

RESEARCH METHODS & REPORTING

Good publication practice for communicating company sponsored medical research: the GPP2 guidelines

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In response to changes in the environment in which authors, presenters, and other contributors work together to communicate medical research the **International Society for Medical Publication Professionals** has updated the good publication practice guidelines

Authors and presenters are responsible for how medical research is interpreted and communicated. Often their work is the product of collaborations with other individuals (such as clinical investigators, biostatisticians, and professional medical writers) from around the world. Some or all of the people who contribute to this collaboration may be employees of research sponsors, contract research organisations, or medical communications agencies that may be funded by pharmaceutical, medical device, or biotechnology companies. The authors, collaborators, and organisations share responsibility for developing articles and presentations in a responsible and ethical manner.

The good publication practice (GPP2) guidelines presented here make recommendations that will help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies. These guidelines apply to peer reviewed journal articles and presentations at scientific congresses.

Evolving standards

The conduct and communication of medical research, including that sponsored by companies, continues to be criticised.¹⁻⁵ Since 2003, when the original good publication practice guidelines were published,⁶ the environment in which medical research is reported has evolved. The Declaration of Helsinki, updated in 2008, places accuracy and completeness among the primary ethical obligations of individuals communicating medical research, and suggests that “reports of research not in accordance with [its] principles should not be accepted for publication.”⁷ Information about clinical trials, including results, is being made accessible in new ways driven by regulations and guidelines from around the world.⁸⁻¹⁵ Standards for the accurate publication and presentation of research have also evolved,¹⁶ and new or updated codes of practice have been developed (table 1). The International Society for Medical Publication Professionals (www.ismpp.org) has been established and certifies the practice of individuals developing articles and presentations sponsored

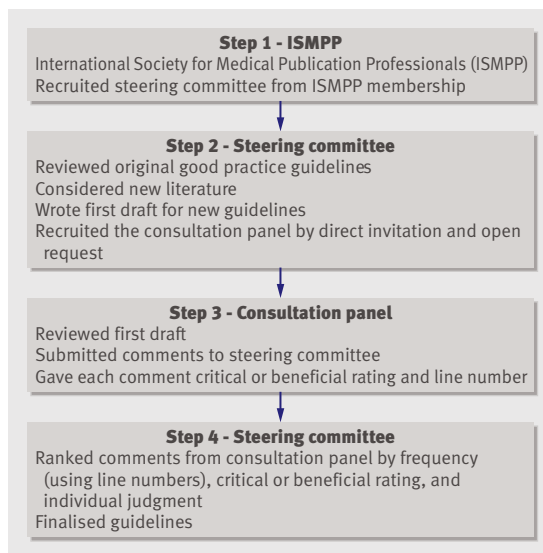
by companies. These guidelines were written in light of these developments.

Methods

The International Society for Medical Publication Professionals invited members with over 10 years of experience in biomedical publishing to develop these guidelines (figure). The 14 members named as contributors to this article responded to the invitation and formed the steering committee. The steering committee reviewed the original guidelines,⁶ discussed items to be included in the revised guidelines (GPP2), and wrote the draft guidelines.

The steering committee recruited an international consultation panel by direct invitation and multiple open requests for volunteers. The draft guidelines were circulated to the 193 people who agreed to be part of the consultation panel for comment. The consultation process was conducted in confidence (table 2).

The 116 sets of comments submitted were blinded and collated, and members of the steering committee



Methods used to write GPP2

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Accepted: 13 October 2009

Cite this as: *BMJ* 2009;339:b4330
doi: 10.1136/bmj.b4330

Table 1 | New or updated codes of practice since 2003

International Society for Medical Publication Professionals (www.ismpp.org)	Code of ethics Position statement: the role of the professional medical writer
Association of American Medical Colleges (www.aamc.org)	Report of task force on industry funding of medical education
American Medical Writers Association (www.amwa.org)	Code of ethics Position statement: the contribution of medical writers to scientific publications
Committee on Publication Ethics (http://publicationethics.org)	Multiple resources for editors
Council of Science Editors (www.councilscienceeditors.org)	White paper on promoting integrity in scientific journal publications
Elsevier (www.elsevier.com/wps/find/editorshome.editors/Introduction)	Publishing ethics resource kit
European Medical Writers Association (www.emwa.org)	Guidelines on the role of medical writers in developing peer reviewed publications
EQUATOR Network (www.equator-network.org)	Reporting guidelines—for example, CONSORT, STROBE, QUOROM/PRISMA, STARD, MOOSE
Federation of American Societies for Experimental Biology (www.faseb.org)	Conflicts of interest in biomedical research—the FASEB guidelines
International Committee of Medical Journal Editors (www.icmje.org)	Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication
Institute of Medicine (www.iom.edu/CMS/3740/47464/65721.aspx)	Conflict of interest in medical research, education, and practice
International Federation of Pharmaceutical Manufacturers and Associations (www.ifpma.org/fileadmin/pdfs/webnews/Revised_Joint_Industry_Position_26Nov08.pdf)	Joint position on the disclosure of clinical trial information via clinical trial registries and databases
International Society for Pharmacoeconomics and Outcomes Research (www.ispor.org/PEguidelines/index.asp)	Pharmacoeconomic guidelines around the world
Pharmaceutical Research and Manufacturers of America (www.phrma.org)	Principles on conduct of clinical trials and communication of clinical trial results
World Association of Medical Editors (www.wame.org/resources/policies)	WAME policy statements prepared by the editorial policy committee, including conflict of interest in peer reviewed medical journals
Wiley-Blackwell (www.wiley.com/bw/publicationethics)	Best practice guidelines on publication ethics: a publisher's perspective

Table 2 | Consultation on first draft of GPP2

Place of work	No invited or volunteered	No agreed to comment	No who commented
Academic centre or university	10	4	4
Journal editor	11	8	7
Journal publisher	18	5	2
Medical communication agency, freelance medical writer	119*	83	52
Drug, medical device, or biotechnology company	109†	76‡	43
Professional organisation	21	17	8

*One email invitation was sent but not delivered.

†Two email invitations were sent but not delivered.

‡One person was lost between invitation and opening of the consultation period.

assessed and ranked them on:

- The frequency of comments received on a particular line number
- The critical or beneficial rating given by members of the consultation panel
- The steering committee member's interpretation of the importance of the comments.

Ranked comments submitted by steering committee members were combined into a composite rank, which was used to create the final guidelines.

Guidelines and recommendations

Roles and responsibilities

Written agreement

We recommend that companies describe obligations for good publication practice in written publication agreements with authors of articles or presentations and with members of writing groups or publication steering committees. We recommend that the written agreement confirms the sponsors' responsibilities to:

- Grant authors full access to study data
- Confirm the authors' freedom to make public or publish the study results
- Provide authors with copies of the sponsor's publication policy.

We recommend that the written agreement confirms

the authors' responsibilities to:

- Plan and produce articles or presentations that are accurate and complete in a timely manner
 - Avoid premature publication or release of study information
 - Avoid duplicate publication
 - Make decisions about practical issues concerning presentation and publication (for example, choice of congress or journal)
 - Disclose potential conflicts of interest in all articles and presentations
 - Identify funding sources in all articles and presentations
 - Ensure authorship is attributed appropriately
 - Acknowledge in all articles and presentations all significant contributions made by individuals and organisations
 - Provide the sponsor with copies of publication policies from the authors' institutions
- We recommend that the written agreement confirms the shared responsibilities of all contributors, including authors and sponsors, and that it:
- Confirms that sponsors will work with investigators, authors, and contributors to report and publish studies in a timely and responsible manner
 - Defines the criteria that will be used to determine authorship for articles and presentations

- Confirms that the sponsor and the investigators will be informed about the publication process
- Provides protection to parties with intellectual property rights, and establishes a reasonable period before study results are made public for intellectual property rights to be protected
- Establishes the right of the sponsor to review, in a timely manner, articles and abstracts before they are submitted, and to share scientific comments with the authors
- Describes what, if any, support for the development of the article or presentation will be provided
- Establishes a process founded on honest scientific debate as the means to resolve scientific differences in interpretation of findings or study presentation
- Establishes that all articles and presentations will conform to good publication practice and other recognised standards (table 1)

We recommend that written agreements for articles and presentations from research studies are made at the earliest opportunity—for example, when the protocol is finalised. Written agreements for other articles and presentations (for example, meta-analyses, sub-analyses, review articles) should be made before the authors begin work.

Written agreements must respect the institutional policies of authors, investigators, and other contributors, as well as those of the sponsor. Individuals must not be asked to violate the policies of their institutions.

Access to data

Sponsors have a responsibility to share the data and the analyses with the investigators who participated in the study. Sponsors must provide authors and other contributors (for example, members of a publication steering committee or professional medical writers) with full access to study data and should do so before the manuscript writing process begins or before the first external presentation of the data. Information provided to the authors should include study protocols, statistical analysis plans, statistical reports, data tables, clinical study reports, and results intended for posting on clinical trial results websites. Sufficient time should be allowed for authors and contributors to review and interpret the data provided and to seek further information if they wish (for example, access to raw data tables or the study database).

Reimbursement

It may be appropriate for companies to reimburse reasonable out of pocket expenses (for example, travel expenses) incurred by contributors or pay for specialised services such as statistical analysis. Details of this

reimbursement must be disclosed. We recommend that no honorariums are paid for authorship of peer reviewed articles or presentations.

Publication steering committee

It may be useful to form a publication steering committee of authors and contributors to oversee and produce articles and presentations from a research study. This committee should be a small working group of individuals; its composition may change over time, and it may include:

- Members of the study steering committee and the protocol development team
- Investigators and other individuals who have expertise in the area and who are willing to interpret the data and write or review articles and presentations
- Employees of, or contributors contracted by, the sponsor company who are involved in the study (for example, clinicians, statisticians, or professional medical writers)

Members of the publication steering committee may become authors, but membership of the committee does not automatically confer authorship. For any given study, we recommend that:

- The publication steering committee is formed early (for example, when the protocol is finalised or at the end of enrolment)
- All study investigators are informed of the committee's membership and responsibilities
- Authors and contributors agree to their roles in the development of an article or presentation before writing begins.

Authors

Recognised criteria should be used to determine which of the contributors to an article or presentation should be identified as authors.

We recommend using the criteria for authorship described in the International Committee of Medical Journal Editors (ICMJE) uniform requirements (box 1).⁸ Guidance regarding authorship is also available from the World Association of Medical Editors¹⁷ and the Council of Science Editors.¹⁸ Criteria used to define authorship may vary among journals and congresses, and we recommend following individual journal and congress requirements when these differ from ICMJE criteria. ICMJE criteria allow assignment of authorship to individuals who have contributed to the analysis and interpretation of a study but who may not have contributed to its conception and design. In these instances, or if authors differ from initial plans, particular care should be taken to attribute authorship and to acknowledge contributions appropriately.

We recommend that authorship criteria are applied consistently to all contributors to an article or presentation, including investigators, sponsor employees, and individuals contracted by the sponsor. All authors listed on an article or presentation must fulfil authorship criteria, and all those who fulfil the criteria must be listed as authors. All authors should agree on the order in which

Box 1 | International Committee of Medical Journal Editors criteria for authorship⁸

Authors “should have participated sufficiently in the work to take public responsibility for relevant portions of the content” and should meet all three conditions below:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; and
- Drafting the article or revising it critically for important intellectual content; and
- Final approval of the version to be published

they appear in an article or presentation (if possible before writing begins) and should agree on any changes in authorship (for example, to ensure authorship reflects actual contributions made) before submission. Before writing begins one author (a lead author, who may also be guarantor) should take the lead for writing and managing each publication or presentation. One author (identified as guarantor) should take overall responsibility for the integrity of a study and its report.

Contributorship and acknowledgments

Contributorship and contributors

Interpretation of authorship criteria varies, and using a contributorship model to describe who did what helps to remove ambiguity.^{8 19-21} We support this approach and recommend that clear, concise descriptions of the role of each contributor during preparation of the article or presentation (including but not limited to the authors) are made in an acknowledgment within the article or presentation.

Individual contributions to an article or presentation that should be acknowledged include study conception and design, conceiving the idea for an article, conducting or managing a study, collecting data, performing statistical analysis, interpreting data, analysing published literature, drafting a manuscript, critically reviewing a manuscript, and approving a manuscript. Permission should be obtained from each individual acknowledged.

Acknowledgments

We recommend that all articles and presentations include an acknowledgment, even if not requested by the journal or congress, to describe:

- Author contributions—for example: “A and B designed the study. C was the study statistician. A and C analysed and interpreted the study data. A reviewed the literature. A, B, and C critically reviewed the manuscript and approved the final version for submission. A accepts overall responsibility for the accuracy of the data, its analysis, and this report”
- Contributions to the article or presentation from people who are not listed as authors, including name and affiliation or employer—for example: “The authors would like to thank D, YZ Pharmaceuticals, for overall management of the trial and E, WX Medical Writing, for drafting the manuscript”
- The role of the sponsor in the study and its reporting, including how the sponsor was involved in the “study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.”⁸ For example: “In collaboration with A and B, YZ Pharmaceuticals, designed the study, analysed, and interpreted the data, and edited the report. Data were recorded at participating clinical centres and maintained by YZ Pharmaceuticals. All authors had full access to the data. The authors had final responsibility

for the decision to submit for publication”

- Funding sources, if any, for the research and for the article or presentation, such as for the work of a professional medical writer. For example: “The study was funded by YZ Pharmaceuticals, the manufacturer of drug F. Medical writing services from WX Medical Writing were funded by YZ Pharmaceuticals.”

When journal or congress submission requirements do not allow inclusion of this information within the article or presentation, we recommend that it is included in a letter that accompanies the submission.

Professional medical writers

Professional medical writers work with authors to prepare abstracts, posters, slides, and manuscripts. They should ensure that authors control and direct writing and that disclosures of funding, potential conflicts of interest, and acknowledgment of contributions are made. They are required to have a good understanding of publication ethics and conventions, and ensure, in part through their collaborations with authors, that their work is scientifically appropriate.²¹⁻²³ Professional medical writers are not ghostwriters. The Association of American Medical Colleges states “transparent writing collaboration with attribution between academic and industry investigators, medical writers and/or technical experts is not ghostwriting.”²⁴ This is echoed by the US Institute of Medicine.²⁵ We recommend that authors and professional medical writers working with authors use a published checklist to discourage ghostwriting.²⁶

We recommend that particular care is taken to ensure appropriate acknowledgment of the contributions made by medical writers and to describe their funding. Companies funding the work of medical writers should ensure that writers follow good publication practice. We refer readers to guidelines from the European Medical Writers Association.²³

Working with authors

Professional medical writers must be directed by the lead author from the earliest possible stage (for example, when the outline is written), and all authors must be aware of the medical writer’s involvement. The medical writer should remain in frequent contact with the authors throughout development of the article or presentation. The authors must critically review and comment on the outline and drafts, approve the final version of the article or presentation before it is submitted to the journal or congress, approve changes made during the peer review process, and approve the final version before it is published or accepted for presentation. Authors may delegate to the medical writer (or to an assistant) the administrative tasks associated with submitting the article or presentation to a journal or congress.

As authors

Professional medical writers, depending on the contributions they make, may qualify for authorship. For example, if a medical writer contributed extensive literature searches and summarised the literature dis-

Box 2 | *BMJ*'s "Who prompted this submission?" questions²⁰

We may ask authors submitting or offering unsolicited articles, particularly reviews and editorials covering topics with related commercial interests, several questions before proceeding. Even if the answers to all of these questions were "yes," we wouldn't necessarily reject the proposal or article. We appreciate that companies can commission some excellent evidence based work and that professional writers can present that evidence in a particularly readable and clear way that benefits readers and learners. We would, however, expect such companies' and writers' contributions to be mentioned in the article. And we would want to know that the *BMJ* article did not overlap by more than 15% with any similar publications or submissions written by the same authors elsewhere. Here are the questions:

- Has anyone (particularly a company or public relations agency) prompted or paid you to write this article?
- Would/did a professional writer contribute to the article, and to what extent?
- Would the *BMJ* article be original, or would it be similar to articles submitted or published elsewhere?

covered, and by doing so helped define the scope of a review article, and if he or she is willing to "take public responsibility for relevant portions of the content"⁸ then he or she may be in a position to meet the remaining ICMJE criteria for authorship.

Conflicts of interest

We recommend that authors disclose financial relationships (for example, any financial relationships or obligation to the research sponsor or other companies, including contractual relations or consultancy fees for scientific, government, or legal services, or equity in the company) and non-financial relationships (for example, personal relationships, including those of immediate family members, and participation in litigation) that could inappropriately influence or seem to influence professional judgment. We recommend that these disclosures are made in all articles submitted for publication in peer reviewed journals, as well as in abstracts and posters submitted to congresses at the time of submission, if space requirements allow, and that they are included in oral presentations and posters at the time of presentation, regardless of whether disclosure is requested by the journal or congress.

For example: "A is a member of a speakers' bureau, has been a consultant for, and has received research grants from YZ Pharmaceuticals. C is an employee of YZ Pharmaceuticals. B has stated that she has no conflicts of interest."

There is no universal standard applied by journals and congresses for disclosure of potential conflicts of interest. Until discussions about how to address conflicts of interest are resolved,^{25 27-29} we recommend authors favour greater, rather than lesser, disclosure.

Recommendations for specific types of articles and presentations*Primary and secondary publications*

A primary article is the first full report of a study. We recommend that all articles and presentations include

statements to indicate whether they are the primary article or first presentation from a study, including for randomised clinical trials; epidemiological, observational, and descriptive studies; non-clinical outcomes research studies; and health economics studies.

Authors preparing secondary articles and presentations (including those that describe exploratory secondary analyses, national or single centre data taken from international or multicentre studies, and alternative analyses or pooled analyses of already published data) must avoid duplicate publication. All post-hoc and exploratory analyses must be clearly identified as such.

Authorship of secondary articles and presentations may differ from that of primary articles and presentations from the same study, depending on, for example, the topic of the article or presentation. We recommend that one or more authors of the primary article from a study contribute to the secondary articles and presentations from the same study.

Duplicate publication

We recommend that the same study results are not published in more than one peer reviewed journal article unless:

- The results are substantially re-analysed, re-interpreted for a different audience, or translated into a different language; and
- The primary publication is clearly acknowledged and cited; and
- The article is clearly presented as an analysis derived from the previously published primary results or is a translation, is not presented as reporting the primary results, and respects copyright law.

Presentations

Congress guidelines should be followed for presentations that describe study results that have been presented at an earlier congress. We recommend that, at the time of submission, authors disclose whether the same results will have already been presented at the time of the congress. With approval from the authors of the primary article, research submitted for presentation at national or local meetings may include authors who do not appear on the primary article (for example, to enable accurate presentation in the appropriate language).

Review articles

We recommend that review articles are comprehensive and that the methods for searching, selecting, and summarising information are clearly stated. We recommend that discussions in review articles founded principally on opinion are clearly identified as such. We also recommend that care is taken to ensure appropriate description of contributions from professional medical writers and other contributors, particularly when they may have contributed to the design of a review article or when they may have suggested the idea for the article. We refer readers to the *BMJ*'s "Who prompted this submission?" guidance (box 2).²⁰

WHAT'S NEW?

GPP2 updates earlier good publication practice guidelines.⁶

New elements include:

- An extensive consultation process was used to write the guidelines
 - Authorship guidance recommends assignment of a lead author and guarantor
 - Contributorship guidance recommends describing the role of the sponsor
 - Recommendations about reimbursement
 - Recommendations for specific types of articles and presentations
 - Recommendations for publication planning and documentation
- Updated elements include:
- Guidance on defining the roles of authors, sponsors, and other contributors
 - Guidance on establishing a publication steering committee
 - Confirmation of the role of professional medical writers

Reporting standards

We recommend that authors follow established reporting standards such as CONSORT, CONSORT for Abstracts, STROBE, PRISMA, MOOSE, and STARD.¹⁶

We offer the following brief recommendations:

- Articles and presentations should be complete, balanced, and clear
- Reference to the unique trial identifier should be included in all articles and presentations that report research from applicable clinical trials
- Interpretation of results should be unbiased, based on findings, and relevant to the audience
- Discussion of results should be unbiased, placed in the context of other relevant literature, and the evidence cited should be balanced
- Limitations of the study design and methodology should be described
- Studies with related findings should be cited, especially when previous results conflict with the results being reported.

Planning, registering, posting, and documenting

Publication planning

Publication plans can help study sponsors ensure that clinical trial results are communicated by presentation or publication to the scientific and medical community in an effective and timely manner. They can also enable sponsors to identify the timelines and resources necessary to meet their obligations for reporting and publishing clinical trial results. Authors retain responsibility for decisions about articles and presentations from individual studies, which may be described in a publication plan.

A publication plan should support authors and publication steering committees (if they exist) in their efforts to ensure appropriate, efficient, and complete communication of results by:

- Identifying submission deadlines for relevant congresses and determining which studies are appropriate to present and might have data available in time
- Identifying areas for new publications (for example, subgroup analyses, topics for pooled data analyses, post-hoc analyses, systematic reviews) and the resources required for them, such as statistical analyses
- Avoiding premature release of results
- Avoiding duplicate publication.

Before publication

Research sponsors must register and post all applicable clinical trials according to the definitions and timelines required of them by relevant legislation and guidelines.⁸⁻¹⁵ Posting clinical trial results according to the US Food and Drug Administration Amendment Act of 2007¹⁰ and the *Joint Position on the Disclosure of Clinical Trial Information*,¹¹ whether before or after submission to a peer reviewed journal, should not preclude consideration for publication.⁸

Authors may present clinical study results at congresses before publication in a peer reviewed journal. Authors and other parties with access to study results should avoid further and more detailed public reporting before publication in a peer reviewed journal, unless the circumstances are exceptional.

Authors should not submit their work for consideration by more than one peer reviewed journal at any one time. All parties should respect embargoes set by journals, congresses, and other media. For example, authors should follow journal instructions when articles are “in press” or published online ahead of print.

Documentation

We recommend that companies, and the organisations or individuals working for them, document how publications are initiated and developed. We recommend that companies implement policies detailing the types of documentation to be retained, including:

- Agreements to participate in the writing process (for example, signed and dated letter, email)
- Details of intellectual input, direction, and contributions, including comments on drafts (emails, notes from teleconferences) or drafts that contain revisions
- Main versions of the draft, to document how comments on previous versions were incorporated
- Workflow and timelines that were used to develop the document, including time taken to review and revise the document
- Approval from authors of the final version to be submitted
- Lists of participants other than authors who were allowed to review or comment on the document.

We recommend that this documentation is maintained for a period defined by the sponsor company's retention policy.

Checklists

Articles and presentations following good publication practice will show the characteristics described in table 3. Written agreements using good publication practice will cover, at a minimum, the items described in table 4.

The International Society for Medical Publication Professionals initiated the development of these guidelines. The opinions expressed here do not necessarily represent those of the authors' employers. We thank the consultation panel for their comments. We thank Elizabeth Wager, Sideview, for her work on the original guidelines⁶ that GPP2 updates (some of the earlier guidance remains in these new guidelines) and for her willingness for ISMP to sponsor the authors to write GPP2. We thank Sheema Sheikh at Excerpta Medica, Elsevier for compiling comments from the consultation.

Contributors: Jane Moore, Medtronic, and John Draper, Peloton Advantage, were

Table 3 | GPP2 checklist for articles and presentations

Characteristic	Check
Integrity	
Accurate, objective, balanced writing	
Full access to data for authors and contributors	
Absence of duplicative publications	
Honest attribution of authorship	
Completeness	
Clear description of research hypotheses	
Reporting the detail required to ensure unbiased presentation	
Complete and honest reference to related work	
Use of unique trial identifiers	
Discussion of limitations of study design and findings	
Making public or publishing results regardless of outcome	
Transparency	
Making clear sources of funding	
Disclosure of potential conflicts of interest	
Acknowledging individuals who have made significant contributions, including but not limited to those made by authors, and by description of these contributions	
Recognising the contributions of research sponsors	
Accountability	
Being accountable for the work and, in the case of authors and presenters, taking public responsibility for the work	
Assigning a guarantor	
Responsibility	
Making public or publishing results in a timely manner	
Respecting intellectual property	
Respecting the responsibilities of contributing individuals and organisations for good publication practice	

Table 4 | GPP2 checklist of basic requirements for written publication agreements

	Check
Does the agreement describe the roles and responsibilities of the sponsor, authors, and contributors?	
Confirmation of full access to data for authors and contributors	
Confirmation of authors' freedom to make public or publish the study results	
Confirmation of the intent to report or publish studies in a timely and responsible manner	
Definition of criteria that will be used to determine authorship	
Requirement that premature and duplicate publication are avoided	
Establishment of right of sponsor to review articles and presentations and responsibility to do so in a timely manner	
Establishment of process founded on honest scientific debate to resolve differences in study interpretation or presentation	
Requirement that intellectual property rights are respected	
Does the agreement confirm that all articles and presentations will conform to good publication practice and other recognised standards?	
Was the agreement established at the earliest opportunity (for example, when protocol was finalised)?	

members of the steering committee and contributed to discussions about the recommendations made in this document (JD in particular on managed care, pharmaco-economic, and health outcomes). CG wrote the first and final draft; WPB wrote the draft sections on publication planning, documentation, and conflict of interest; DB, EAF, CSM, and MP contributed to outline, intermediate drafts, and revisions; VBW wrote the draft sections on authors, contributorship, acknowledgments, and medical writers; JMC the draft duplicate publication section, JME the draft review articles section, JAG the draft publication steering committee section, and YEY the draft access to data section. MEM compiled steering committee comments after the consultation, and contributed to outline, intermediate drafts, and revisions. All the authors contributed to the literature analysis and review before writing these guidelines. All the authors contributed to the outline and to the first and subsequent drafts, to interpretation of the comments gathered during the consultation phase, and reviewed the final draft. All the authors approve this document and CG is the guarantor.

Funding: The International Society for Medical Publication Professionals provided the contributors with meeting and teleconferencing facilities and web conferencing technology.

Competing interests: All authors are members of the International Society for Medical Publication Professionals a not for profit organisation with membership comprising pharmaceutical, biotechnology, and device industries; medical communications agencies; publishers; and independent medical writers. The society is funded by its membership. WPB and JME have stock in Johnson & Johnson; VBW has stock in Novo Nordisk and Parexel; JMC has stock in AstraZeneca; JAG has stock in Wyeth; and MP has stock in Cephalon. CG is a council member of the Committee on Publication Ethics. JAG was an employee of Wyeth, which was acquired by Pfizer in October 2009. VBW was previously employed by Novo Nordisk to work with publications.

Provenance and peer review: Not commissioned; externally peer reviewed.

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- FoodandDrugAdministrationAmendmentsActof2007/default.htm.
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