

Development and communication of the AMWA-EMWA-ISMPPP Joint Position Statement on the role of professional medical writers

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A CLEAR OBJECTIVE

- Evidence of the value of professional medical writing support is increasing, and various guidelines on the role of medical writers now exist.¹ Our aim was to develop a unified set of concise, practical, evidence-based guidelines for responsible medical and scientific writing and authoring. Our intent is that this document will serve as a reference for professionals engaged in the generation of medical/scientific publications.

The Joint Position Statement describes, for the first time, a global standard for professional medical writers.

A COLLABORATIVE PROCESS

- A Writing Committee was established that consisted of four members from three leading professional organizations, representing more than 6500 medical communicators around the world. The Committee consisted of members from the:
 - American Medical Writers Association (AMWA)
 - European Medical Writers Association (EMWA)
 - International Society for Medical Publication Professionals (ISMPPP)
- The Writing Committee agreed on the scope, development process and timelines of the Joint Position Statement.
- The Joint Position Statement was reviewed by representatives of AMWA, EMWA and ISMPPP who were appointed by the relevant Executive Committee or Board of Trustees and were located in Europe, North America and Asia.
- A broader Joint Outreach Committee was established to coordinate and deliver a multi-channel communications strategy focusing on key activities and online media platforms run by AMWA, EMWA and ISMPPP.
- The Joint Position Statement was launched at the European Meeting of ISMPPP on 17 January 2017. It has also been presented at the EMWA conference in May and an AMWA webinar, and published in a peer-reviewed journal with an associated commentary.^{2,3}

LESSONS LEARNED

Keep it short and sweet
By keeping a tight focus on the intended scope of the Joint Position Statement, the Writing Committee was able to finalize the statement within just 4 months and create something that could be translated quickly and easily.

Do not reinvent the wheel
Individual position statements from each organization were already published and contained the principal elements used to construct the Joint Position Statement. Drawing on and referencing these and other existing statements/guidelines ensured acceptance from the organizations concerned.

Host it on a single dedicated webpage
To make the Joint Position Statement easy to find, and to ensure that communication metrics can be monitored accurately in future, the Joint Position Statement and subsequent versions will be hosted on a central webpage; separate organizational communications will refer directly to this central webpage.

Form a core team of multi-organization representatives
Representatives should be involved in the process from the start to ensure clarity and unity of the goal and strategy. Involving representatives from three leading professional organizations in the development of the Joint Position Statement was beneficial for the overall project; it facilitated rapid approval and allowed multiple opportunities to communicate the Joint Position Statement globally throughout the year following its launch in January 2017.

Plan your communication strategy well in advance
The success of the Joint Position Statement relied on a team of dedicated volunteers who were focused on the dissemination of the statement. Continuous coordination and monitoring of global communication activities have proved essential to ensure that efforts to create awareness of the Joint Position Statement were appropriate and effective.

CONCLUSION

- The Joint Position Statement explains the value of professional medical writing to evidence-based medicine by summarizing current evidence on the professional medical writer's role in the ethical, accurate and timely disclosure of research results.
- This is the first unified position statement on the role of professional medical writers, and replaces previous position statements and guidelines from the participating organizations.
- Key learnings from this development and communication process are applicable for future initiatives and highlight the benefits of a well-coordinated, global, cross-organizational approach in order to maximize the impact of the Joint Position Statement.

THE JOINT POSITION STATEMENT

AMWA-EMWA-ISMPPP Joint Position Statement on the role of professional medical writers
Released January 2017

Introduction
This Joint Position Statement of the American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPPP) describes the appropriate role of professional medical writers in the development of medical and scientific publications, including:

- articles and supplementary content (e.g. video abstracts) for publication in peer-reviewed journals
- abstracts, posters and oral presentations for dissemination at scientific congresses.

This Joint Position Statement is in line with up-to-date guidelines from several other international organizations.

Types of publications covered

Reflects relevant guidelines and statements

Responsibilities of professional medical writers
Professional medical writing support helps authors and sponsors to disclose their research in peer-reviewed journals and at scientific congresses in an ethical,¹⁴ accurate^{15,16} and timely¹⁷ manner, with the ultimate aim of advancing patient care. Professional medical writers have extensive knowledge of ethical publication guidelines.^{18,19} When assisting authors with communication of the results of company-sponsored research, they must:

- follow Good Publication Practice (GPP3) guidelines and International Committee of Medical Journal Editors (ICMJE) recommendations^{1,2}
- consult appropriate reporting guidelines (e.g. CONSORT²⁰ and others collated by the EQUATOR network²¹)
- ensure that the authors and sponsors are aware of their obligations under these guidelines^{1,2,20,21}
- keep up to date with advances in medical communications ethics and best practices.

Ethical – accurate – timely

Follow relevant guidelines and best practices

Provide appropriate, accurate and current information

Responsibilities of authors who collaborate with professional medical writers
Authors who choose to collaborate with a professional medical writer on manuscripts or congress presentations must:

- ensure that they, as authors, have access to all relevant information (e.g. protocols, statistical analysis plans, statistical analyses and clinical study reports)
- provide intellectual input before writing commences and throughout content development
- ensure that the final text fully reflects the views of, and is approved by, all authors
- affirm the appropriateness of the final choice of journal or congress
- acknowledge the provision of medical writing support, including the nature of the support, and the name, highest relevant qualifications (e.g. degree or professional credential) and affiliation of the professional medical writer accountable for the support provided, and acknowledge the funding sources for the provision of medical writing support (see Box)
- recognize as a co-author all contributors (including a professional medical writer) who meet the ICMJE authorship criteria.¹

Reflects ICMJE authorship criteria

Emphasizes the need to acknowledge medical writing support

WHO: accountable medical writer, editor, other, as appropriate, and his or her qualifications. WHERE: location

WHO: funder. WHERE: location

Box. Example of template disclosure statement for professional medical writing support
"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>)."

WHAT: details of type of support provided

HOW: within specific guidelines

A SUMMARY OF RESULTS

- Over 10 878 unique page views in the first month after launch
- Member organizations are undertaking translations into German, Italian, French and Spanish

Notable online mentions

Medical Writer Joint Position Statement Released by AMWA, EMWA and ISMPPP, London, UK, 17 January 2017.

The American Medical Writers Association (AMWA), European Medical Writers Association (EMWA) and International Society for Medical Publication Professionals (ISMPPP) today released a Joint Position Statement on the role of professional medical writers, which is the first unified position statement on the role of professional medical writers from three leading professional organizations.

Top publications news stories of the year so far: The Publication Plan website top 5.

In case you missed any of the publications-related news on The Publication Plan website (www.thepublicationplan.com) in January and February, here's a quick roundup of the most popular articles of 2017 so far:

- New Medical Writer Position Statement from AMWA, EMWA and ISMPPP: <https://thepublicationplan.com/2017/01/17/new-medical-writer-joint-position-statement-released-by-amwa-emwa-and-ismpp/>

ARCS JOBS AND NEWS BULLETIN. AMWA-EMWA-ISMPPP Joint Position Statement on the role of professional medical writers.

Australian clinical investigators working on industry-sponsored clinical trials and industry sponsors should be aware of a new international statement that outlines the responsibilities of authors and medical writers when developing medical and scientific publications. Learn more...



CALL TO ACTION

The Joint Position Statement Communications Committee calls on you to:

- read the Joint Position Statement
 - AMWA: http://www.amwa.org/position_statement
 - EMWA: <http://www.emwa.org>
 - ISMPPP: <http://www.ismpp.org/advocacy>
- attend a presentation at a forthcoming event
- recommend endorsement of the Joint Position Statement by related organizations
- update your own publication policies accordingly.

Disclosures

This initiative was funded by AMWA, EMWA and ISMPPP. Art Gertel is an independent consultant under the auspices of MedSciCom, LLC and is a Past President of AMWA and a Fellow of both AMWA and EMWA. Christopher Winchester is an employee, Director and shareholder of Oxford PharmaGenesis, Oxford, UK, and is Chair Elect of ISMPPP. Karen Woolley is an employee of the Envision Pharma Group, a Professor at the University of Queensland and the University of the Sunshine Coast, Australia, an Honorary Fellow of AMWA and a Life Member of ARCS, and has served on the ISMPPP Board of Trustees. Yvonne Yarker is President of Medicite, LLC, Immediate Past Chair of the ISMPPP Board of Trustees, an author of the Good Publication Practice Guidelines (GPP2 and GPP3) and a member of AMWA.

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