How to Publish Research: A Step-By-Step Guide to Good Practice

Updated with GPP 2022!

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Planning the Trial

- Trials in humans should follow the Declaration of Helsinki (see www.wma.net) and authors should seek approval for trial conduct from an independent local, regional or national review body (e.g., ethics committee, institutional review board) (ICMJE)
- If informed consent has been obtained, this should be indicated in the published article (ICMJE)

Trial Registration

- Trial registration is required by many national and international guidelines and laws as well as by many journals and conferences (GPP)
- Trial registration numbers should be included on all publications, even if not required by the journal, to facilitate automatic linking to registry information (GPP)
- Some journals encourage pre-registration of protocols as registered reports before data collection (GPP)
- To be considered for publication in ICMJE member journals, clinical trials must be registered in a publicly available clinical trial registry, i.e., any registry that is a primary register for the WHO International Clinical Trials Registry Platform (see www.who.int/clinical-trials-registry-platform) (ICMJE)
- Authors are responsible for ensuring they have met the requirements of funding and regulatory agencies regarding the reporting of results in clinical trial registries (ICMJE)
- The clinical trial registration number should be included at the end of the article abstract (ICMJE)

Publication Agreement

- Companies should describe their obligations, and those of the authors, to ensure awareness of and adherence to ethical practices in a written agreement before work on a publication begins; this should include agreements regarding confidentiality and any data embargoes (GPP)
- The agreement should:
  - disclose the sponsor's role in the review of the publication or presentation (e.g., for medical accuracy, IP protection, or other legal or regulatory review), and provide a reasonable timeline for review to be completed (30 days is the recommended maximum)
  - describe what, if any, editorial and other support may be available for publication development
  - commit authors to take responsibility for the content, accuracy, and completeness of the publication (GPP)
- Authors should avoid entering agreements with sponsors that interfere with their access to the trial data or their ability to analyze, interpret and publish the data independently (ICMJE)

Steering Committee

- The creation of a publication steering committee is recommended for each clinical/research program and for large clinical trials expected to generate multiple peer-reviewed outputs (GPP)
- The criteria for membership should consider the needs and complexities of the research, as well as inclusivity across geographies, demographics, and job roles (GPP)
- The steering committee should be formed before results are available and all members should receive a charter outlining their responsibilities (GPP)
- In the event of a collaborative alliance between two or more organizations, the steering committee should have representation from all alliance partners, unless otherwise specified (GPP)
- Patients, caregivers, and patient advocates may be appropriate members of a steering committee and may serve as consultants, authors or contributors to publications, depending on journal/conference requirements (GPP)
- All investigators should be informed of the steering committee's membership and its responsibilities (GPP)
- Membership of the steering committee does not automatically confer authorship (GPP)
- Steering committees should meet at least annually and be formally disbanded once all relevant deliverables are complete (GPP)

Publication Working Group/Authors

- A publication working group should be formed by the steering committee, lead author, or publication professional for each publication to ensure appropriate and transparent authorship decisions (GPP)
- Reasonable efforts should be made to include all people who made intellectual contributions to trial design, analysis, and/or data interpretation as authors (GPP)
- The authors should work together to agree the order in which they will be listed; the CRediT system may be useful to build consensus around questions of authorship and byline order. The lead author may settle disputes; however, in cases of equal contributions, deferring to a neutral criterion such as alphabetical or reverse alphabetical order is recommended (GPP)
- Paid employment related to trial conduct, analysis or publication development does not disqualify a person from authorship (GPP)
- All persons who fulfill the authorship criteria according to ICMJE (see below) must be listed, including company-employed authors and contractors, for example, patients and professional medical writers (i.e., there should be no ghost authors or relinquished authors) (GPP)
- Authors should provide their ORCiD number to ensure transparency in their identity (GPP)
- Authorship should be based on:
  1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; AND
  2. Drafting the work or reviewing it critically for important intellectual content; AND
  3. Final approval of the version to be published; AND
  4. 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 (ICMJE)
- All individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript (ICMJE)
- It is the collective responsibility of the authors to determine that all people named as authors meet all four criteria; this is not the role of journal editors (ICMJE)
- Authors should be accountable for their own work and be able to identify which co-authors are responsible for other parts (ICMJE)
- Authors should be able to take public responsibility for the work and should have confidence in the accuracy and integrity of the contributions of their co-authors (ICMJE)
- When a large multi-author group has conducted the work, the group should ideally decide who will be an author before the publication is initiated, and reconfirm prior to submission (ICMJE)
- The 5-step framework can be followed to determine authorship: establish an authorship working group of core contributors before patient enrolment begins; determine which authorship contributions will be deemed substantial; implement a process to track progress towards substantial contributions; assess the documented contributions to invite those with substantial contributions to be authors; and ensure invited authors meet ICMJE criteria throughout the process (MPIP)
- Authors should be identified at an early stage (EMWA)

Author Payment

- Payment should never be made (or offered) simply to attract someone to be an author or influence an author's opinion (GPP)
- Companies may reimburse reasonable out-of-pocket, publication-related expenses (e.g., travel and accommodation) (GPP)
- Reimbursement of patients, patient advocates and/or steering committee members for their time throughout publication development is permitted (GPP)
- Companies may pay for publication activities (e.g., statistical analysis, medical writing, editing); any payments should reflect the services provided and be at fair market value (GPP)

Lead Author

- Before writing begins, a lead author should be identified who will direct the content development; joint authorship is increasingly common and acceptable if all authors agree (GPP)
- A lead author should be selected, based on their expertise and existing contributions to the intellectual work of the research being reported. This author should meet ICMJE authorship criterion 1 (GPP)

Corresponding Author

- The corresponding author is responsible for overseeing the submission process and managing communications with the journal (GPP)
- The corresponding author takes primary responsibility for communication with the journal during submission, review, and publication but duties may be delegated to one or more co-authors (ICMJE)
- The corresponding author should be available to respond to editorial queries in a timely way (ICMJE)
- The corresponding author typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and disclosures of relationships and activities, are properly completed and reported (ICMJE)
- One author should function as the primary contact between the journal and the other authors (corresponding author) (MPIP)
- The corresponding author does not need to be the lead author, but should be selected for their ability to help coordinate the review and revision process (MPIP)

Contributors

- Include a clear and concise description of the role of each author and any listed nonauthor contributors (e.g., statisticians, professional medical writers, and research personnel) in the publication, even if not required by the journal (GPP)
- Contributors to an article may include, but are not limited to, individuals who provided purely technical help, writing assistance, or general support (ICMJE)

Professional Medical Writers

- Professional medical writers should have a good understanding of publication ethics and current publication guidelines (GPP)
- Professional medical writers should be in frequent contact with the authors during the development of the manuscript (GPP)
- Documentation (e.g., author agreements, meeting minutes, publication drafts, comments and approvals) should be retained in an auditable format, in line with sponsor policies (GPP)
- A professional medical writer facilitates the development of articles (EMWA)
- Unless they have made a substantial contribution to the analysis or interpretation of the data and feel able to take public responsibility for the work, professional medical writers generally do not meet authorship criteria (EMWA)
- Professional medical writers are considered to be legitimate contributors to articles (WAME)
- Professional medical writers must follow GPP guidelines and ICMJE recommendations, consult appropriate reporting guidelines (e.g., CONSORT), ensure authors/sponsors are aware of their obligations, and keep up to date with advances in best practice (AMWA-EMWA-ISMPP)

Trial Data

- Sponsors must provide authors and other contributors with full access to all trial information necessary to prepare the publication or presentation as well as to appraise the quality and robustness of the findings (e.g., study protocol, statistical analysis plan, and trial report and relevant anonymized data) before writing begins (GPP)
- Authors and sponsors should establish a process based on honest scientific debate to resolve differences in interpretation of findings or data presentation (GPP)
- Authors should agree as to who will perform final checks for data accuracy. Authors should fulfill this responsibility as regards data; a professional medical writer, if not a byline author, should not perform the final data check (GPP)
- Manuscripts submitted to ICMJE journals reporting clinical trial results must contain a data sharing statement (ICMJE)

Journal Selection

- Authors and sponsors should discuss practical issues such as the choice of journal and conferences, with suggestions from publication professionals, but recognize that the authors have the final decision (GPP)
- Open-access or free-to-access options for publications should be used whenever possible and funds for this purpose considered when planning budgets (GPP)
- Pre-submission inquiries to journal editors about specific datasets or publications should only be done with the agreement of the authors (GPP)
- Authors should be aware of predatory or pseudo journals that accept and publish almost all submissions; they may charge article processing fees and claim to perform peer review even if they do not (ICMJE)
- The journal choice should reflect the most appropriate means of disseminating the trial findings to the target audience (MPIP)

Primary and Secondary Publications

- Author lists should remain consistent for a specific dataset, and encore presentations should list the same authors as the original presentation (GPP)
- If a colleague served as an author for a conference presentation and opts out of the byline for a subsequent manuscript, this earlier authorship should be either noted in an acknowledgment or cited (GPP)
- Care must be taken to avoid the appearance of duplicate or redundant publications (GPP)
- Encore publications and translations should be considered only to meet specific scientific needs and/or reach audiences who would otherwise lack access (GPP)
- Secondary analyses should cite any primary publication and clearly state that they contain secondary analyses (ICMJE)
- Secondary publication of materials already available in other journals or online may be justifiable when intended to disseminate important information to a wider audience, e.g., guidelines in a different language (ICMJE)
- The primary article should always be accepted for publication before other articles reporting secondary endpoints (MPIP)

PLS and Enhanced Content

- Each journal publication should be accompanied by a plain language summary (PLS) and should ideally be peer reviewed; review by a lay person, patient or plain language expert may be helpful (GPP)
- A PLS follows plain language principles and may serve many audiences, while lay summaries of publications are intended for nonexperts. A well-designed PLS may serve both functions (GPP)
- Any publication might be augmented by enhanced content, including a PLS or lay summary; these can be in text, video, audio, podcast, or infographic format (GPP)

Reporting Standards

- Results should be submitted for publication within 18 months of trial end for licensed products; for investigational products, results should be submitted within 12 months of product approval or 18 months of product discontinuation (GPP)
- Publications should follow established reporting standards for specific study types (e.g., those found on the EQUATOR Network) (GPP)
- The manuscript should follow established reporting guidelines (e.g., CONSORT for randomized trials, PRISMA for systematic reviews, STROBE for observational trials etc. as found on the EQUATOR network) (GPP)
- Authors should consult guidelines for the reporting of specific trial types, e.g., CONSORT; this helps to describe trials in enough detail for effective evaluation (ICMJE)

Outline and Subsequent Drafts

- The authors control and direct the publication content. The professional medical writer must receive direction from the authors before they undertake any writing, including an outline (GPP)
- The authors should be fully involved at all stages of publication and comments should be documented and made available to all authors (GPP)
- If conflicting comments are received, consensus should be reached through discussion with all authors/contributors (GPP)
- The sponsor should have the right to review drafts in a timely manner to ensure accuracy, adherence to regulatory requirements, and protection of intellectual property (GPP)
- Authors should have sufficient time to comment on the drafts of an article (EMWA)

Final Draft

- Authors are responsible for the content, accuracy, and completeness of the publication and its final approval (GPP)
- Once authors are satisfied with the publication draft, the professional medical writer should manage the review and approval process through the sponsor, following applicable processes (GPP)
- Nonauthor contributors should not be expected to approve the final manuscript, but a courtesy copy may be provided before submission (GPP)
- People with commercial job roles should not be involved in publication review or approval (GPP)

Figures/Tables and Copyright

- Copyright of published content may be held by the publisher, so authors may need permission to reuse their own work (GPP)
- Copyright permissions for the reproduction of previously published materials should be retained in accordance with sponsor policies (GPP)
- Written permission should be obtained from the copyright holder to reproduce any previously published figures or tables; permission is required irrespective of authorship or publisher, except for documents in the public domain (ICMJE)

Acknowledgments

- Nonauthor contributors who provided technical expertise, trial investigators or participants (often as a group), should be included in an acknowledgment statement. People who reviewed the publication and provided helpful advice may also be acknowledged (GPP)
- Each person named in the Acknowledgments should review the wording and provide written permission to be included (GPP)
- The authors will disclose, at a minimum, the professional medical writer's name, professional qualifications, affiliation, funding source, and any other information required by the journal or conference (GPP)
- Those persons who are acknowledged must provide their written permission, as acknowledgment may imply endorsement of a trial's data and conclusions (ICMJE)
- At submission, the journal should require authors to disclose whether they used artificial intelligence (AI)-assisted technologies. Humans are responsible for any submitted material that included the use of AI-assisted technologies (ICMJE)
- The precise role and affiliations of professional medical writers must be disclosed (WAME)
- Authors should acknowledge professional medical writing support, including its nature; the names, highest relevant qualification, and affiliation of the writer accountable; and the funding source for the writing support (AMWA-EMWA-ISMPP)

Conflicts of Interest/Disclosures

- Authors and sponsors should disclose all sources of funding and other sources of support, as well as relevant financial and nonfinancial relationships that could be perceived to bias their work or influence professional judgment (GPP)
- If no time frame for disclosure is specified by the journal or conference, it is recommended to follow the ICMJE disclosure form and use a 36-month disclosure window (GPP)
- Articles should be published with statements declaring authors' conflicts of interest and sources of support for the work and details of the role of the sponsor in the trial design, the collection, analysis and interpretation of data, writing the report, and the decision to publish (ICMJE)
- Perceptions of conflicts of interest are as important as actual conflicts of interest; an author's complete disclosure demonstrates a commitment to transparency and helps to maintain trust in the process (ICMJE)
- The ICMJE has developed a Disclosure Form to facilitate and standardize authors' disclosures (ICMJE)
- Authors should declare whether they had access to the trial data (ICMJE)

Contributorship

- Using a contributorship model to describe each person's role in the development of a publication or presentation is encouraged (GPP)
- Clear, concise descriptions of the roles and affiliation of each author and any listed nonauthor contributors should be included within each publication or presentation (GPP)
- Some journals now request and publish information relating to the contributions of each named participant in the research (ICMJE)
- Contributors may be acknowledged individually or as part of a group, e.g., Clinical Investigators, as long as their contributions are specified (ICMJE)

Pre-prints

- Urgent public health needs may necessitate the use of pre-prints for clinical trial data in limited circumstances to collect feedback or share critical information (GPP)
- Since pre-prints generally are not peer reviewed, they should not be a routine element of publication planning or data dissemination for company-sponsored trial data (GPP)
- Pre-prints should meet the same standards for rigor, completeness, and ethics as a peer-reviewed publication. All authors must agree to posting on a pre-print server (GPP)
- Pre-print servers should clearly identify pre-prints as not peer reviewed; require author disclosures and funding sources; have clear processes for users concerns; and document pre-print withdrawals and publication in a peer-reviewed journal (ICMJE)
- It is the authors' responsibility to ensure that pre-prints are amended to point readers to subsequent, peer-reviewed versions of the work (ICMJE)
- Pre-prints should be clearly distinguished from peer-reviewed publications, i.e., watermarked, and should clearly disclose the lack of formal peer review in the article (AMWA-EMWA-ISMPP)
- Pre-publication checks of pre-prints should be extensive, using a comprehensive checklist (AMWA-EMWA-ISMPP)
- Articles on pre-print servers that have been subsequently fully published should be marked as such and linked via the DOI to the final published version (AMWA-EMWA-ISMPP)

Journal Submission

- Authors should approve the publication version to be submitted and state a commitment to take public responsibility for the work, which may be done via email (GPP)
- Authors should not submit the same manuscript, in the same or different languages, simultaneously to more than one journal (ICMJE)
- Articles should comply with the target journal's requirements regarding:
  - format, style, language, length/word limit, graphic sizes, document format, etc.
  - cover letters
  - copyright transfer forms/license agreements, and/or
  - disclosures (MPIP)

Responding to Peer Reviewers' Comments

- Authors should evaluate peer review comments before a professional medical writer undertakes any revisions; if applicable, a sponsor employee should be responsible for obtaining any necessary reviews (e.g., intellectual property) of the updated materials (GPP)
- Substantial revisions as a result of peer-review may warrant the addition of new authors and/or acknowledgments, and should be approached in accordance with journal guidelines (GPP)
- A peer-reviewed journal is under no obligation to follow reviewer recommendations; the journal editor is ultimately responsible for the selection of all content (ICMJE)
- All reviewer and journal editor comments should be addressed before the article is re-submitted (MPIP)
- The journal editor should be advised if it is not possible to meet the original deadline for responding to reviewers' comments (e.g., if extra analysis is required) (GPP)
- In the event of rejection comments, authors may consider submitting to a second-choice journal with itemized rebuttals and relevant updates (portable peer-review) (AMWA-EMWA-ISMPP)

Acceptance/Rejection

- It is worthwhile addressing the suggestions of the peer reviewers if the article is rejected but will be re-submitted to a different journal (MPIP)
- Once an article has received final acceptance it may be cited as being "in press" (GRP)

Publication

- The authors of articles discussed in correspondence/online journal forums have a responsibility to respond to any substantial criticisms of their work (ICMJE)

Embargoes/Social Media

- Social media posts should only be made by appropriate accounts and should not violate embargoes; requests regarding social media posts should be managed by the corresponding author, who should consult/inform the other authors (GPP)
- Embargoes must be respected, e.g., authors, sponsors, and institutions should not issue press releases about accepted articles without consulting the journal (GPP)
- Many journals embargo content before publication (ICMJE)

Guideline Sources/Abbreviations

- AMWA-EMWA-ISMPP — American Medical Writers Association, European Medical Writers Association & International Society for Medical Publication Professionals (AMWA-EMWA-ISMPP) joint position statement on medical publications, preprints, and peer review. Curr Med Res Opin 2021;37(5):861-6 — http://journal.emwa.org/writing-better/amwa-emwa-ismpp-joint-position-statement-on-the-role-of-professional-medical-writers/
- EMWA — European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. Curr Med Res Opin 2005;21(2):317-21 — http://www.emwa.org/documents/about_us/EMWAguidelines.pdf
- EQUATOR — Enhancing the QUAlity and Transparency Of health Research — http://www.equator-network.org/
- GPP — Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. Ann Intern Med 2022;175(9):1298-304 — https://www.ismpp.org/gpp-2022
- GRP — Getting Research Published: an A to Z of Publication Strategy (3rd edition, 2015) — Taylor & Francis
- ICMJE — International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals - May 2022 — http://www.icmje.org/recommendations/
- MPIP — Medical Publishing Insights and Practice. Authors' Submission Toolkit: a practical guide to getting your research published. Curr Med Res Opin 2010;26(8):1967-82 — https://www.mpip-initiative.org/toolkit.html; http://www.mpip-initiative.org/uploads/pdf/authorstoolkitPDF.pdf
- MPIP: 5-step authorship framework — https://mpip-initiative.org/5-step-framework.html
- WAME — World Association of Medical Editors. Policy Statements — https://www.wame.org/policies

Version 4-b - Published May 2023