GPP2 FAQs

Q. What is GPP2?

A. GPP2 stands for "Good Publication Practice for Communicating Company-Sponsored Medical Research: The GPP2 Guidelines." Landmark guidelines on Good Publication Practice (GPP) were published in 2003 emphasizing the importance of pharmaceutical companies publishing sponsored clinical trials in a responsible and ethical manner. This document updates those guidelines.

Q. What was ISMPP's role in the development of the GPP2 guidelines?

A. With the agreement of Liz Wager and the other authors of GPP, ISMPP initiated the development of GPP2 through the formation of an ISMPP GPP2 Steering Committee led by Chris Graf. An extensive consultation process was used to write GPP2, including the 14 members of the Steering Committee and consultation with 116 individuals and organizations globally.

All of the contributors were members of ISMPP, who provided meeting, teleconferencing facilities, and web conferencing technology. In addition, ISMPP updated and assumed responsibility for the original GPP website, which can be accessed as follows: www.gpp-guidelines.com

Q. Why was ISMPP so interested in leading the development of GPP2?

A. The primary reason was we saw a need to respond to legislative, guidance, and ethical developments that have occurred since the original guideline was published in 2003. ISMPP's goals include supporting the educational needs of medical publication professionals and to develop best practices that ensure the rigorous maintenance of all ethical standards for reporting results of medical research.

For example, legislation in the US requires pharmaceutical, biotech, and medical device companies to make public the results from a large proportion of the studies they sponsor. This has an impact on what companies ensure is published, as well as the timing of the publication. The consequence of this is that the nature of the relationships between companies and authors/investigators regarding their work practices require more thought and definition.

Legislation and/or guidelines similar to US posting legislation are appearing around the world. One example is the European Commission, which now mandates that the list of fields contained in the 'EudraCT' clinical trials database are made public, which is a change from past years.

Q. Is GPP2 also for professional medical writers?

A. GPP2 is for the types of communications that are made in the academic world, namely peer-reviewed journal articles and presentations at scientific meetings. So yes, in addition to authors and investigators, other individuals (like professional medical writers) who contribute, in any particular way, to the communication of clinical

information from studies that are sponsored by pharmaceutical, biotech and medical device companies are part of GPP2.

By the way, there are more than 25 new recommendations in GPP2, and the inclusion of medical device and biotechnology companies is one of these.

Q. How does GPP2 assist individuals and organizations maintain ethical publication practices?

A. First of all, GPP2 provides updated, reasonable, and balanced guidance, drawing on recognized good practices, adapted to the particular areas of need among its audience. While we believe GPP2 provides the right guidance, they are not the total answer. For any guideline to make a real difference, the recommendations need to be "acted" on by the community they serve. Without this they are not worth much!

Again, this is why ISMPP has been so involved in the development and dissemination of GPP2. With the publication of GPP2 in *BMJ*, we believe even broader adoption of best publication practices will occur and the bar will be raised even higher regarding reporting of results of medical research.

It's also important to remember that GPP2 is not intended to replace other existing guidelines, such as ICMJE. In fact, they were written to work in concert with these other guidelines.

Q. What specifically is new or updated on GPP2?

A. There are too many things to mention here. However a short list would include:
- Guidance on defining the roles of authors, sponsors, and other contributors
- Authorship guidance recommending assignment of a lead author and guarantor
- Guidance on establishing a publication steering committee
- Contributorship guidance that recommends describing the role of the sponsor
- Confirmation of the role of professional medical writers and guidance on appropriate working practices
- Recommendations about reimbursement and honoraria
- Recommendations for specific types of articles and presentations
- Recommendations for publication planning and documentation
- Checklists for articles and presentations

Q. Where can I get a copy of the GPP2?

A. A PDF of GPP2 can be accessed on www.gpp-guidelines.com.