

## Journal watch



# GPP2 guidelines: Recommendations for good publication practice in biomedical research

by Nancy Milligan and Adam Jacobs



This edition of journal watch focuses on the new good publication practice guidelines (GPP2), which were published by the International Society for Medical Publication Professionals (ISMPP) in the *British Medical Journal* in November last year [1]. GPP2 updates the earlier guidelines [2] and makes recommendations that aim to “help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies”. The guidelines apply to peer reviewed journal articles and presentations at scientific congresses.

## Methods used to develop GPP2

Briefly, the ISMPP recruited a steering committee from ISMPP members with more than 10 years experience in biomedical publishing. The 14 volunteers considered the original guidelines and reviewed new literature on the subject before drafting the new guidelines after discussion. The steering committee recruited (by invitation and open requests for volunteers) an international consultation panel of 193 people, who reviewed the draft guidelines and submitted comments on them. Members of the steering committee assessed and ranked the comments based on their frequency, their critical or beneficial rating, and their importance. The comments were then used to create the final guidelines.

## Role of medical writers

We were pleased to read that the new GPP2 guidelines support the valid role that professional medical writers can play in the communication of medical research, and we were especially pleased to see the declaration that medical writers, if they are properly acknowledged, should not be considered ghostwriters. The guidelines go on to give advice to medical writers when working with authors; in essence, writers should ensure:

- Close collaboration with authors (for example, all authors should be aware of medical writer involvement; there should be direction from the lead author from an early stage of the project; authors should ultimately control and direct the writing; authors should review and comment on the outline and the subsequent drafts and approve the final version and any versions after peer review)
- Funding and potential conflicts of interest are declared
- Appropriate acknowledgment of medical writing contributions are made
- Authorship is attributed if appropriate (for example, if the medical writer has contributed extensively to literature searches and helped define the scope of the article)

The position of GPP2 reflects EMWA’s own published guidelines on the legitimate role of medical writers in the development of ethical publications [3]; the EMWA guidelines are also referred to in the article.

## Authorship and contributorship

GPP2 suggests that “particular care should be taken to attribute authorship and to acknowledge contributions appropriately”. The guidelines recommend assignment of a lead author (to take the lead for writing and managing the work) and a guarantor (to take overall responsibility for the integrity of a study and its report); the lead author and guarantor can be the same person. They also recommend using the International Committee of Medical Journal Editors criteria for authorship [4] to attribute appropriate authorship for a piece of work. Briefly, to be considered an author, each individual “should have participated sufficiently in the work to take public responsibility for appropriate portions of the content” and have made “substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data”; been involved in “drafting the article or revising it critically for important intellectual content”; and have given their “final approval of the version to be published” [4]. GPP2 states that all listed authors should fulfil these authorship criteria (if not, they would be considered a “guest author”) and all those who fulfil the criteria should be listed as authors (if not, they would be considered a “ghost author”).

GPP2 goes on to support the use of a contributorship model to describe exactly who did what during a project, and therefore hopefully help to avoid any ambiguity. It is suggested that clear, concise descriptions of the role of each individual contributor (including but not limited to the authors) are made in an acknowledgement within the article or presentation. Individual contributions could include study conception or design, conceiving the idea for an article, conducting or managing a study, data collection, statistical analysis, data interpretation, analysis of published literature, drafting a manuscript, critically reviewing a manuscript, and manuscript approval. We would normally expect the contributions a medical writer makes to be acknowledged in this way. It is also important that each individual gives their permission to be acknowledged.

## Acknowledgements and conflicts of interest

GPP2 recommends that all articles and presentations include an acknowledgements section, which should fully recognise author contributions and contributions of all individuals not listed as authors, such as medical writers (as discussed

more fully in the section above); the involvement of the sponsor in the study and its reporting; and the funding sources for the research and reporting (which would include funding of any medical writing services).

It is also recommended that authors disclose all potential financial and non-financial conflicts of interest that could inappropriately influence or seem to influence professional judgement.

### Other features of the guidelines

The updated guidelines also make some other specific recommendations on:

- Roles and responsibilities: companies should produce at the earliest opportunity written agreements that describe their obligations for good publication practice and clearly layout the responsibilities of sponsors, authors, and other relevant contributors
- Access to data: sponsors should provide authors and other contributors with full access to study materials including protocols, statistical analysis plans, statistical reports, data tables and listings, and clinical study reports
- Publication steering committee: it might be useful to form a steering committee of authors, investigators, and other contributors to oversee the publications and presentations from a study; they also suggest that steering committee members may become authors, but membership does not automatically confer authorship
- Specific types of projects: authors should be explicit about whether articles or presentations are primary or secondary and care should be taken to avoid duplicate publications; journal or congress guidelines should be followed; review articles should be comprehensive and clearly describe the methods used for searching, selecting, and summarising the information; established reporting standards such as CONSORT, STARD, STROBE, PRISMA, and MOOSE [5] should be followed
- Publication planning, registering, posting, and documenting: using a publication plan can help ensure appropriate, efficient, and complete communication of study results; sponsors should follow relevant legislation and guidelines on registering and posting clinical trials; companies should implement policies detailing the types of documentation to produce and retain during a study and reporting

Finally, GPP2 provided a checklist that they recommend following to ensure good publication practice for articles and presentations. The checklist included five areas for consideration: integrity, completeness, transparency, accountability, and responsibility.

### Response from EMWA

In a rapid response to the article, Adam Jacobs (EMWA Press Officer) and Helen Baldwin (EMWA President) applauded the updated guidelines and the advice they give for promoting ethical publication standards. They do however bring up two areas of concern. Firstly, they noticed that the

recommendation published in the original GPP guidelines that “companies should endeavour to publish the results from all of their clinical trials of marketed products” appears to be missing in GPP2. They argued that to avoid publication bias that it is important that both positive and negative results are published. Secondly, they were concerned that the role of the publication steering committee described in GPP2 was ambiguous, suggesting that they appear to allow for the possibility that employees of the sponsor company could be members of the steering committee without being authors of the publication. This seems to be dangerously close to ghost authorship and therefore Jacobs and Baldwin suggest that it is important to ensure that sponsor employees should either be named authors or, if not, they should have no input into the content of the publication.

In response to these concerns, the GPP2 authors agreed that ghost authorship is unacceptable and point out that contributorship statements should be used to describe exactly who did what.

### Was it worth it?

The GPP2 guidelines were developed following an extensive consultation process involving a great many people and considerable effort. It might be reasonable to ask what this effort has achieved in improving on the original GPP guidelines. In truth, the answer is probably “not very much”. Yes, some things are new, for example the recommendation that authors are not paid an honorarium for being authors. However, none of the new items is really earth-shattering, and not all the items listed in a “what’s new?” box within the guidelines are even new anyway (for example “contributorship guidance recommends describing the role of the sponsor”, which was already recommended in the original GPP). However, one thing that is new is that the guidelines were written under the auspices of ISMP, so even if the GPP2 guidelines have not moved the cause of publication ethics greatly forward (although of course it is always helpful to restate ethical principles and make it more likely that they will be widely known), they have certainly succeeded in generating publicity for ISMP.

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