

NEW CLARITY

The Good Publication Practice guidelines are being updated to keep up with the rapidly changing environment

The notion of Good Publication Practice (GPP) Guidelines was initially conceived a decade ago during a retreat of what is now the Council of Science Editors. At the time, there was a lack of clarity in the way that the interested parties - academia, pharma and the publishers - could, and should, co-exist to promote a healthy and credible environment for biomedical publishing. When the first guidelines were published in 2003, the mission was very clear: to encourage and facilitate responsible and ethical publication practice in the pharmaceutical industry. All that remained was to solicit endorsement of the guidelines from the many interested parties.

Since that time, pharma publication practice has become an increasingly hot topic. Purported cases of publication-related 'misconduct' or alleged misdemeanours (some high-profile) come to light, it seems, every month. Major headlines in both lay and biomedical media often put big pharma at the centre of the stories, many of which are not limited to the broadsheets:

- 'Pfizer employees sought to suppress negative Neurontin study' - *Wall Street Journal*
- 'A quick fix would stop drug firms bending the truth' - *The Guardian*
- 'Industry-sponsored clinical research: a broken system' - *JAMA*
- 'The ADVANTAGE seeding trial: a review of internal documents' - *Annals of Internal Medicine*.

At the same time, publication conduct outside of the biomedical industry has also come under the spotlight. Authors from the Office of Research Integrity writing in *Nature* concluded that in taxpayer-funded research programmes "falsified and fabricated research records, publications, dissertations and grant applications are much more prevalent than has been suspected to date".

In partial defence of pharma, many of the more disturbing headlines refer to events that occurred at least as long ago as the initial publication of GPP, if not before. In the past five

or so years, many companies (such as Merck and Pfizer) have established, and made public, new publication policies that both govern and openly declare their intended conduct.

Perhaps it is less that the publication of industry-sponsored clinical research is broken, and more that conduct all round could (or should) be better.

THE CHALLENGE OF CHANGE

The 'first-generation' GPP rapidly became widely referred to as a fundamental set of guidelines for publication planners, medical writers and others working in, for, or with the biomedical industry to communicate biomedical information.

The world continued to turn and, since 2003, the environment in which biomedical research is communicated has evolved. There is now a new Declaration of Helsinki (released October 2008), and it specifically refers to the ethical communication of biomedical research. Certain clinical trial results must now, within a defined time frame, be made public - recommended by the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA's) new international guidelines and required by law in the US. Professional organisations have emerged to support and even certify individuals involved in the development of biomedical communications sponsored by industry - such as the International Society for Medical Publication Professionals (ISMPP), which has just established a professional certification process.

Since no 'control' is possible, we can only assume, from the frequency with which the GPP Guidelines are referenced in communications between interested individuals, that members of the original working group have achieved their objective: the "encouragement and facilitation of responsible and ethical publication practice in the pharmaceutical industry".

THE TIME IS NOW

The recent introduction of FDA legislation (Food and Drug Administration Amendment Act of 2007) has certainly turned up the heat for publication planners. Posting of results 12 months after a

study closes means that data from most industry-sponsored clinical trials (at the moment, Phases 2 and 3 studies) will be released into the public domain quickly and in some detail on the website (clinicaltrials.gov). In response, clinical publications will need to keep up: an investigator's analysis and interpretation of their clinical trial data published in a peer-reviewed journal article will naturally lose impact if the same data have already been digested and discussed following posting on clinicaltrials.gov.

Prompted in part by the new requirements on trial registration and results disclosure, pharma companies are increasingly obliged to demonstrate that they are beyond reproach and must do so not only by developing highly visible publication policies indicating transparency, but also the necessary measures to check compliance with these policies. A natural extension of this is that we can expect to see more well-considered, high-quality publication planning, coupled with provision of appropriately acknowledged medical writing support for authors and investigators, within an agreed framework that endeavours to make the process more transparent and efficient, ensuring that published results can keep up with posted results.

The endorsement and adoption of the 2003 GPP Guidelines by academia, pharma and publishers has gone some way to enhance those relationships. It seems clear, therefore, that these same guidelines need to be updated to further embrace this positive outcome and include relevant guidance on the most recent legislation that impacts all parties - much of which has emerged within the last five years. Indeed, the initial working group acknowledged that the best guidelines 'emerge from an iterative process... and that GPP will evolve as a result of future discussions'.

Organisations such as ISMPP have served to promote such dialogue for more than four years, bringing together interested parties with a shared vision to strive for continual improvement in the medical publishing process. Key to this endeavour is the need for transparency at all levels, and an understanding that the professional medical writer will increasingly play an essential role in facilitating accurate and timely publication

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of clinical trial data. Encouraging signs that perceptions may finally be changing were found in the Association of American Medical Colleges (AAMC) guidelines on Industry Funding of Medical Education (www.aamc.org/industryfunding), published in June 2008. The AAMC guidelines appropriately defined ghostwriting as "the provision of written material that is officially credited to someone other than the writer(s) of the material", with the key clarification that "transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting". It is this distinction that is fundamental to the entire process and a core principle of the ISMPP Code of Ethics.

It is in this evolving environment that 'second generation' GPP (or GPP2) is taking shape. GPP2 is set to deliver best-practice guidance for the post-FDA Amendment Act - or 'post-posting' era.

In early autumn 2008 the ISMPP Standards and Best Practices Committee issued a call for member volunteers to lead the development of GPP2, and recruited 14 individuals from various backgrounds. The GPP2 Steering Committee performed a ground-up review of GPP, and wrote a draft for GPP2 founded on the tried and trusted old-fashioned values that it shares with good scientific practice.

It concluded: 'Good scientific practice embraces all the procedures and practices that are necessary for planning, conducting and reporting research and scholarship within a framework of scientific integrity.'

GLOBAL CONSULTATION

The next phase that the GPP2 Steering Committee entered was a global consultation. In mid-December, a panel of more than 170 individuals and organisations around the world were sent the first draft of GPP2, and given a month to comment. The individuals and organisations being consulted included all the stakeholders you might imagine, from medical directors and publication directors in pharma and medical device companies, to professional society board members, academic researchers, guidelines

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experts, and clinicians, editors and publishers.

Those taking part in the global consultation can expect to see GPP2 contain guidance that is underpinned by the principles of integrity, accuracy, objectivity, completeness, accountability, transparency and intellectual property. GPP2 will offer specific guidance on agreeing roles and responsibilities for all contributors, on appropriate planning, on establishing writing groups, and on the working relationship between authors, medical writers, other contributors, and research sponsors.

COMPILING THE COMMENTS

Once the panel of reviewers had submitted their comments, the Steering Committee set to work compiling, considering and correcting the first draft of GPP2. The aim was to create a set of guidelines that has most meaning to the largest possible group of individuals. Once that is done (the Steering Committee has its eyes set on mid-February), the guidelines will be ready to be made public, with public presentation and launch at the 5th Annual ISMPP meeting to be held in Philadelphia, US, in April.

Plans for publication of the final set of GPP2 guidelines are undecided at time of going to press. Interested individuals should bookmark the website www.gpp-guidelines.org, since GPP2 is likely to make its way there eventually.

The inquisitiveness and enthusiasm (and sometimes warmth) of individuals recruited to the panel for the Global Consultation indicate an appetite for new GPP. It will undoubtedly help those involved in the publication and communication of clinical information funded by companies to keep up with the rapidly changing environment and continue to support the mission of the original Working Group: 'to encourage and facilitate responsible and ethical publication practice in the biomedical sector'.

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