMJE. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals Boston, USA: International Committee of Medical Journal Editors, 2017. Available from: http://www.icmje.org/icmje-recommendations.pdf (Accessed 21 Mar 2017).
12. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c332.
13. Network E. Enhancing the quality and transparency of health research Oxford, UK: Centre for Statistics in Medicine, University of Oxford, 2016. Available from: http://www.equator-network.org/ (Accessed 03 July 2017).
14. Clark J, Gonzalez J, Mansi B *et al.* Enhancing transparency and efficiency in reporting industry-sponsored clinical research: report from the Medical Publishing Insights and Practices initiative. *Int J Clin Pract* 2010;64:1028–33.
15. ORCID. Open researcher and contributor ID (ORCID) Bethesda, USA: ORCID 2017. Available from: https://orcid.org/ (Accessed 04 July 2017).
16. Rivero-Arias O. Is a simple "Thank you" too much to ask? *BMJ* 2009;339:b3683.
17. Bhatia R, Anthony B. Clinical trials: do the patients get the thanks they deserve? *Curr Med Res Opin* 2015;31(Suppl 9):S19 [poster 5].
18. Gristwood T, Farrow P, Hill C *et al.* When should medical writers be listed as authors? *Curr Med Res Opin* 2014;30 (Suppl 1):S22 [poster 29].
19. Powell-Smith A, Goldacre B. The TrialsTracker: automated ongoing monitoring of failure to share clinical trial results by all major companies and research institutions. F1000Res 2016;5:2629.

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