

Medical Writers at the Core of Transparency

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Countless organizations and individuals, including patients, research participants, and funders, call for greater transparency in the reporting of clinical trials research, and there is a growing body of legal and regulatory requirements to this end.¹⁻³ However, a definition of transparency is surprisingly elusive. For some, transparency means meeting the minimum legal reporting requirements in a timely fashion. Others have higher ethical expectations and define transparency as accelerating and broadening the release of information about medical and scientific advances. Some feel that transparency is incorporating patient input into the design, execution, and publication of clinical trials.⁴ Calls for transparency in the publication process involve requests for sharing published data and for opening and unblinding the peer review system. What does transparency mean for medical writers? Some medical writers and publications professionals may define transparency for the medical writing profession as ensuring complete disclosure of conflicts of interest, financial support, and medical writing assistance.

Medical writers and editors are clearly critical to the implementation of publication best practices. Their roles have been validated both in principle, in the form of a joint statement⁵ from AMWA, the European Medical Writers Association, and the International Society for Medical Publication Professionals (ISMPP); and in practice, as research has found that involvement of medical writers is associated with improved reporting of clinical trial results,^{6,7} that authors value many aspects of the role of medical writers,⁸ and that medical writers (and the pharmaceutical industry) are rarely involved in publications retracted for misconduct.⁹ Medical writers have the opportunity to continue to serve as gatekeepers for appropriate transparent practices in publications. In particular, medical writers have the responsibility of working with authors and clinical trial

sponsors to encourage adherence with best practices and sponsor policies, including appropriate and complete reporting of contributions and disclosures,¹⁰ disclosure of medical writing and editorial support (putting an end to ghost and guest authorship), and thorough and accurate reporting of efficacy and safety results with correct clinical context.

As publications professionals, we can all appreciate the writing discipline as an evolving and dynamic space with shared values at its core. Because expectations within the publications arena continuously evolve as new requirements are implemented, medical writers must continuously educate themselves on these changes to continue to be valued partners in the development of publications that adhere to contemporary best practices.

Ultimately, improving transparency as expectations and requirements evolve rests with each individual engaged in the content development and disclosure process. Fortunately, there are a number of tools to guide us as we consider what transparency means and how we, as individuals, can incorporate transparent practices in our day-to-day work. Professional guidelines, including Good Publication Practice (ie, GPP3)¹¹ and recommendations from the International Committee of Medical Journal Editors (ICMJE),¹² are an excellent starting point and are supplemented by the work of others, including that of Medical Publishing Insights & Practices (MPIP), a collaborative initiative founded by the pharmaceutical industry (current corporate sponsors include Amgen, AstraZeneca, Biogen, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Global Services, LLC, Merck, and Pfizer) and ISMPP. In 2010, a group of journal editors and industry representatives from MPIP member organizations met to discuss actions within the publications industry that could improve transparency and credibility in publication of industry-sponsored research, which led to the publication of 10 recommendations.¹⁰

Building on these general recommendations and complementing existing guidance from the CONSORT group,^{13,14} journal editors and MPIP collaborated again in 2014 to provide consensus recommendations on the reporting of adverse events.¹⁵ While industry-sponsored studies were the focus of both of these guidances, they can equally be applied to the reporting of all research, regardless of funding source or research type.

MPIP (<https://www.mpip-initiative.org/>) was founded to elevate trust, transparency, and integrity in reporting the results of industry-sponsored research. Through collaboration with key stakeholders, MPIP works to understand the issues and challenges in reporting industry-sponsored research, publish its findings, and develop tools to improve credibility and transparency. At the core of these efforts is *Transparency Matters* (<https://www.mpip-initiative.org/transparencymatters/index.html>), a global education platform and call to action. At this resource hub, all interested parties, including medical writers, authors, life-science companies, journal editors, and others with a vested interest in the transparent reporting of clinical trials results, can find research, tools, and recommendations to improve the level of transparency when reporting the results of clinical research.

We invite you to join us in our mission and add your voice to the conversation! *Transparency Matters* encourages stakeholder engagement through 2 key initiatives:

1. Take the **Transparency Pledge** (<https://www.mpip-initiative.org/transparencymatters/takethepledge.html>) and commit to transparent publication practices when reporting pharmaceutical and biomedical research.
2. Contribute to **What Transparency Means to Me** (<https://www.mpip-initiative.org/transparencymatters/wtmtm.html>)—a space for those involved in reporting research to share their perspectives on transparency and how it can be best achieved when disclosing data. Expert insight on relevant and timely topics such as the ICMJE data sharing statement, predatory journals and congresses, and future perspectives in peer review is shared on the Transparency and Data Sharing Blog (<https://www.mpip-initiative.org/transparencymatters/wtmtmblog.html>).

Tell us! What does transparency mean to YOU? Submit a quote or imagery to be published on our website and be a voice in this conversation! <https://www.mpip-initiative.org/transparencymatters/wtmtmquotes.html>

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