

GPP3 – what is it, why is it necessary and what is new?

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Abstract

The good publication practice for pharmaceutical companies (GPP) guidelines were first published in 2003, then revised in 2009 (GPP2) and most recently in 2015 (GPP3). The latest version reflects the changes that have occurred in legislation concerning dissemination of data from clinical trials, mainly focussed on the pharmaceutical industry. These guidelines are intended to serve as a basis for publication professionals to establish transparent and ethical working practices within the pharmaceutical industry. The need for such guidance and the main differences in the latest version are introduced.

Background

The term *Medical Writing* encompasses a wide field of diverse forms of written communication that seemingly only medical writers themselves can understand and distinguish. The different demands and requirements for writing regulatory documents, clinical study reports, grant applications, and publications mean that medical writers usually become specialised in one or two areas. For example, a writer may have the background, skill set, and familiarity with the legislative requirements to work on both regulatory and clinical documents but may have little or no knowledge about the intricacies of narrative writing or publications. Due to increasing legislation and control in almost all aspects of medical writing, medical

writers have continued to become more specialised over the past two decades, as reflected in the specific training certificates offered by the EMWA Professional Development Programme.

Most facets of medical writing have always been regulated by legislation, and training can be focussed on meeting those needs. However, one area where it has been assumed that training is not needed is that of medical communications, namely, manuscripts for peer-reviewed journals, abstracts, posters, and slide presentations for conferences. The prevailing belief is medical writers learn how to write these documents during their university education through expertise passed on by their PhD or Master's supervisor, who in turn had learned from their peers. This belief persists in academia, where despite the need to publish the results of scientific projects to add to one's curriculum vitae or support grant proposals, little or no consideration is given to how such publications should be written.

The same situation existed in the pharmaceutical industry in the 20th century, with publication being the final uncontrolled, unregulated stage of a process that generated clinical results through a strictly controlled process, from

protocol to regulatory submission. The simple view was that scientists would run their experiments and publish the data, driven by the need of academics to have papers to secure tenure and further grants, and by the need for industry to promote their products. The interface between the two was a grey area that few understood and most never questioned. However, as negative headlines about the pharmaceutical industry became increasingly frequent, public trust rapidly dissipated, leading to increasing demands from many stakeholders to increase and enforce data dissemination and transparency for industry-sponsored clinical trials.

Regulation of publications

The result of demands for increased data dissemination and transparency was a sequential increase in legislated requirements for public reporting of clinical trials. This



began with voluntary registration of clinical trials on internet sites such as the US-based ClinicalTrials.gov and EudraCT in Europe. Editors of major scientific and medical journals immediately supported these requirements and added punctual registration of clinical trials as a criterion for the acceptance of manuscripts based on clinical trials. As companies realised they would no longer be able to publish their studies in the top journals without registering their trials, they rapidly accepted this requirement. When this was followed by the requirement to report the results of those trials on the same sites, it was also quickly accepted by industry. Currently, the final stage of public disclosure is becoming established, giving qualified researchers access to patient-level data from company-sponsored clinical trials through internet sites.

This leaves the final form of data sharing, the writing and publishing of scientific and medical papers in peer-reviewed journals, as the last area for which there is no legislation. Publication is still a voluntary exercise – there is no legal obligation to publish – driven only by the ethical commitment inherent in the International Conference on Harmonization (ICH) to make all data public and in the knowledge that an unpublished study is a wasted opportunity to demonstrate not only full transparency but also the benefits of a product.

Failure to publish all clinical trial data has been waved in the face of the industry as evidence of malpractice. Accusations that poor or *negative* data are being hidden are common. Furthermore, compliance with the requirement to register clinical studies on ClinicalTrials.gov has exacerbated this situation. Even though there are many reasons for which a study may never be published (e.g. it may never have been conducted or was never completed), industry is being held to account when a paper does not appear. This ignores the published evidence that company-sponsored research is more widely reported than academic trials.¹

One of the problems is that industry may not always control publication of results from clinical trials that they sponsor. Of course, even scientists who do not need additional publications for their curricula vitae may still want to publish, but industry-sponsored clinical trials often involve dozens of academic investigators, not to mention *in-house* experts who are equally valid contributors to the research, so who owns the data and is therefore responsible for its publication can be unclear. Another limitation to publishing everything is that corporate enthusiasm – and therefore budget support – to publish relies on the novelty or interest in the data, and something that is not particularly novel or beneficial for a product may not obtain the resources needed to generate and submit a manuscript punctually.

Good Publication Practice – 2003

It was against this background and the lack of regulations that a meeting of academics, journal editors, and industry representatives was organised in 1998 by the Council of Biology Editors. The aim was to establish clear guidelines and standards for industry-sponsored biomedical research publications. It took another 5 years for the results of that first meeting to come to fruition, with the publication in 2003 of Good publication practice for pharmaceutical companies (GPP).² This document was the first to provide standards for industry-based manuscripts, but it was restricted to a relatively small set of issues: the obligation to publish everything, the role of professional medical writers in assisting with

manuscripts, and a first brief approach to a major issue for all manuscripts, authorship. Although GPP was rapidly taken up by medical writers as guidance within their companies, even at its inception it was evident that many topics had not been considered and that a more comprehensive guidance document was required.

As with the original guidelines, GPP2 resulted in numerous unanswered questions and requests to include more detail and additional topics.

GPP2 – 2009

The next iteration of GPP – GPP2 – was published six years later, in 2009.³ GPP2 was a more complete document written by a larger author panel (12 vs. 3 in the original GPP) representing pharmaceutical companies, publishers, communication agencies, and independent medical writers. Before submission, the guidelines were also reviewed by a wide review panel that included representatives from academia and journal editors. GPP2 was more comprehensive than GPP and introduced or supported new concepts, including written publication agreements, publication steering committees, checklists, and the contributorship model, while reinforcing the authorship guidelines proposed by the International Committee of Medical Journal Editors (ICMJE) and adherence to trial registration and results posting requirements.

As a more detailed document with many concepts more precisely covered, GPP2 was ideal for helping publication professionals establish internal guidelines and ways of working. Having such externally written guidance also lent credence to the idea that publication professionals brought value to their employers and reinforced the ability of writers to insist on ethical working practices.

GPP3 – 2015

As with the original guidelines, GPP2 resulted in numerous unanswered questions and requests to include more detail and additional topics. The most recent version, GPP3, published in late 2015, has therefore continued to build on the original guidelines.⁴ It focusses on the core values of GPP and GPP2 and also adds further detail and an improved organisation to enhance clarity and eliminate redundancy. Sections already present in GPP2 have been built upon and updated, taking into account the evolution of publication and data dissemination practices. GPP3 starts with a list of 10 key publication principles, which are intended to support the six core principles of GPP: integrity, transparency, completeness, accuracy, accountability and responsibility. These 10 principles can also serve as a checklist for authors and medical writers.

Authorship

Notable changes in publication practice occurred following revisions to the ICMJE requirements for authorship in 2010 and 2013 (and which have been further revised in December 2015). These include addition of a fourth criterion to the original three criteria for authorship:⁵

“Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.”

Authorship is a grey area that seems to generate more disputes and problems in manuscript preparation than any other – despite the ICMJE criteria and the extensive attention it gives to the subject of authorship.⁵ GPP3 therefore also addresses authorship, with the intent of clearly identifying and defining authorship. A specific intention is to eliminate, once and for all, the practices known as guest authorship and ghostwriting. Publication professionals are aware of these concepts and avoid them, but having them defined in GPP3 makes it easier to communicate this knowledge to colleagues and ensures that they are recognised as unacceptable practices.

Another authorship issue that frequently arises is the question of payment and reimbursement of an author's time for their role in manuscript development. GPP3 provides additional guidance and clarity on this divisive issue – even the authors of GPP3 had differing perspectives. Other authorship issues, such as author number, author order, deceased authors, and authors no longer with the company, are specifically addressed in a table.

Role of professional medical writers

Two common questions for publication professionals are how they justify their role in manuscript preparation and why they are not then themselves authors? GPP3 attempts to address both questions, notably by presenting published data supporting the importance of medical writers in improving the quality of submitted manuscripts. In defining the need for professional writers,

GPP3 also provides recommendations on how they should work with authors. A key recommendation is to clearly establish defined roles and responsibilities before writing starts. Also discussed is how the role of the medical writer may, in certain circumstances, result in authorship. As in GPP2, GPP3 recommends written agreements for authors, medical writers, and agencies, as well as establishing publication steering committees. GPP3 also recommends that, for transparency, any writing contribution must be acknowledged along with the source of funding for such support.

GPP3 supports use of the contributorship model of authorship, wherein each author's role in the work is clearly defined and potential conflicts of interest, financial or otherwise, are disclosed, even if the target journal does not request such information. GPP3 recommends calling such information *Disclosures* because this term carries no negative connotation and is more likely to encourage greater disclosure of both financial and non-financial sources of potential conflict of interest. Use of the contributorship model may also identify gaps in contributions that should be covered by the author panel. For example, if no one is identified as having performed statistical analyses, who was responsible for ensuring the accuracy of the data or the appropriateness of the analytical methods employed? Finally, GPP3 discusses the use of author groups for large trials.

Types of articles

Noting the impact that data posting may have on publications, some guidance is given on appropriate timing. GPP3 establishes the principle that the primary publication must be published before secondary articles, which themselves must clearly identify and refer to the primary article. GPP3 briefly touches on the different types of scientific article that may be written, with some indication of the

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guidance already available for different types (e.g. PRISMA guidelines for systematic reviews). This section also covers encore presentations at different congresses.

Data sharing

Important areas of evolution since GPP2 have included clinical trial data dissemination following trial registration with data posting and data sharing with researchers.

GPP3 recognises and fully endorses all aspects of clinical trial reporting, while noting that it does not substitute for publication as a means of presenting and explaining the data in context. More importantly, data posting does not constitute prior publication, nor does it cover the ethical obligation to publish, as the researcher has an obligation to present the work in the context of current knowledge and note the contribution that the work makes.

An important point raised in GPP3 is that any publication of clinical trial data – abstract, poster or paper – should include the appropriate trial registration identifier to allow readers to identify the study. This also helps ensure that data are not published in duplicate, even unintentionally. Having mentioned duplicate publication, GPP3 does note that certain exceptions can be made for encore presentations of abstracts and posters at scientific congresses in different specialties or geographies. Equally, GPP3 advises that every effort be made to minimise plagiarism, including self-plagiarism, a concept addressed for the first time in GPP3.

Towards GPP4

GPP3 is just the latest evolution of an established process. Undoubtedly, there will be a GPP4, which will take into account further evolution in the fields of data dissemination and publication. The timing and content of GPP4 are yet to be determined. In the meantime, the GPP3 Steering Committee acknowledges that



questions will arise in the interim; so the committee, in conjunction with the International Society for Medical Publication Professionals (ISMPP), has established an online repository of questions and answers and relevant resources on publication practice (<http://www.ismpp.org/gpp3>). Further questions about GPP3 can be submitted to its authors at gpp3@ismpp.org. In future, the ISMPP-GPP3 website may serve not only as a resource but also as a platform for recruiting new members to the GPP team to work on GPP4.

What will GPP4 bring? That remains to be seen, but the feedback from reviewers of GPP3 and subsequent comments from users gives a strong hint. Typical comments have included “make it for academics too!”

“send it to universities,” and “maybe the next step for GPP3 could be guidelines for non-company-sponsored medical research?” GPP3 is endorsed by an increasingly wide range of organisations concerned with scientific communication and medical writing, including EMWA, the American Medical Writers Association, the Committee on Publication Ethics, the European Association of Science Editors, and the Japan Medical and Scientific Communicators Association. Perhaps, with the support of such organisations, GPP4 will become the go-to model for all writers of medical communications, not only of industry-sponsored studies, for increasing transparency and the quality of clinical trial reporting.

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Keith served in EMWA as President and as Editor of *The Write Stuff* (forerunner of *Medical Writing*). He has worked with various organisations concerned with ethical reporting of clinical trials, including ISMPP and TIPPA, and was a member of the Steering Committee and author for GPP3.