

**THEME ARTICLE**

# An Overview of the 2022 Update of Good Publication Practice (GPP) Guidelines: A Medical Writer’s Perspective

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**ABSTRACT**

This year marks the 20-year anniversary of the Good Publication Practice (GPP) guidelines, a set of principles and recommendations pertaining to peer-reviewed or peer-orientated publications arising from research funded by or conducted in collaboration with industry sponsors. Since the publication in the initial GPP guidelines in 2003, GPP guidelines have undergone several updates, with the latest iteration (GPP 2022 update) published in August 2022. The latest GPP guidelines built upon prior work and continue to strengthen principles and refine practices to reflect a rapidly evolving field of biomedical publishing. This article summarizes what is new in the latest GPP update and provide a quick document tour to help readers navigate the GPP 2022 document. In addition, a section from the perspective from medical writers and editors provides a preview of principles and practical guidance relevant to our day-to-day work. It is expected that further dissemination and discussion of the latest GPP 2022 update will continue to take place among publication professionals, medical writers, authors, journal editors and publishers, and other stakeholders, who share common goals of transparency, accountability, and quality of publications arising from company-sponsored biomedical research.

The Good Publication Practice (GPP) guidelines are a set of principles and recommendations pertaining to peer-reviewed or peer-orientated publications arising from research funded by or conducted in collaboration with industry sponsors, typically pharmaceutical, biotechnology, and medical device companies.

This year marks the 20-year anniversary of the first GPP guidelines that were published in 2003.<sup>1</sup> These initial GPP guidelines were developed to promote transparency and to establish standards for publication practice used by pharmaceutical companies. Since then, GPP guidelines have undergone several updates to reflect changes within the publication field and to provide additional practical guidance on publication processes and procedures. These updates

include the GPP<sup>2</sup> published in 2009 and the GPP<sup>3</sup> published in 2013. Good Practice for Conference Abstracts and Presentations (GPCAP)<sup>4</sup> was published in 2019 to provide guidance specifically for congress abstract and presentations. The latest update of the GPP guidelines, the GPP 2022 update, was published in August 2022.<sup>5</sup> To facilitate better tracking of updates, the current and future GPP updates will carry the date of the update (instead of a version number). Table 1 summarizes GPP iterations published to date; all GPP guidelines are free to access by the public.

**Table 1. GPP Iterations**

GPP Iteration	Year of Publication	Citation
GPP 2022	2022	DeTora LM, Toroser D, Sykes A, et al. Good publication practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. <i>Ann Intern Med.</i> 2022;175(9):1298-1304. <a href="https://doi.org/10.7326/m22-1460">https://doi.org/10.7326/m22-1460</a>
GPCAP	2019	Foster C, Wager E, Marchington J, et al. Good practice for conference abstracts and presentations: GPCAP. <i>Res Integr Peer Rev.</i> 2019;4:11. <a href="https://doi.org/10.1186/s41073-019-0070-x">https://doi.org/10.1186/s41073-019-0070-x</a>
GPP3	2015	Battisti WP, Wager E, Baltzer L, et al. Good publication practice for communicating company-sponsored medical research: GPP3. <i>Ann Intern Med.</i> 2015;163(6):461-464. <a href="https://doi.org/10.7326/m15-028">https://doi.org/10.7326/m15-028</a>
GPP2	2009	Graf C, Battisti WP, Bridges D, et al. Good publication practice for communicating company-sponsored medical research: the GPP2 guidelines. <i>BMJ.</i> 2009;339:b4330. <a href="https://doi.org/10.1136/bmj.b4330">https://doi.org/10.1136/bmj.b4330</a>
Original GPP	2003	Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. <i>Curr Med Res Opin.</i> 2003;19(3):149-154. <a href="https://doi.org/10.1185/030079903125001767">https://doi.org/10.1185/030079903125001767</a>

GPCAP, Good Practice for Conference Abstracts and Presentations; GPP, Good Publication Practice.

One may wonder about the process for developing the GPP guidelines. As described in the Methods sections of the GPP guidelines (GPP2 and onward),<sup>2-3,5</sup> with support from the International Society for Medical Publication Professionals (ISMPP), a steering committee was invited and formed, then members of the steering committee wrote the guidelines and managed review of the drafts by selected expert reviewers or a wider range of volunteers. The steering committees (typically also serving as the author groups) have consisted of experienced professionals representing various constituencies involved in publishing company-sponsored biomedical research. For example, in the latest GPP 2022 update, the author group represents different geographic regions (Asia, Europe, and North America) and includes members from pharmaceutical, biotechnology and device companies, medical communication agencies, journal editors and publishers, and academic institutions.

It is worth noting that GPP guidelines identify best practices based on a wide range of existing guidelines. These include broader guidance on scholarly publishing by the International Council of Medical Journal Editors (ICMJE),<sup>6</sup> various reporting standards such as CONSORT<sup>7</sup> and guidelines collected by the EQUATOR Network,<sup>8</sup> as well as ethical principles maintained by professional organizations such as American Medical Writers Association (AMWA),<sup>9</sup> the European Medical Writers Association (EMWA),<sup>10</sup> the ISMPP,<sup>11</sup> the Council of Science Editors,<sup>12</sup> and the World Association of Medical Editors,<sup>13</sup> to name a few.

GPP guidelines are intended to be a living document that reflects current practice and will be subject to revisions as the field changes and expands. The sections below summarize what is new in the latest GPP update and provide a quick document tour to help readers navigate the GPP 2022 document.

## WHAT IS NEW IN THE GPP 2022 UPDATE

Many principles of prior GPP guidelines remain. The GPP 2022 update<sup>5</sup> reflects the changes in the publication field as well as the expanding role of the publication professionals. The updated guidelines strengthen the core values of GPP such as ethics, transparency, inclusivity, accountability, and responsibility. The GPP 2022 update also includes a significantly expanded and reorganized supplement document, intended to provide more detailed guidance on day-to-day work in various process steps of publication planning, development, review, and approval.

Below is an overview of themes of changes and additions in the GPP 2022 update since the previous iteration (GPP3).<sup>3</sup> For a detailed list of changes, the readers can refer to the table in the main body of the GPP 2022 update.

### • Principles of GPP were augmented and strengthened.

- GPP principles incorporate updated references to key ethical documents, such as ICMJE recommendations and the Declaration of Helsinki. The AMWA-EMWA-ISMPP joint statement on the role of professional medical writers was also cited.
- Updated “Ethical Principles” include a total of 23 principles (compared with 10 principles in GPP3), divided into 5 areas:
  - General principles for ethics and good publication practice.
  - Principles for protecting research and data integrity.
  - Principles to promote transparency.
  - Principles to support inclusivity.
  - Principles for authorship, contributorship, and accountability.
- “Practical Planning Principles” were added to describe principles guiding practical aspects of work processes.

### • New topics were included to reflect changes and advances in the publication field.

- GPP 2022 specifies a wider scope of research (eg, translational and biomarker studies, nonclinical research, health economics, real-world evidence, and outcomes research) and reflects advances of in biomedical publishing (eg, enhanced content, plain language summaries, preprints, and social media posting about peer-reviewed publications).
- Guidance is given regarding plain language summaries and enhanced content.
- GPP 2022 recommends inclusivity in publication activities (eg, cultural differences and region-specific needs) and in people and teams involved in publications (eg, the composition of steering committees, author groups, and publication teams).
- The guidelines also address the potential role of patients in publication activities.

### • The supplement was significantly expanded and reorganized.

- In GPP 2022, the supplement was significantly expanded and reorganized to provide more detailed guidance on various publication process steps in a logical order (see the next section for more details).

## HOW TO NAVIGATE THE GPP 2022 UPDATE – A QUICK TOUR OF THE DOCUMENT

The overall format of the GPP 2022 update<sup>5</sup> is similar to that of GPP3;<sup>3</sup> main principles are presented in the main body, and more detailed guidance and recommendations are

summarized in the supplement. The updated document, especially the supplement, contains a large amount of information. It may be hard to read the entire document in one sitting or to remember all the details. The summary below provides a quick tour of the document that may help readers to get familiar with the structure of GPP 2022 so they may locate relevant information more easily.

- **Main body**
  - “Ethical Principles” and “Practical Planning Principles” are presented.
  - The main body also includes methods used for developing GPP 2022, the scope and format of GPP, how to use GPP, as well as conclusions and future directions.
  - A detailed table summarizes key changes and additions since the previous iteration.
  - Specific sections in the supplement are called out in GPP principles in the main body to aid in quick cross referencing.
- **Supplement**
  - The expanded and reorganized supplement provides detailed guidance on various process steps, organized in sections A-I (summarized in Table 2).
  - Each section of the supplement may be used as a standalone document to help explain the process and best practices to publication stakeholders. The overall supplement can be used as a tool for publication team education and for guiding the development of publication policies and procedures at certain organizations.

## A PERSPECTIVE FROM MEDICAL WRITERS AND EDITORS

Many medical writers and editors, whether employed by company sponsors, by medical communication agencies or contract research organizations, or are self-employed, are involved in the development of publications of company-sponsored biomedical research. Medical writers, with professional expertise in scientific communication and in ethical publication principles, assist authors and sponsors to disclose and communicate research findings in an ethical, accurate, and timely manner.

Following on from GPP3,<sup>3</sup> GPP 2022<sup>5</sup> continues to emphasize the professional roles of medical writers. A notable update is that under “General Principles for Ethics and Good Publication Practice” in the main body text, it was made clear that medical writers should be treated ethically and enabled to follow ethical practice.

**Table 2.** Summary of Supplement Sections A-I in the GPP 2022 Update<sup>5</sup>

Section	Topic	Content (Section Headings, Titles of Supplement Tables and Figures)
A	Publication Types	- Primary and secondary publications - Reviews and meta-analyses - Scientific conferenced presentations - Other publication types - Enhanced content and plain language summaries
B	Publication Professional Roles and Professional Development	- Professional roles - Professional development - Sharing best practices - Developing publications policies and procedures - Supplement Table 1. Team education: essential events and timing for clinical research publications
C	Ethical Principles: Additional Detail	- Commitment to peer-reviewed publications - Publications as scientific exchange - Special considerations for communicating with the public - Additional significant considerations
D	Publication Steering Committees	- Responsibilities - Formation and ending - Membership - Charter - Meetings and communication - Supplement Figure 1. Suggested life cycle of a publication steering committee
E	Publication Plans	- Principles - Review and approval of publication plans - Supplement Table 2. Principles for publication plans - Supplement Table 3. Special considerations for the publication plan
F	Publication Working Groups	- Responsibilities - Initiation - Membership - Meetings and communication - Ending
G	Authorship and Contributorship Determination	- Principles - Author agreements - Additional considerations - Process - Supplement Table 4. Suggested author agreement contents
H	Publication Process	- Journal and conference selection - Data sharing - Working with professional medical writers - Publication kick off - Publication draft - Review and approval - Acknowledgment, disclosures, and author statements - Journal submission, peer review, and page proofs - Post publication activities - Supplement Table 6. Relevant criteria for journal and conference selection - Supplement Figure 2. Overview of the publication process
I	Documentation Guidelines	- Guidelines

In the GPP 2022 supplement, medical writers can also find relevant practical guidance on day-to-day work in several sections, including Section B “Publication Professional Roles and Professional Development,” Section D “Publication Steering Committees,” Section F “Publication Working Groups,” Section G “Authorship and Contributorship Determination,” and Section H “Publication Process.”<sup>5</sup>

Below are just a few examples of practical guidance relevant to medical writers:

- Roles of medical writers, along with roles of authors, other contributors, and reviewers, should be defined prospectively (Supplement Section D), and the employment of professional writing support should be agreed by authors (Supplement Section G).
- Medical writers, as with all publication contributors, qualify as authors if they meet authorship criteria (Supplement Section G).
- Medical writers should work under author direction.
- Medical writers should attend relevant meetings such as kick off or data dissemination meetings so they can capture authors’ views and directions (Supplement Sections F, H).
- If they are not a byline author, a medical writer should not be asked to perform final data integrity check (Supplement Sections F, H) to help ensure adherence to ICMJE authorship criteria.
- Medical writing support needs to be disclosed. Typically, the writer’s name, professional qualifications, affiliation, and funding source are disclosed at a minimum, along with any other information required by the journal or conference (Supplement Section H).
- Medical writers should engage in professional development and in sharing best practices (Supplement Section B).

Medical writers are highly encouraged to keep GPP guidelines on hand as a key reference and to consult them when questions or uncertainties arise at work. Even if one may not find the exact answers for every work situation, the principles and processes described in the GPP guidelines may provide an approach for developing solutions.

Medical editors often work closely with medical writers to ensure that the publications are clear and concise, with a format and style suitable for the target audience, and meeting requirements by the journals, publishers, and scientific conferences. Editors are often knowledgeable on topics related to journals and publishers (eg, journal styles, copyright requirements, and predatory publishing). Their insights into language use can help make enhanced content and plain language summaries more effective for different

audiences. For medical editors and those who work with medical editors, the detailed publication process described in the latest GPP guidelines can help identify where an editor’s insights and input are needed.

For medical writers and editors, besides reading the published GPP document, there are other resources to learn about the latest GPP guidelines. For example, the ISMPP held an ISMPP U webinar “Introducing GPP 2022” on September 21, 2022,<sup>14</sup> and the EMWA held a webinar “Good Publication Practice 2022: Focus on Medical Writing” on March 8, 2023.<sup>15</sup> There are likely more discussions at various professional organizations on the latest GPP guidelines.

## CONCLUSION

Since the publication in the initial GPP guidelines 20 years ago, GPP guidelines have undergone several updates, with the latest iteration (GPP 2022 update) published in August 2022.<sup>5</sup> Over the years, GPP guidelines have become a cornerstone of principles and standards for publications of company-sponsored biomedical research. The latest GPP guidelines built upon prior work and continue to strengthen principles and refine practices to reflect a rapidly evolving field of biomedical publishing.

Disseminating the newest GPP guidelines and incorporating them into day-to-day work requires continuous effort. It is expected that further dissemination and discussion of the latest GPP 2022 update will continue to take place among publication professionals, medical writers, authors, journal editors and publishers, and other stakeholders, who share common goals of transparency, accountability, and quality of publications arising from company-sponsored biomedical research.

## Acknowledgments

The author thanks Lisa M. DeTora, PhD, MS, Dikran Toroser, PhD, and Zoë Preston, MPhil, for providing critical review of this manuscript.

**Author declaration and disclosures:** *The author notes no commercial conflict of interest in relation to this article. The views and opinions expressed in this article are those of the author and do not necessarily reflect the views of the author’s employer.*

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