Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

Wendy P. Battisti, PhD; Elizabeth Wager, PhD; Lise Baltzer; Dan Bridges, PhD; Angela Cairns; Christopher I. Carswell, MSc; Leslie Citrome, MD, MPH; James A. Gurr, PhD; LaVerne A. Mooney, DrPH; B. Jane Moore, MS; Teresa Peña, PhD; Carol H. Sanes-Miller, MS; Keith Veitch, PhD; Karen L. Woolley, PhD; and Yvonne E. Yarker, PhD

This updated Good Publication Practice (GPP) guideline, known as GPP3, builds on earlier versions and provides recommendations for individuals and organizations that contribute to the publication of research results sponsored or supported by pharmaceutical, medical device, diagnostics, and biotechnology companies. The recommendations are designed to help individuals and organizations maintain ethical and transparent publication practices and comply with legal and regulatory requirements. These recommendations cover publications in peer-reviewed journals and presentations (oral or poster) at scientific congresses. The International Society for Medical Publication Professionals invited more than 3000 professionals worldwide to apply for a position on the steering committee, or as a reviewer, for this guideline. The GPP2 authors reviewed all applications (n = 241) and assembled an 18-member steering committee that represented 7 countries and a diversity of publication professions and institutions. From the 174 selected reviewers, 94 sent comments on the second draft, which steering committee members incorporated after discussion and consensus.

The resulting guideline includes new sections (Principles of Good Publication Practice for Company-Sponsored Medical Research, Data Sharing, Studies That Should Be Published, and Plagiarism), expands guidance on the International Committee of Medical Journal Editors' authorship criteria and common authorship issues, improves clarity on appropriate author payment and reimbursement, and expands information on the role of medical writers. By following good publication practices (including GPP3), individuals and organizations will show integrity; accountability; and responsibility for accurate, complete, and transparent reporting in their publications and presentations.

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For author affiliations, see end of text.
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Incomplete, inaccurate, misleading, or delayed reporting of medical research may result in poorly informed decision making and reduce the efficiency and quality of health care (1). Therefore, scientific and clinical research should be reported in a complete, accurate, balanced, and timely manner. Such research is often initiated by, or involves collaboration with, commercial organizations, such as pharmaceutical, biotechnology, medical device, and diagnostics companies. This updated Good Publication Practice guideline, known as GPP3, is designed primarily to help individuals and organizations maintain ethical practices when they contribute to the communication of this type of research. The principles of GPP3 apply to all research, however, so we expect that this guideline will be applicable to all medical and health care professionals involved in publications.

The GPP guideline, published in 2003 (2) and updated in 2009 (as GPP2) (3), has been widely adopted. In an international survey of almost 500 people involved in publishing industry-sponsored research, more than 90% of respondents said they routinely referred to GPP2, which is a similar proportion to those who reported using International Committee of Medical Journal Editors (ICMJE) guidelines (4). The GPP guidelines have also been endorsed by medical journals (5) and cited in their instructions to authors.

The latest revision, GPP3, reflects changes in the medical publications environment and aims to clarify and strengthen the principles and practices described in earlier versions. This guideline also reflects some important changes from GPP2 (Table).

Throughout the guideline, we use the term "publications" to include the full range of formats published in peer-reviewed journals (for example, original research articles, short reports, reviews, or letters to the editor) and "presentations" to include abstracts, posters, and slides for oral presentations at scientific congresses. "Sponsors" are organizations that provide primary support, which may include funding, for a study. "Publication professionals" are professional medical writers, publication planners, and publication managers, usually working either in or for companies. This guideline does not cover regulatory documents, medical education programs, or marketing or advertising materials, all of which are regulated or accredited by specific national or regional authorities.

METHODS

In August 2013, an e-mail invitation was sent to more than 3000 professionals from around the world, including International Society for Medical Publication Professionals (ISMPP) members (n = 1630); persons invited to review GPP2 (n = 288); and a distribution list from the Medical Publishing Insights and Practices initiative that included approximately 1400 investigators, researchers, and journal editors. Candidates were invited to volunteer as members of the GPP3 steering committee or reviewers (or both). Eight GPP2 authors screened the applications (n = 241). Of 118 steering committee applicants, 11 were chosen and joined 7 of the former GPP2 authors to provide a broad range of perspectives (from 7 countries, including employees of pharmaceutical, biotechnology, medical device, and

Table. What Is New in GPP3?

Guidance on updated ICMJE 2013 authorship criteria
Guidance on common issues about authorship
Guidance and improved clarity on author payment and reimbursement
Additional clarity on what constitutes ghost or guest authorship
Expanded information on the role and benefit of professional medical writers
Guidance for appropriate data sharing
Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues

GPP3 = Good Publication Practice 3 guideline; ICMJE = International Committee of Medical Journal Editors.

medical communication companies; freelance writers; journal editors; and publishers). From that first round of invitations, 153 applicants agreed to participate as reviewers. Personal invitations from steering committee members added 21 editors and academics to the reviewer list (Figure).

The steering committee used a repeated survey process to reach consensus on the scope, title, and format for the new version. After agreement on the outline, subcommittees updated or developed specific sections. The draft GPP3 guideline was circulated to the reviewer panel after a first full draft was developed, edited, reviewed, and approved by the steering committee (Figure).

The 94 sets of responses, comprising more than 2100 comments, were anonymized, collated, assessed, and ranked by steering committee members based on the frequency of comments received on a particular section, whether reviewers had marked the comment as critical (that is, a substantive disagreement) or beneficial (that is, a clarification or suggestion), and the steering committee members' interpretation of the importance of the comment.

The list of ranked comments was then reviewed and discussed by the steering committee. Subcommittees for each section also evaluated all comments relating to their section and revised that section accordingly.

Role of ISMPP

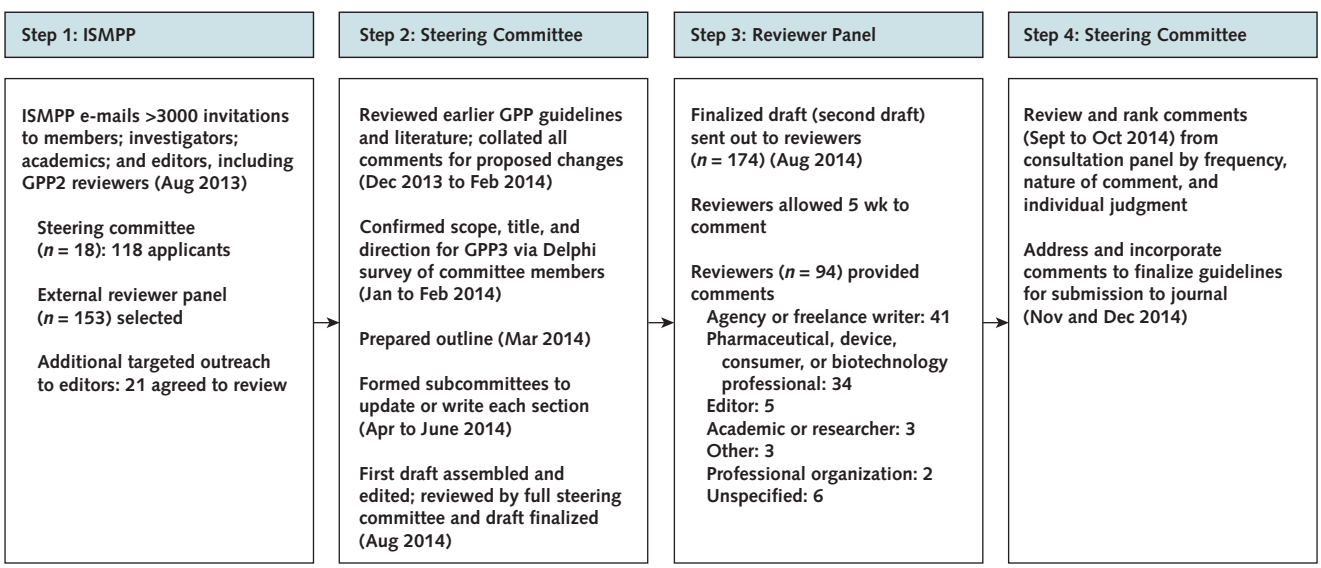
The development of the GPP3 guideline was initiated and sponsored by ISMPP. The sponsor provided the resources to help assemble the GPP3 steering committee by providing administrative assistance, granting access to the mailing list of ISMPP members, sending out e-mails to members and potential reviewers, managing the database of respondents, setting up the reviewer Web site, and updating the GPP Web site. Several of the steering committee members are also members of the ISMPP Board of Trustees. However, they acted as individuals, and not on behalf of ISMPP, in contributing to GPP3. The ISMPP staff did not direct or control the content of this guideline.

PRINCIPLES OF GOOD PUBLICATION PRACTICE FOR COMPANY-SPONSORED MEDICAL RESEARCH

1. The design and results of all clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner.

2. Reporting and publication processes should follow applicable laws (for example, Food and Drug Administration Amendments Act of 2007) and guidelines (for example, ICMJE recommendations and reporting guidelines found on the Enhancing the QUAlity and Transparency Of health Research [EQUATOR] Network).

Figure. Methods used to develop GPP3.



GPP = Good Publication Practice; ISMPP = International Society for Medical Publication Professionals.

3. Journal and congress requirements should be followed, especially ethical guidelines on originality and avoiding redundancy (that is, duplicate publication).

4. Publication planning and development should be a collaboration among all persons involved (for example, clinicians, statisticians, researchers, and publication professionals, including medical writers) and reflect the collaborative nature of research and the range of skills required to conduct, analyze, interpret, and report research findings.

5. The rights, roles, requirements, and responsibilities of all contributors (that is, authors and any nonauthor contributors) should be confirmed in writing, ideally at the start of the research and, in all cases, before publication preparation begins.

6. All authors should have access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

7. The authors should take responsibility for the way in which research findings are presented and published, be fully involved at all stages of publication and presentation development, and be willing to take public responsibility for all aspects of the work.

8. Author lists and contributorship statements should accurately reflect all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors should also be disclosed.

9. The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research should be fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings should also be disclosed.

10. All authors and contributors should disclose any relationships or potential competing interests relating to the research and its publication or presentation.

For the complete GPP3 guideline, please see **Appendix 1** (available at www.annals.org).

FUTURE DIRECTIONS

We hope that GPP3 will complement the many useful guidelines and recommendations that are available (for example, those from the American Medical Writers Association, Council of Science Editors, Committee on Publication Ethics, European Association of Science Editors, European Medical Writers Association, ICMJE, International Federation of Pharmaceutical Manufacturers & Associations, ISMPP, Medical Publishing Insights and Practices, and World Association of Medical Editors) and encourage adherence to and further research on responsible publication practices. We recognize that, to be effective, guidelines must be evidence-based, well-understood, and widely followed. This requires active research, promotion, education, and monitoring. Awareness and knowledge of publication guidelines are generally high among publication professionals, especially those working in biopharmaceutical and medical communication companies and those who belong to organizations, such as ISMPP, American Medical Writers Association, and European Medical Writers Association (4). However, work is needed to ensure that good practice is followed in all sectors and all world regions. We encourage journals, congresses, and academic institutions to endorse GPP3 and help disseminate it throughout the research community.

From Janssen Research & Development, Raritan, New Jersey; Sideview, Princes Risborough, United Kingdom; Novo Nordisk, Bagsværd, Denmark; Nucleus Global, London, United Kingdom; Ashfield Healthcare Communications, Macclesfield, United Kingdom; PharmacoEconomics, Springer International Publishing, Cham, Switzerland; New York Medical College, Valhalla, New York; MedImmune, Gaithersburg, Maryland; Pfizer, New York, New York; Medtronic, Mounds View, Minnesota; Bristol-Myers Squibb, Philadelphia, Pennsylvania; Baxalta, Deerfield, Illinois; Keithveitch Communications, Amsterdam, The Netherlands; ProScribe (Envision Pharma Group), Sydney, Australia; and Medicite, Yardley, Pennsylvania.

Note: Inquiries about the GPP3 guideline can be made at gpp3@ismpp.org.

Disclaimer: The opinions expressed in this guideline by the authors do not necessarily represent those of their employers.

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Disclosures: Dr. Battisti is an employee of Janssen Research & Development and reports nonfinancial support from the ISMPP outside the submitted work. Dr. Wager reports personal fees from various universities, scholarly societies, drug companies, and publishers for training and consultancy outside the submitted work. Ms. Baltzer is an employee of Novo Nordisk and owns stock in the company. Dr. Bridges is an employee of Nucleus Global, which provides medical education services, including medical writing and publication planning, to the pharmaceutical industry; he is a member of the Board of Trustees of ISMPP, which is a not-for-profit organization that is focused on the ethical and effective publication of medical research to inform treatment decisions. Ms. Cairns is an employee of Ashfield Healthcare Communications, which provides services, including publication planning and professional medical writing, to pharmaceutical, medical device, and diagnostics industries and authors; she has served on several ISMPP committees, including the Certification Board of Trustees. Mr. Carswell is a salaried employee of Springer Science+Business Media. Dr. Citrome reports personal fees from Actavis (Forest), Alexza Pharmaceuticals, Alkermes, Bristol-Myers Squibb, Eli Lilly, Forum Pharmaceuticals (En-Vivo), Genentech, Janssen, Jazz Pharmaceuticals, Lundbeck, Merck, Medivation, Mylan, Novartis, Noven Pharmaceuticals, Otsuka, Pfizer, Reckitt Benckiser, Reviva Pharmaceuticals,

Shire, Sunovion Pharmaceuticals, Takeda Pharmaceutical Company, Teva Pharmaceutical Industries, and Valeant Pharmaceuticals International for consultancy; personal fees from Actavis (Forest), AstraZeneca, Janssen, Jazz Pharmaceuticals, Lundbeck, Merck, Novartis, Otsuka, Pfizer, Shire, Sunovion Pharmaceuticals, Takeda Pharmaceutical Company, and Teva Pharmaceutical Industries for work as a speaker; other items (stocks [small number of shares of common stock] and long-term ownership) from Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Merck, and Pfizer outside the submitted work; and is the Editor-in-Chief of the *International Journal of Clinical Practice*. Dr. Gurr reports work with MedImmune and Bristol-Myers Squibb under a contract with Aerotek Scientific outside the submitted work and holds Pfizer stock. Dr. Mooney is a Pfizer employee, holds Pfizer stock, and is on the Board of Trustees and a steering committee member of the Medical Publishing Insights and Practice initiative. Ms. Moore is a member of ISMPP; she is an employee and shareholder of Medtronic. Dr. Peña reports stock awards from Bristol-Myers Squibb and AstraZeneca outside the submitted work; she is an employee of Bristol-Myers Squibb and the Board of Trustees chair for ISMPP. Ms. Sanes-Miller reports employment at AstraZeneca from 2008 to 2012 and stock in the company. She is currently employed at Baxalta and has stock in the company. She was a member of the ISMPP Certification Board of Trustees from 2010 to 2014 and chair from 2013 to 2014; she is currently a member of ISMPP. Dr. Veitch is a freelance consultant in medical publications, having previously managed publication groups at GlaxoSmithKline Biologicals, Sanofi Pasteur, and Novartis Vaccines and Diagnostics; he has recently been a paid consultant for Takeda Vaccines and the Bill & Melinda Gates Foundation and is a member of the ISMPP European Union committee. Dr. Woolley reports personal fees from ProScribe (Envision Pharma Group) outside the submitted work; she is actively involved in not-for-profit organizations that encourage ethical medical publication practices. Dr. Woolley voluntarily serves on the Board of Trustees of ISMPP, which has sponsored the development of GPP3. She conducts research on the value and integrity of medical publication professionals and provides ethical medical writing support and training courses, particularly to authors from low- and middle-income countries. Dr. Yarker reports nonfinancial support from ISMPP and Ashfield Healthcare during the conduct of the study; she is the chair elect of the ISMPP Board of Trustees, past chair of the ISMPP Ethics Committee, and past treasurer of the ISMPP Board of Trustees. In addition, Drs. Battisti, Bridges, Gurr, Woolley, and Yarker; Ms. Cairns; Ms. Moore; and Ms. Sanes-Miller are ISMPP Certified Medical Publication Professionals. Further details about contributorship and the steering committee for GPP3 can be found in **Appendix 2** and **Appendix 3** (available at annals.org), respectively. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-0288.

Requests for Single Reprints: Elizabeth Wager, PhD, Sideview, 19 Station Road, Princes Risborough, Buckinghamshire HP27 9DE, United Kingdom; e-mail, liz@sideview.demon.co.uk.

Current author addresses and author contributions are available at www.annals.org.

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Current Author Addresses: Dr. Wager: Sideview, 19 Station Road, Princes Risborough, Buckinghamshire HP27 9DE, United Kingdom.
Ms. Baltzer: Novo Nordisk A/S, Novo Alle 1, DK-2880 Bagsværd, Denmark.
Dr. Bridges: Nucleus Global, Admiral House, 76–78 Old Street, London EC1V 9AZ, United Kingdom.
Ms. Cairns: Ashfield Healthcare Communications, Victoria Mill, Windmill Street, Macclesfield, Cheshire SK11 7HQ, United Kingdom.
Mr. Carswell: Adis International, 41 Centorian Drive, Private Bag 65901, Mairangi Bay, Auckland, New Zealand 0754.
Dr. Citrome: New York Medical College, 11 Medical Park Drive, Suite 106, Pomona, NY 10970.
Dr. Gurr: MedImmune, 1 MedImmune Way, Gaithersburg, MD 20878.
Dr. Mooney: Pfizer, 235 East 42nd Street, New York, NY 10023.
Ms. Moore: Medtronic, 8200 Coral Sea Street, Mail Stop MVS-66, Mounds View, MN 55112.
Dr. Peña: Bristol-Myers Squibb, Route 206 and Province Line Road, Mail Stop J43-05, Princeton, NJ 08543.
Ms. Sanes-Miller: Baxalta, 1 Baxter Parkway, Deerfield, IL 60015.
Dr. Veitch: Keithveitch Communications, Pieter Aertszstraat 48-3, 1073 SP Amsterdam, The Netherlands.
Dr. Woolley: ProScribe-Envision Pharma Group, Level 1, 6-10 Talavera Road, Macquarie Park, NSW 2113, Sydney, Australia.
Dr. Yarker: Medicite, 1493 Scarlet Oak Road, Yardley, PA 19067.

Author Contributions: Conception and design: W.P. Battisti, E. Wager, D. Bridges, A. Cairns, C.I. Carswell, L. Citrome, J.A. Gurr, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.
Analysis and interpretation of the data: W.P. Battisti, E. Wager, L. Baltzer, D. Bridges, A. Cairns, C.I. Carswell, J.A. Gurr, L.A. Mooney, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.
Drafting of the article: W.P. Battisti, E. Wager, L. Baltzer, D. Bridges, A. Cairns, C.I. Carswell, L. Citrome, J.A. Gurr, L.A. Mooney, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.
Critical revision of the article for important intellectual content: W.P. Battisti, E. Wager, L. Baltzer, D. Bridges, A. Cairns, C.I. Carswell, L. Citrome, J.A. Gurr, L.A. Mooney, B.J. Moore, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.
Final approval of the article: W.P. Battisti, E. Wager, L. Baltzer, D. Bridges, A. Cairns, C.I. Carswell, L. Citrome, J.A. Gurr, L.A. Mooney, B.J. Moore, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.
Administrative, technical, or logistic support: W.P. Battisti, A. Cairns, B.J. Moore, T. Peña, K. Veitch, Y.E. Yarker.
Collection and assembly of data: W.P. Battisti, L. Baltzer, D. Bridges, C.I. Carswell, J.A. Gurr, L.A. Mooney, B.J. Moore, T. Peña, C.H. Sanes-Miller, K. Veitch, K.L. Woolley, Y.E. Yarker.

Appendix 1: GPP3 Guideline and Recommendations

1: Publication Processes

1.1: Publication Planning

Publication plans help research sponsors ensure that findings are published and presented in a responsible, ethical, complete, and timely manner. Plans also establish timelines and necessary resources (6). However, authors must retain responsibility for decisions about the content and timing of individual publications and presentations.

Publication plans should support authors and publication steering committees (section 1.2) by

- ensuring that both positive and negative findings are published;
- ensuring timely presentation of data by identifying abstract submission deadlines for relevant congresses and determining when data will be available for presentation;
- prioritizing the primary publication (reporting prespecified primary end points or objectives) over any secondary publications;
- ensuring background information (for example, new methods or techniques) is published before clinical data using those techniques are presented or published;
- identifying scientific and clinical needs for additional publications (for example, reports of secondary or subgroup analyses, pooled data analyses, or systematic reviews); and
- avoiding redundant (sometimes called "duplicate") publication (section 1.5).

The sponsor should develop publication plans internally using a cross-functional publications team that may include clinicians, statisticians, preclinical and translational scientists, health outcomes specialists, medical affairs representatives, and publication professionals. Commercial functions should neither direct publication planning or development nor be involved in publication review or approval (4, 7).

1.2: Publication Steering Committees

A publication steering committee may be formed to plan and oversee the development of publications and presentations from a study or group of studies. The publication steering committee is initiated by the sponsor, usually by a person with responsibility for the study (for example, the clinical study lead) or a publication professional, who in consultation with a multidisciplinary group of colleagues (for example, clinicians and statisticians) selects the steering committee chair and members. The publication steering committee may be a subgroup of the trial steering committee, which is responsible for the design and execution of the study.

As with any committee, the publication steering committee will work more efficiently if the number of participants is limited. The committee's composition may change over time and include study investigators, employees of the sponsor (for example, scientists, clinicians, or statisticians), contractors involved in the study, persons with expertise in the therapeutic area, or publication professionals (for example, publication planners, managers, or medical writers).

Members of the publication steering committee may become authors (section 2.3) if they meet all ICMJE (or journal-specific) authorship criteria, but committee membership does not automatically confer authorship. We recommend that

- the committee is formed before results are available (for example, before database lock) to allow time for adequate discussion and initial planning of all proposed presentations and publications;
- a charter or guidance document describing the roles and responsibilities of the publication steering committee is developed, especially if the research involves international and multi-institution collaboration;
- all study investigators are informed of the committee's membership and its responsibilities;
- the committee meets as often as required and as data become available to review and update the publication plan; and
- members of the committee agree to their role or roles (if any) in the development of each publication or presentation (for example, author, contributor, writer, or reviewer) before writing begins.

We also recommend that an authorship working group is formed by members of the publication steering committee to ensure appropriate and transparent authorship decisions, which is described in the recent Medical Publishing Insights and Practices authorship framework initiative (8).

1.3: Studies That Should Be Published

Findings from all clinical trials (including noninterventional studies involving human participants) should be made public, ideally by publication in a peer-reviewed journal. Research results should be submitted for publication in a peer-reviewed journal regardless of whether the findings are positive, negative, or inconclusive or whether the studied intervention is investigational, is licensed, or has been discontinued or withdrawn from the market (9–11). However, not all studies produce publishable data. In such situations (for example, when the data are of limited scientific or clinical value or in the case of multiple journal rejections), posting results on a public Web site, trial registry site (for example, ClinicalTrials.gov or the European Clinical Trials Database [EudraCT]), or data repository may be an option for disclosure.

1.3.1: Timing of Publications. For licensed products, manuscripts should ideally be submitted within 12 months (or 18 months at the latest) of study completion, allowing for congress presentation first (if required). For investigational products, manuscripts should be submitted within 12 months (or 18 months at the latest) of product approval or within 18 months of product discontinuation (10).

The primary publication or publications should clearly, accurately, and comprehensively describe the methods and results for the primary study outcome or outcomes, as defined in the protocol, and safety data. Secondary outcomes, exploratory analyses, and post hoc analyses should be clearly identified as such; these may be included in the primary publication or published separately, in which case they should clearly reference the primary publication and should not be published before it.

Public posting of summaries of clinical trial results on trial registries (for example, ClinicalTrials.gov or EudraCT) does not constitute prior publication and does not preclude the ethical obligation to attempt to publish the complete methods and findings (7). Likewise, presentation of results at congresses does not constitute or substitute full publication in a peer-reviewed journal.

1.4: Premature Publication

Embargoes set by journals, congresses, or other media must be respected. For example, authors, sponsors, and institutions should not issue a press release about an article that has been accepted for publication without consulting the journal.

1.5: Redundant (or Duplicate) Publication

Specific findings from a particular study should not be published in more than 1 peer-reviewed journal unless certain conditions are met (7), including

- the results are substantially reanalyzed, reinterpreted for a different audience, or translated into another language;
- the primary publication is clearly acknowledged and cited and the trial registration number of the original research is included; and
- the publication is clearly presented as an analysis derived from the primary publication results or marked as a translation, with appropriate permission obtained from the previous publisher and copyright laws upheld.

Reuse of material from the authors' previous publications ("self-plagiarism" or "text recycling") should generally be avoided; however, exceptions may include descriptions of study methods or data sources

(for example, mortality statistics or safety registries). Note that copyright of published or presented content may be held by the publisher, so authors may need permission to reuse their own work.

1.6: Plagiarism

Plagiarism, the practice of taking or closely imitating the work of others without their authorization and representing it as one's own, is unethical and unacceptable (12–14). Care should be taken to ensure that any publication or presentation is original and that any copied or republished material is clearly identified as such, appropriate copyright permission is obtained, and the original author or authors and copyright holder are appropriately acknowledged (15, 16).

1.7: Trial Registration and Public Posting of Data

National and international guidelines, including the Declaration of Helsinki (9), require clinical trials to be registered on public Web sites (for example, ClinicalTrials.gov or EudraCT) before participants are enrolled. Some legislation also requires a summary of key findings of certain trials to be posted on the same Web site within a specified period after study completion. Many journals have made trial registration a prerequisite for publication (7). We support these initiatives.

Clinical trial registration or identifier numbers should be included in all presentations and publications, including abstracts, that present findings from a registered study or studies so that the source may be identified, even if this is not required by the journal or congress. Unregistered clinical trials should be declared as such, and the reason for nonregistration should be provided.

1.8: Documentation

Companies should have policies and procedures in place to document the complete process of publication and presentation development and ensure maintenance of shareable data that could be requested after publication (17). All nonsponsor-affiliated authors should be informed of such processes and the types of documents that will be retained.

Recommended documents to be retained by the sponsor include the following:

- all study-related data that support the publication (in a shareable format);
- agreements to participate in the publication development process (for example, written agreement [section 2.1], e-mails, and minutes from author meetings or teleconferences);
- details of intellectual input and other contributions, including comments on drafts;
- versions of the draft to document how comments were incorporated;
- a list of contributors other than authors who were allowed to review or comment on drafts;
- the decision on who would submit the abstract or manuscript;
- approval from authors of the final version to be submitted and the version to be published;
- disclosures from all authors and a contributorship listing (that is, who did what on the document); and
- journal or congress peer-reviewer comments and the authors' responses.

These documents should be retained according to the sponsor company's policies or procedures, or regulatory agreements that may exist, and in a way that can be audited.

2.0: Roles and Responsibilities

2.1: Written Agreement

Sponsors have a duty to ensure ethical practices are applied across all of the publications and presentations that they support. Companies should describe these obligations, and those of authors, in a written agreement with authors before work on a publication begins. The written agreement is generally not a legal document, but its receipt should be acknowledged by the authors.

The agreement should commit the authors and sponsors to work together to

- follow current good publication practices and other recognized standards;
- ensure that publications and presentations are complete, accurate, balanced, transparent, and produced in a responsible and timely manner;
- ensure that authorship and contributorship are attributed appropriately and that all meaningful contributions made by individuals and organizations are acknowledged (with permission);
- establish a process based on honest scientific debate to resolve differences in interpretation of findings or data presentation;
- disclose relevant financial and nonfinancial relationships in all publications and presentations, including potential competing interests, all sources of funding, and other types of support for the study;
- discuss practical issues, such as the choice of journal or congress, and recognize that the authors have the final decision; and
- avoid premature publication or release of study information.

In addition, the agreement should commit sponsors to

- provide authors with access to all of the study information necessary to prepare the publication or

presentation (for example, the protocol, statistical analysis plan, and study report) before writing begins, allow relevant access to anonymized patient-level data, and provide reasonable additional analyses in support of the publication on request;

- inform authors of the publication process to be followed and provide a copy of their publication policy on request;
- describe what, if any, editorial and other support may be available for development of the publication or presentation and ensure that authors are aware of, and agree to, any support to be provided;
- advise the authors of the sponsors' financial reporting requirements (if any) to comply with transparency laws and regulations, if this is relevant to editorial or other support provided by the sponsors; and
- disclose any role the sponsors will have in review of the publication or presentation (for example, for medical accuracy, intellectual property protection, or other legal or regulatory review).

The agreement should also commit the authors to take responsibility for the content, accuracy, and completeness of the publication or presentation; work together to agree to the order in which authors will be listed (for example, in descending order of contribution to the research and publication or alphabetically after the primary author); and inform the sponsors of relevant publication policies from the authors' institutions.

The agreement should state that the authors are responsible for all final decisions on publication content, for final approval of the versions for submission, and of the version for publication or presentation. It should confirm the authors' freedom to publish the study results without hindrance from the sponsors and respect the sponsors' right to review drafts in a timely manner to ensure accuracy, adherence to any regulatory requirements, and protection of their intellectual property. It should also respect the institutional policies of authors, investigators, and other contributors and policies of the sponsors. We recommend that authors should not enter into agreements that do not uphold these principles.

2.2: Authors' Access to Data

Sponsors must provide authors and other contributors with full access to relevant aggregated study data (ensuring patient anonymity is maintained) before work on a publication or presentation begins (11, 18) and any missing or final data as soon as they become available. These data should include all prespecified primary and secondary outcomes and ancillary information necessary to accurately and correctly appraise the quality and robustness of the findings (for example, study protocol, statistical analysis plan, statistical report, validated data tables, and clinical study report) and reasonable additional analyses requested by the authors. Patient confidentiality must be respected, and identifiable individual-level information should be anonymized or removed where necessary.

2.3: Authorship

2.3.1: Qualifications for Authorship. We recommend using the ICMJE authorship criteria, updated in 2013, unless the target journal or congress has different requirements (Appendix Table 1) (7). To qualify, authors must meet all 4 ICMJE criteria listed in Appendix Table 1; they should be able to identify which of their coauthors are responsible for specific parts of the work and have confidence in the integrity of their contributions. The ICMJE also recommends that persons who meet the first criterion (Appendix Table 1) should be given the opportunity to meet the other authorship criteria. It is recognized, however, that many may be involved in the design and execution of clinical trials; in our opinion, it is not feasible to offer the opportunity of authorship to all of them. Priority should be given to the key contributors who have the necessary background to analyze or interpret the findings (20).

2.3.2: Application and Guidance. Authorship criteria should be applied consistently. All authors listed on a publication or presentation must fulfill the authorship criteria (that is, there should be no guest authors), and all persons who fulfill the criteria must be listed as authors, including company- or sponsor-employed authors and contractors (that is, there should be no ghost authors). Before writing begins, the author group should identify a lead author who will direct the content development and a corresponding author who will be responsible for communicating with the journal or congress (these may, but do not have to be, the same person) (11). Appendix Table 2 lists some of the common issues about authorship and provides some guidance.

Authorship must not be used as a reward or gift for services rendered. For example, trial enrollment or technical assistance (for example, laboratory assistance, data acquisition, statistical programming, clinical trial management, or editing services) are not themselves criteria for authorship. Likewise, acquisition of funding or supervision of a research group or department is insufficient to qualify someone as an author. Authorship must represent not only a substantial intellectual contribution to both the research being reported and the development of the publication (or presentation) but also a willingness and ability to take public responsibility for these (Appendix Table 1).

2.3.3: Author Payment and Reimbursement. Companies may reimburse reasonable publication- or presentation-related out-of-pocket expenses (for example, travel and accommodation) incurred by authors and other contributors and pay for publication activities

(for example, statistical analysis, medical writing, editing, or similar services) to assist authors in the development of publications and presentations. Any such payments should reflect the services provided and be at fair market value. Details of any payments (or other forms of compensation) to authors and contributors must be fully disclosed and comply with applicable regulations and company, institutional, journal, and congress policies. Payment should never be made (or offered) simply to attract someone to be an author or influence an author's opinion. As it is difficult to prove specific intent, sponsors may choose to adopt policies that prohibit compensation for time spent authoring a publication or presentation. Payments should not be made to authors who are employed by an institution or organization that is already in receipt of funding to undertake and publish the research.

2.4: Professional Medical Writers

2.4.1: Role of the Professional Medical Writer. Professional medical writers may assist authors in preparing publications and presentations. Properly trained and experienced writers can help authors with the development of publications in a compliant, complete, and timely manner, particularly when authors have limited time or knowledge of publication ethics and current publication and reporting guidelines (7, 21–23). In addition to technical expertise, medical writers should have a good understanding of publication ethics and current publication guidelines. Training programs are provided by various organizations (for example, ISMPP, American Medical Writers Association, European Medical Writers Association, and Drug Information Association), and certification programs with enforceable codes of conduct have been introduced (ISMPP certification Web site, www.ismpp.org/certification; American Medical Writers Association certification Web site, www.amwa.org/certification).

Professional medical writers have a responsibility to ensure that findings are presented clearly, accurately, and without any intent of misleading readers (21, 24, 25). Emerging evidence suggests that the use of professional medical writers may enhance publication quality and has been associated with a reduced risk for retractions due to misconduct (26, 27).

Properly acknowledged professional medical writers are not ghostwriters (24, 28, 29). Professional medical writers should strive to ensure that authors disclose the writer's involvement and funding source and that all contributors follow good publication practices (4). The contributions of professional medical writers, their funding sources, and any other potential competing interests must be disclosed (as with all other nonauthor contributors [section 2.5]). We encourage journal editors to ask authors to complete a checklist (30) to ensure that ethical guidelines have been followed and any writing or editorial assistance is appropriately acknowledged (section 2.5).

2.4.2: Working With Authors. Before beginning work, a professional medical writer should confirm the following in writing:

- The authors will control and direct the content of the publication or presentation. The writer must receive direction from the authors at the earliest possible stage (for example, before the outline is prepared).
- All authors have agreed to the writer's involvement.
- All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities.
- The authors will disclose, at a minimum, the writer's name, professional qualifications, affiliation, funding source, and any other information required by the journal or congress.
- Good publication practices (7) will be followed.

During the development of the manuscript or presentation, the writer should be in frequent contact with the authors and ensure that the authors' contributions are documented. The writer should work with the sponsor and eligible authors to ensure that all listed authors meet applicable authorship criteria (for example, as described by the ICMJE). If needed, translation services should be provided to authors to ensure they can provide detailed feedback and contribute fully.

With the corresponding author's permission, and if allowed by the journal or congress, a medical writer (or an appropriately supervised delegate) may complete the administrative tasks associated with submitting the publication to the journal or presentation to the congress.

2.4.3: As Authors. Medical writers generally do not meet accepted authorship criteria, but there may be exceptions (for example, if they contribute substantially to a review article). If writers qualify for authorship (that is, meet ICMJE or journal-specific criteria), they should be listed as authors and their financial relationship with the sponsor should be disclosed.

2.5: Contributorship and Acknowledgments

We support the use of a contributorship model to describe each person's role in the development of a publication or presentation because this should reduce ambiguity about contributions to the work (7). Clear and concise descriptions of the role of each author and any listed nonauthor contributors (for example, statisticians, medical writers, and research personnel) should be included within the publication or presentation.

All specific journal or congress requirements for acknowledgment and disclosure should be followed.

Each person named in the acknowledgment section should review the wording describing his or her contribution and provide written permission to be included. Nonauthor contributors listed in the acknowledgment section should not be expected to approve the final manuscript or presentation, but a courtesy copy may be provided before submission. The role (if any) of the sponsor (for example, funding of the study, its publication, or writing support; involvement in the design of the study or the collection, analysis, or interpretation of the data; or review of the manuscript) should always be clearly disclosed (7).

Even if not required by the journal or congress, all publications and presentations should include the following details (7):

- Author contributions; for example, "Authors A and B designed the study. Authors A and C analyzed and interpreted the study data. Author A reviewed the literature. All authors critically reviewed the manuscript and approved the final version for submission."
- Contributions to the publication or presentation and the affiliations of any nonauthor contributors; for example, "Under the direction of the authors, Writer D (ST Medical Writing) drafted the initial version of the manuscript, and Company U provided overall trial management, performed the statistical analyses and verified the accuracy of the data presented. The sponsor (Company V) was responsible for study design, and provided a formal review of the publication, but the authors had final authority, including choice of journal."
- Sponsorship and funding sources, such as sponsorship of the study; provision of funding for an independent study; any payments to the authors; and funding of professional medical writing support, statistical analyses, or other professional services. For example, "The study was sponsored by XY Pharmaceuticals, the manufacturer of drug Z. All authors received travel expenses from XY Pharmaceuticals to meet and plan the preparation of the manuscript. Medical writing services provided by Writer D from ST Medical Writing were funded by XY Pharmaceuticals."
- Names of persons who did not contribute to the manuscript or presentation development but who deserve to be acknowledged for their contribution to the study, such as study investigators, persons who provided important technical expertise, or the participants (as a group).

When journals or congresses do not allow inclusion of this information within the publication or presentation, we recommend that it is included with the submission (if possible; for example, in a cover letter or supplementary file). At a minimum, this information should be documented in the project file.

2.6: Disclosures

When discussing relevant relationships authors may have with commercial (or noncommercial) entities, the term "disclosures" may be preferable to "conflicts of interest" or "competing interests" because these latter terms may imply actual (rather than perceived or potential) conflicts and may inadvertently prevent full disclosure if the authors interpret them narrowly or fail to consider other relationships that may affect the manuscript.

Authors should disclose financial and nonfinancial relationships that could be perceived to bias their work or influence professional judgment. In general, this means disclosing the names of, and relationship with, all pharmaceutical, biologics, medical device, and diagnostics manufacturers in which an author (or close family member) is employed, is a contractor, provides services, or has otherwise collaborated in commercial or scientific pursuits—even in the absence of direct monetary remuneration. The stock holdings and issued or pending patents of an author or family member may also be relevant. Any institutional, company, and journal disclosure requirements should also be followed. If no time frame for disclosure is specified, we recommend following the ICMJE disclosure form and using a 36-month disclosure window. Disclosure statements should be provided (on submission) for each author of a publication (31) or congress abstract (if space requirements allow). Disclosure statements should also be included in slides for oral presentations and on posters.

3.0: Recommendations for Specific Types of Publications and Presentations

3.1: Primary and Secondary Publications

For the purpose of this guideline, we define a primary publication as the first full report in a peer-reviewed journal of the primary outcomes of a study and secondary publications as additional reports of secondary or exploratory objectives, subgroup analyses, or post hoc analyses.

Primary publications should be published before any secondary publications. The primary publication or first presentation of any type of study should indicate this fact (to distinguish it from any subsequent secondary publications or presentations) and should include the clinical trial identifier.

Secondary publications should always reference the primary publication, provide the trial identifier (for example, the trial registration number), and be clearly identified as secondary publications. Secondary publications should be scientifically justified based on their value in contributing to scientific knowledge or clinical practice. Authors preparing secondary publications and presentations should avoid redundancy (that is, duplication of previously published data) and unjustified splitting

of study findings across several publications. Previous congress presentations of a study should be disclosed when a manuscript is submitted to a journal.

Authorship of secondary publications and presentations may differ from that of primary publications and presentations from the same study. We recommend that 1 or more authors of the primary publication of a study contribute to any secondary publications and presentations, either as an author or contributor, to ensure appropriate understanding and interpretation of the original study and subsequent analyses.

3.2: Presentations at Scientific Congresses

Congress guidelines should be followed for abstract submissions and presentations. Authors should disclose prior presentations at other congresses (if the abstract submission system allows) and include the trial registration number, if possible. The same authorship criteria used for journal publications (for example, as described by the ICMJE) should be used for congress presentations. A repeated presentation of the data to different congresses is permissible to reach different audiences, provided that the congress permits this "encore" presentation and copyright requirements are respected. Encore presentations should usually have the same authorship as the original presentation. However, authorship of encore presentations at national or local meetings may differ slightly (for example, to enable presentation in the appropriate language in situations where the congress does not allow nonauthor presenters), provided that all original authors agree.

3.3: Review Articles

Review articles should be comprehensive, and the methods used for searching, selecting, and summarizing information should be clearly stated. For systematic reviews, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines should be followed. Narrative literature reviews should have a clear scientific or clinical rationale (for example, educational need or literature gap) for publication. Discussions or recommendations founded principally on opinion rather than on a synthesis of the available evidence should be clearly identified as such. The sponsor's role, if any, should be acknowledged (for example, funding for medical writing or editorial support and review of the data for scientific or medical accuracy).

4.0: Reporting Standards

Authors should follow established reporting standards for specific study types (for example, CONSORT [Consolidated Standards of Reporting Trials], STROBE [STrengthening the Reporting of OBservational studies in Epidemiology], and PRISMA). These and other reporting guidelines are available on the EQUATOR Network (www.EQUATOR-network.org).

5.0: Data Sharing

Sharing and public posting of clinical trial data, including full study reports and individual patient-level data, have the potential to advance science, increase the efficiency of clinical research, and enhance transparency and trust in the process. We support these initiatives. However, publishing patient-level data may also raise concerns about confidentiality. Regulations, recommendations, and journal requirements in this area are evolving rapidly (17, 32–34). Some journals have introduced requirements to make original data, including patient-level data and redacted protocols, available in repositories or on request to qualified researchers (35, 36) or require protocols for review and public posting (37, 38). Other journals (including *Annals of Internal Medicine*) require a data-sharing statement (39).

Journal requirements for data sharing must be respected (39, 40).

We recommend that, in addition to following applicable rules, legislation, and guidelines, sponsors grant access to patient-level data to qualified researchers on request. Supplied reports should be redacted to protect patient confidentiality.

Methods of data analysis, presentation, and the definition of the study end point (which varies by local law) should be fully described and defined in all reports (including clinical trial registries) and publications.

Appendix 2: Contributorship

Authors are listed in order of lead and second author, based on their contributions, with subsequent authors listed in alphabetical order. All of the authors contributed to the outline, first and subsequent drafts, and assessment and incorporation of the comments received during the review phase; further, they approved the final draft. All of the authors reviewed each draft critically and met ICMJE criteria for authorship. All others who contributed to this document, but who did not meet authorship criteria, are acknowledged. Dr. Battisti initiated the development of GPP3 (along with Dr. Yarker), was the chair of the steering committee, and oversaw the guideline development process, including the assembling, editing, and formatting of each complete draft. Ms. Baltzer was the subcommittee lead for sections 3.0 and 4.0 and a member of the subcommittees that developed portions of sections 1.2 through 1.8 and 2.0. Dr. Battisti wrote the first draft of the abstract, introduction, aims and scope, and methods and participated as a member of the subcommittees for section 2.3. Dr. Bridges was the subcommittee lead for section 2.0 and a member of the subcommittee that developed sections 1.1 and 1.3 through 1.8. Ms. Cairns was the subcommittee lead for section 2.5 and a mem-

ber of the subcommittee that developed sections 2.1 through 2.3 and 2.6. Mr. Carswell was the subcommittee lead for section 2.3, wrote the first draft, and revised subsequent versions of that section. Dr. Citrome was the subcommittee lead for section 2.6, wrote the first draft and revised subsequent versions of that section, and was a member of the subcommittees that developed sections 1.2 and 2.1 through 2.3. Dr. Gurr was the subcommittee lead for section 1.2 and a member of the subcommittees that developed the sections 2.1, 2.2, 2.4, and 2.5. Dr. Sanes-Miller was a member of the subcommittees on sections 2.3 and 2.6 and contributed to these and other sections. Dr. Mooney was a contributor to sections 1.2, 1.3, and 5.0 and verified all references with Dr. Peña. Ms. Moore tracked the communications with the additional solicited reviewers and was a subcommittee member for sections 2.4 and 2.5. Dr. Peña participated as a subcommittee member for sections 2.6 and 5.0 and verified all references with Dr. Mooney. Dr. Veitch was the subcommittee lead for sections 1.7, 2.3, 2.4, and 5.0. Dr. Wager had the idea for including a section on general principles, wrote the first draft, and was the subcommittee lead for that section; she participated as a member of the subcommittee for section 2.4 and edited the entire manuscript before and after the review stage for clarity and consistency. Dr. Woolley was the subcommittee lead for section 2.4 and the Future Directions paragraph. Dr. Yarker initiated the development of GPP3 along with Dr. Battisti and participated as a member of the subcommittees that developed sections 1.2, 2.4, and 3.0. In addition, Dr. Wager wrote much of the first version of GPP (on which GPP2 and GPP3 were based); further, Drs. Battisti, Bridges, Gurr, and Yarker and Ms. Sanes-Miller were coauthors of GPP2.

Appendix 3: Steering Committee

Aya Tokaji (McCann Complete Medical Group, MDS-CMG Japan, Tokyo, Japan); Chris Graf (Wiley Blackwell, Oxford, United Kingdom); and Mina Patel, PhD (Biogen, Cambridge, Massachusetts), were members of the steering committee and contributed to discussions about some of the recommendations made in this document. Chris Graf was the lead author, and Dr. Patel was a coauthor of GPP2. Chris Graf shared details about the processes used for GPP2 at the initiation of the GPP3 project.

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Appendix Table 1. Authorship Criteria

ICMJE 2013 Criteria	GPP3 Guidance
Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work	"A substantial contribution is an important intellectual contribution, rather than technical assistance, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication" (19). Simply collecting data (e.g., enrolling many patients) would not necessarily be considered a qualifying criterion for authorship. Some examples of what might represent a substantial intellectual contribution include actively guiding the scientific or medical content of the publication or presentation, statistical analysis and interpretation, crafting of the discussion, and developing the protocol.
Drafting the article or revising it critically for important intellectual content	This criterion refers to revisions beyond minor corrections for grammar, language, formatting, or layout. The key is sustained intellectual contribution, the provision of substantial comments, and approval of the final version. Although preferred, it is not always feasible or necessary for authors to comment on every stage of manuscript development.
Final approval of the version to be published	To give final approval, it is necessary to have carefully read the entire manuscript from start to finish.
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	Each author is accountable for the work and should have confidence in the integrity of the other authors' contributions. Each author should be able to identify who wrote each section.

GPP3 = Good Publication Practice 3 guideline; ICMJE = International Committee of Medical Journal Editors.

Appendix Table 2. Common Issues About Authorship

Issue	GPP3 Guidance
Number of authors	Consideration should be given to the number of qualified authors needed to take responsibility for the publication. To some extent, this will depend on the complexity of the research and of the publication, but it would be unusual in biomedical research (with few exceptions) to require >10 authors to meet this need. A high number of authors calls into question whether they could all have provided "substantial intellectual contribution." Fewer authors are often preferable, and others can be acknowledged (e.g., as nonauthor contributors or collaborators). Some journals limit the number of authors allowed on a publication.
Author sequence	Authors should decide how this will be determined at the initiation of the work, including the designation of the lead and corresponding authors, who may or may not be the same person. Final order, however, should be based on authors' actual roles and contributions in the development of the publication (and therefore cannot be agreed upon until this is complete). Those who made the greatest contribution are generally listed first, but alphabetical order may also be used. It may be useful to describe in the contributorship section of the publication whether alphabetical order or some other convention was used to determine author order.
Addition or removal of author	In certain circumstances during the development of a publication, it may be necessary to add or remove an author (e.g., if an author fails to provide a substantial contribution or approve the final version of the work). In such cases, all authors should agree to the change. Only in rare cases, such as the work substantially changing in response to reviewer comments, should addition or removal of an author be considered after submission. For encore presentations of abstracts at local language congresses where presenters are required to be an author, an additional name may be added to the author list (with all authors' permission) for the purpose of presenting on behalf of the group in the local language. This person should be clearly identified as "Presenting on behalf of. . ." in the abstract author byline if possible but at least in the presentation.
Death or incapacity of an author	Should an author die after completing a major part of the work (i.e., fulfilling criteria 1 and 2 in the **Table**), posthumous authorship can be considered if agreed to by all other authors. We suggest, as a first step, seeking advice on correct attribution and process from journal instructions or the editorial office. If the journal agrees to posthumous authorship but requires submission forms to be signed, then in the case of a sponsor-employed author or a contractor, a supervisor may be the most appropriate proxy. Otherwise, a family member or person with power of attorney should be approached (19). In all cases, efforts should be made to contact the family of the deceased author to inform them of the intention and request their consent to the listing or acknowledgment.
Change of affiliation	If an author changes affiliation before the work is published, his or her affiliation should reflect where the major part of the work was done. The current affiliation and contact details should be listed in a footnote or in the acknowledgment section. Change of affiliation alone is not a valid reason to remove an author from a publication if he or she meets authorship criteria.
Company- or sponsor-employed authors	Sponsor-employed scientists and clinicians are often qualified to participate as authors of company-sponsored research publications and should have that opportunity. Such authors should not be denied authorship because of concerns about perception of bias. Whatever criteria are used to determine authorship should be applied equally to company employees, contractors, and others.
Professional writers as authors	Professional medical writers who meet applicable authorship criteria should be listed as authors. If writers do not meet authorship criteria, their contribution should be disclosed (e.g., as a nonauthor contributor in the acknowledgment section). Writers who were not involved with study design, data collection, or data analysis and interpretation (e.g., those developing a primary publication from a clinical study report) generally do not meet ICMJE authorship criteria. However, professional writers working on other types of publication (e.g., literature reviews) may qualify as authors. For guidance on professional writers as authors, please see section 2.4.

GPP3 = Good Publication Practice 3 guideline; ICMJE = International Committee of Medical Journal Editors.