Author

Payment



Corresponding

Author

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

conferences (GPP)

data collection (GPP)

registries (ICMJE)

abstract (ICMJE)

Outline and

Trial registration is required by many

national and international guidelines

Trial registration numbers should be

required by the journal, to facilitate

included on all publications, even if not

automatic linking to registry information

Some journals encourage pre-registration

of protocols as registered reports before

To be considered for publication in ICMJE

registry, i.e., any registry that is a primary

register for the WHO International Clinical

Trials Registry Platform (see www.who.int/

Authors are responsible for ensuring they

clinical-trials-registry-platform) (ICMJE)

have met the requirements of funding

the reporting of results in clinical trial

The clinical trial registration number

Subsequent Drafts

The authors control and direct the

writing, including an outline (GPP)

publication content. The professional

the authors before they undertake any

consensus should be reached through

The sponsor should have the right to

review drafts in a timely manner to

Authors should have sufficient time to

comment on the drafts of an article (EMWA)

requirements, and protection of

intellectual property (GPP)

discussion with all authors/contributors

ensure accuracy, adherence to regulatory

medical writer must receive direction from

should be included at the end of the article

and regulatory agencies regarding

registered in a publicly available clinical trial

member journals, clinical trials must be

and laws as well as by many journals and





Companies should describe their obligations,

practices in a written agreement before work

on a publication begins; this should include

agreements regarding confidentiality and

the review of the publication or

accuracy, IP protection, or other legal

or regulatory review), and provide

describe what, if any, editorial and

other support may be available for

commit authors to take responsibility

completeness of the publication (GPP)

Authors should avoid entering agreements

a reasonable timeline for review

to be completed (30 days is the

recommended maximum)

publication development

for the content, accuracy, and

with sponsors that interfere with their

access to the trial data or their ability to

analyze, interpret and publish the data

independently (ICMJE)

presentation (e.g., for medical

and those of the authors, to ensure

any data embargoes (GPP)

The agreement should:

awareness of and adherence to ethical

disclose the sponsor's role in



Publication Working Group/Authors

Authors should be identified at an early stage (EMWA)

Secondary Publications

Author lists should remain consistent for a specific dataset, and

encore presentations should list the same authors as the original

and opts out of the byline for a subsequent manuscript, this earlier

Encore publications and translations should be considered only to

meet specific scientific needs and/or reach audiences who would

Secondary analyses should cite any primary publication and clearly

Secondary publication of materials already available in other journals

or online may be justifiable when intended to disseminate important

The primary article should always be accepted for publication before

information to a wider audience, e.g., guidelines in a different

authorship should be either noted in an acknowledgment or cited (GPP)

If a colleague served as an author for a conference presentation

Care must be taken to avoid the appearance of duplicate or

state that they contain secondary analyses (ICMJE)

other articles reporting secondary endpoints (MPIP)

Primary and

presentation (GPP)

redundant publications (GPP)

otherwise lack access (GPP)



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)

Enhanced Content

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

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)

Journal

Selection

decision (GPP)

the authors (GPP)

Authors and sponsors should discuss

practical issues such as the choice of

from publication professionals, but

journal and conferences, with suggestions

recognize that the authors have the final

Open-access or free-to-access options for

publications should be used whenever

Pre-submission inquiries to journal editors

should only be done with the agreement of

about specific datasets or publications

Authors should be aware of predatory or

pseudo journals that accept and publish

almost all submissions; they may charge

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)

article processing fees and claim to perform

possible and funds for this purpose

considered when planning budgets

Trial Data



Medical Writers

Professional

Contributors

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 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

Acknowledgments

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be retained in accordance with sponsor policies (GPP) Written permission should be obtained

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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)

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 Al-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)

Standards

Reporting

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) The authors should be fully involved at all stages of publication and comments should be documented and made available to all reporting standards for specific study types (e.g., those found on the EQUATOR Network) (GPP) If conflicting comments are received,

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)

> 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

Each journal publication should be accompanied by a plain language summary

PLS and

language expert may be helpful (GPP) A PLS follows plain language principles summaries of publications are intended for nonexperts. A well-designed PLS may serve both functions (GPP)

(PLS) and should ideally be peer reviewed;

review by a lay person, patient or plain

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

Conflicts of

Authors and sponsors should disclose all sources of funding

If no time frame for disclosure is specified by the journal or

of data, writing the report, and the decision to publish (ICMJE)

The ICMJE has developed a Disclosure Form to facilitate and

or influence professional judgment (GPP)

and use a 36-month disclosure window (GPP)

standardize authors' disclosures (ICMJE)

and other sources of support, as well as relevant financial and

nonfinancial relationships that could be perceived to bias their work

conference, it is recommended to follow the ICMJE disclosure form

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

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)

Authors should declare whether they had access to the trial data (ICMJE)

Interest/Disclosures

Contributorship

Using a contributorship model to describe each person's role in the development of a publication or presentation is encouraged

Clear, concise descriptions of the roles and affiliation of each author and any listed nonauthor contributors should be included within each publication or presentation Some journals now request and publish

information relating to the contributions of each named participant in the research

Contributors may be acknowledged individually or as part of a group, e.g., Clinical Investigators, as long as their contributions are specified (ICMJE)



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

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

company-sponsored trial data (GPP)

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

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)

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)

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)

Reimbursement of patients, patient advocates and/or steering committee members for their time throughout publication development is permitted

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)

Author



authors agree (GPP)

Lead

Before writing begins, a lead author should be identified who will direct the content development; joint authorship is increasingly common and acceptable if all

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)

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)



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

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-

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)

Journal **Submission**



Sponsors must provide authors and other

contributors with full access to all trial

publication or presentation as well as to

findings (e.g., study protocol, statistical

appraise the quality and robustness of the

analysis plan, and trial report and relevant

anonymized data) before writing begins

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

the final data check (GPP)

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

Manuscripts submitted to ICMJE journals

a data sharing statement (ICMJE)

reporting clinical trial results must contain

information necessary to prepare the

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

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

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)

(e.g., intellectual property) of the updated materials (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)

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) (GRP) In the event of rejection comments, authors may consider submitting to a second-choice journal with itemized rebuttals and relevant

Acceptance/ Rejection

Publication

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

It is worthwhile addressing the suggestions of the peer reviewers if the article is

have a responsibility to respond to any

The authors of articles discussed in correspondence/online journal forums

> 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)

Guideline Sources/ Abbreviations

AMWA-EMWA-ISMPP American Medical Writers Association, European Medical Writers Association & nternational 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

European Medical Writers Association (EMWA) guidelines on the role of

medical writers in developing peer-reviewed publications. Curr Med Res Opin Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. Ann Intern Med 2022;175(9):1298-304

Getting Research Published: an A to Z of Publication Strategy (3rd edition, 2015)

International Committee of Medical Journal Editors (ICMJE) Recommenda

for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Publishing Insights and Practice. Authors' Submission Toolkit: a practical guide to getting your research published. Curr Med Res Opin

World Association of Medical Editors. Policy Statements

copyright transfer forms/license agreements, and/or point readers to subsequent, peer-reviewed versions of the work (ICMJE) disclosures (MPIP)

Pre-publication checks of pre-prints should be extensive, using a

updates (portable peer-review) (AMWA-EMWA-ISMPP)

Many journals embargo content before publication (ICMJE)