

Costello Medical Publications Policy

2022



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Costello Medical Publications Policy

Costello Medical supports the development of a range of publications for the pharmaceutical and healthcare industries, including manuscripts, abstracts, congress presentations and enhanced publication content. 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 and publication 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 [AMWA-EMWA-ISMP 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 \(GPP\) 2022 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 reviewing 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 ICMJE criteria will be recognised in the publication's acknowledgements. For example, contributors who do not make a substantial intellectual contribution to the development of the publication by providing comments on at least one draft of the publication are not fulfilling their responsibilities as authors, and their contribution to the work will be recognised in the acknowledgements section, rather than as authors.

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 **Enhancing the QUALity and Transparency Of health Research [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. 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.
6. All intellectual property and copyright laws will be respected.
7. Costello Medical will ensure that all correspondence with authors, clients and journals is documented accurately and completely, using publication management software as per our client's policies.

8. Costello Medical will ensure that clients and authors are aware of and understand their obligations related to industry standards and best practice guidelines, as described above. Costello Medical will be responsible for advising clients and authors should there be any deviation from these guidelines.

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 excellent knowledge of [GPP 2022](#) guidelines, ICMJE authorship criteria and other 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 protocols, statistical analysis plans, statistical analyses, clinical study reports and study data to enable them to take full accountability for the accuracy and integrity of the work.
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, including the development of a publication outline before a Medical Writer assists with publication 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, while considering that a plain language summary should be prepared for any clinical trial publication and ideally all biomedical publications.
6. Involve patients in publication planning and development so that they are eligible to qualify as authors on the proposed publications, as appropriate.
7. 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.
8. Acknowledge the funding sources for the provision of medical writing support.
9. Disclose potential conflicts of interest in all publications and presentations, in accordance with journal/congress guidelines.
10. Include a data sharing statement in all publications reporting results from clinical trials, as described in the [2017 ICMJE recommendations](#).⁶
11. 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 (GPP) 2022 guidelines (<https://www.ismpp.org/gpp-2022>)."

Costello Medical Authorship Policy

As stated above, Costello Medical support the use of the International Committee of Medical Journal Editors (ICMJE) recommendations to define eligibility for authorship.³ As such, Medical Writers usually do not qualify for authorship of a publication and their role should instead be acknowledged. However, in situations where employees of Costello Medical do make a substantial contribution to a work (i.e. fulfil Criterion 1, for example through the design and development of a systematic literature review, economic model, statistical analysis or real-world study) which results in a publication, those employees should be offered authorship, provided they subsequently fulfil Criteria 2, 3 and 4.

In this situation, Costello Medical may still receive payment for the provision of medical writing services, which may include drafting of the publication. However, no direct payment (i.e. direct payment to that individual from the client) for activities associated with authorship will be made, and that individual will not receive any additional payment for authorship above their salaried employment with Costello Medical. The positioning of Costello Medical authors within the overall authorship order should be reflective of their contributions to the work, where the first and last authors represent the most significant contributions.

In the event that several Costello Medical employees fulfil the first criterion of the ICMJE criteria and there is a need to restrict the number of authors to adhere to journal requirements or client publication policies, the individuals (usually no more than 3) with the highest contributions to the project will be selected as authors for the subsequent publication.

Should you have any queries regarding Costello Medical's scientific publications policy, please contact Helen Chambers (UK Head of Publications): helen.chambers@costellomedical.com.

References

1. AMWA-EMWA-ISMP 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.
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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.