Costello Medical Publications Policy

2019

Costello Medical
50/60 Station Road
Cambridge, CB1 2JH, United Kingdom
+44 (0) 1223 913 020
www.costellomedical.com

Costello Medical Publications Policy

Costello Medical supports the development of a range of publications for the pharmaceutical and healthcare industries, including manuscripts, abstracts and congress presentations. In addition to providing medical writing support and scientific expertise, we maintain close involvement throughout the publication process – from strategic guidance at project conception, to submission of the finished product and support at international congresses.

Costello Medical is committed to developing scientific publications of the highest quality, integrity and transparency. In order to achieve this, we have developed a publications policy summarising our minimum publication standards, which we have closely aligned to the 2017 AMWA-EMWA-ISMPP joint position statement on the role of professional medical writers.[1]

Publication Development – the Role of Costello Medical

To ensure all publications meet the highest levels of quality, integrity and transparency, Costello Medical will adhere to the following:

1. All publications will be developed in accordance with Good Publication Practice (GPP3) guidelines.[2]
2. Costello Medical will support the use of the International Committee of Medical Journal Editors (ICMJE) recommendations to define eligibility for authorship.[3] According to the ICMJE, authors must meet all four of the following criteria:
    a. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
    b. Drafting the work or revising it critically for important intellectual content; AND
    c. Final approval of the version to be published; AND
    d. 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.

Any contributor not meeting the ICJME criteria will be recognised in the publication's acknowledgements.

3. When planning publication timelines, Costello Medical will ensure that adequate time is allocated to author review and approval steps.
4. All publications will be developed in accordance with the appropriate reporting guidelines (all guidelines are available on the **E**nhancing the **QUA**lity and **T**ransparency **O**f health **R**esearch [EQUATOR] Network website),[4] e.g. CONSORT for randomised controlled trials.
    a. Costello Medical will ensure that all authors and sponsors understand these guidelines and are aware of their obligations.
5. Where relevant, all publications will state clinical trial identifiers (e.g. National Clinical Trial [NCT] numbers) and include references to primary publications.

Industry-sponsored or -funded conference abstracts and presentations will be developed in accordance with Good Practice for Conference Abstracts and Presentations (GPCAP) recommendations,[5] and Costello Medical will support authors in aligning their presentations to both these recommendations and individual conference requirements.

Staff Training and Development

Costello Medical believes that staff training and development are central to ensuring all publications meet industry standards.

1. All members of our Publications division have a good knowledge of the GPP3 guidelines, ICMJE authorship criteria and relevant reporting guidelines. The Publications division provides advice and support for publications developed by project teams based in other specialist divisions.
2. Through attendance at relevant conferences, external training, and internal training by our ISMPP Certified Medical Publication Professional™ (CMPP™) certified senior team, all members of Costello Medical's Publications division are encouraged to actively keep up to date with any advances in medical communications ethics and best practices.
3. This knowledge is disseminated internally to ensure that all Costello Medical employees involved in publication development are aligned on standard operating procedures.

Publication Development – the Role of Study Sponsors and Authors

Costello Medical will work closely with authors and study sponsors to ensure all publications meet industry standards. To achieve this, study sponsors and authors are expected to:

1. Ensure all authors have full access to all relevant information, including study data, protocols, statistical analysis plans, statistical analyses and clinical study reports.
2. Ensure that secondary publications avoid redundancy and that data from the same study are not split across multiple publications without appropriate justification.
3. Provide intellectual input from authors before writing commences and throughout content development.
4. Ensure that the final text fully reflects the views of, and is approved by, all authors.
5. Confirm the appropriateness of the final choice of journal or congress.
6. Acknowledge the provision of medical writing support, including the nature of the support, and the name, highest relevant qualifications and affiliation of the professional medical writer accountable for the support provided.
7. Acknowledge the funding sources for the provision of medical writing support.
8. Include a data sharing statement in all publications reporting results from clinical trials, as described in the 2017 ICMJE recommendations.[6]
9. Recognise as co-authors all contributors (including professional medical writers) who meet the ICMJE authorship criteria.

Example Acknowledgements Statement:

"The authors thank [name and qualifications] of [company, city, country] for providing medical writing support/editorial support [specify and/or expand as appropriate], which was funded by [sponsor, city, country] in accordance with Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3)."

Should you have any queries regarding Costello Medical's scientific publications policy, please contact Danielle Sheard (Head of Publications): danielle.sheard@costellomedical.com.

References

1. AMWA-EMWA-ISMPP joint position statement on the role of professional medical writers. Released January 2017. Accessed at http://journal.emwa.org/writing-better/amwa-emwa-ismpp-joint-position-statement-on-the-role-of-professional-medical-writers/ on 16th July 2019.
2. Battisti WP, Wager E, Baltzer L, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Annals of Internal Medicine 2015;163(6):461-464.

3. International Committee of Medical Journal Editors. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. Updated December 2018. Accessed at http://www.icmje.org/recommendations/ on 16th July 2019.

4. Enhancing the QUAlity and Transparency Of health Research [EQUATOR] Network. Accessed at https://www.equator-network.org/reporting-guidelines/ on 16th July 2019.

5. Foster C, Wager E, Marchington J, et al. Good practice for conference abstracts and presentations: GPCAP. Research Integrity and Peer Review 2019;4(1):11.

6. Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials – a requirement of the International Committee of Medical Journal Editors. New England Journal of Medicine 2017;376(23):2277-2279.

