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Planning the trial

Clinical trials in human subjects should be approved by an Institutional Review Board or an Independent Ethics Committee

IFPMA/EFPIA/JPMA/PhRMA

Clinical trials in human subjects should Follow the Declaration of Helsinki

– **www.wma.net**

ICMJE

Clinical trials in animals should follow institutional and national guidelines for the care and use of laboratory animals

ICMJE

Protocols for randomized controlled trials should follow the SPIRIT guidelines

EQUATOR

The sponsor should develop publication plans using a cross-functional publications team

GPP3

Commercial functions should not direct publication planning

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Clinical trial registration

Trial registration is required by many national and international guidelines and laws and is required by many journals

GPP3

Clinical trial registration numbers should be included on all publications even if this is not required by the journal

GPP3

Unregistered trials should be declared as such, and the reason for nonregistration provided

GPP3

In order to be considered for publication in ICMJE member journals, clinical trials must be registered in a publicly available clinical trial registry

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Publication agreement

Companies should provide authors with a copy of their publication policy on request

GPP3

Companies should describe their obligations, and those of the authors, to ensure ethical practices in a written agreement before work on a publication begins

GPP3

The agreement should commit authors and sponsors to work together to ensure that publications are complete, accurate, balanced, transparent, and produced in a responsible and timely manner

GPP3

The agreement should describe the publication process including the role the sponsors will have in reviewing the publication (if any)

GPP3

The agreement should describe what, if any, editorial and other support may be available for publication development

GPP3

Sponsors should advise authors of any financial reporting requirements relevant to providing editorial and other support

GPP3

The agreement should commit authors to take responsibility for the content, accuracy, and completeness of the publication

GPP3

The agreement should confim the authors' freedom to publish study results without hindrance from the sponsor

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Steering committee / writing group

A publication steering committee may be formed to plan and oversee the development of publications

GPP3

The committee should be formed before results are available

GPP3

All investigators should be informed of the committee's membership and its responsibilities

GPP3

Membership of the steering committee does not automatically confer authorship

GPP3

For studies involving many investigators, a writing group should be set up

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Authors

An authorship working group should be formed by the publication steering committee to ensure appropriate and transparent authorship decisions

GPP3

The authors should work together to agree the order in which they will be listed

GPP3

Authorship criteria should be applied consistently

GPP3

All authors listed on a publication must fulfill the authorship criteria (i.e., there should be no guest authors)

GPP3

All persons who fulfill the authorship criteria must be listed, including company-employed authors and contractors (i.e., there should be no ghost authors)

GPP3

Authorship must represent a substantial intellectual contribution to both the research being reported and the development of the publication and a willingness to take public responsibility for these

GPP3

Authorship must not be used as a reward or gift for services rendered

GPP3

Authorship should be based on:

- substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data
- drafting or revising the work critically for important intellectual content
- final approval of the version to be published
- 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

Authors should be accountable for their own work and be able to identify which co-authors are responsible for other parts (ICMJE)

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

Authors should be identified at an early stage

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Author payment

Companies may reimburse reasonable out-of-pocket, publication-related expenses (e.g., travel and accommodation)

GPP3

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

GPP3

Payment should never be made (or offered) simply to attract someone to be an author or influence an author's opinion

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Corresponding author

The author group should identify a corresponding author who will be responsible for communicating with the journal

GPP3

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

The corresponding author takes primary responsibility for communication with the journal during submission, review, and publication

ICMJE

The corresponding author should be available to respond to editorial queries in a timely way

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Lead author

Before writing begins, the author group should identify a lead author who will direct the content development

GPP3

The lead and corresponding author may, but do not have to, be the same person

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Contributors

Include a clear and concise description of the role of each author and any listed nonauthor contributors (e.g., statisticians, medical writers, and research personnel) in the publication even if not required by the journal

GPP3

Contributors to an article may include, but are not limited to, individuals who provided purely technical help, writing assistance, or general support

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Professional medical writers

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

All authors must agree to the involvement of a medical writer

GPP3

Writers should be in frequent contact with the authors during the development of the manuscript

GPP3

Medical writers should have a good understanding of publication ethics and current publication guidelines

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Study data

Sponsors must provide authors with access to all the information necessary to prepare the publication (e.g., protocol, statistical analysis plan, study report) and should allow relevant access to anonymized patient-level data

GPP3

Sponsors must provide authors and other contributors with full access to relevant aggregated study data before work on a publication begins

GPP3

Authors and sponsors should establish a process based on honest scientific debate to resolve differences in interpretation of findings or data presentation

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Journal selection

Authors and sponsors should discuss practical issues such as the choice of journal and recognize that the authors have the final decision

GPP3

The journal choice should reflect the most appropriate means of disseminating the study findings to the target audience

MPIP

It may be appropriate to approach a journal with a pre-submission inquiry to determine if the research is suitable for publication

MPIP

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Primary and secondary publications

So long as certain criteria are met, it is acceptable to publish primary and secondary articles from a single clinical trial

IFPMA/EFPIA/JPMA/PhRMA

A primary publication is the first full report in a peer-reviewed journal of the primary outcomes of a study; secondary publications are additional reports of secondary or exploratory objectives, subgroup analyses, or *post hoc* analyses

GPP3

Primary publications should be published before any secondary publications

GPP3

Secondary publications should always reference the primary publication and be clearly identified as secondary publications

GPP3

One or more authors of the primary publication of a study should contribute to any secondary publications to ensure appropriate understanding and interpretation of the original study

GPP3

The primary article should always be accepted for publication before other articles reporting secondary endpoints

MPIP

Secondary analyses should cite any primary publication and clearly state that they contain secondary analyses

ICMJE

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Redundant publication

Sponsors and authors should avoid redundant publication

GPP3

Specific findings from a particular study should not be published in more than one journal unless they are reanalyzed or translated, the primary publication is clearly acknowledged, permission is obtained from the publishers, and copyright laws are upheld

GPP3

Reuse of material from the authors' previous publications should generally be avoided but exceptions may include descriptions of methods or data sources

GPP3

Secondary publications should avoid redundancy and unjustified splitting of study findings across several publications

GPP3

Editors of different journals may agree to publish the same article jointly if they consider this is in the best interest of public health, such publications should include a statement making this clear to readers

ICMJE

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Reporting standards

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

GPP3

Publications should follow established reporting standards for specific study types (e.g., those found on the EQUATOR Network)

GPP3

Articles should be considered for publication in the scientific literature regardless of whether the results are positive or negative

IFPMA/EFPIA/JPMA/PhRMA

The article should follow established reporting guidelines (e.g., CONSORT, PRISMA, STROBE etc.)

EQUATOR

Results should be submitted for publication within 18 months of the study end (for licensed products) or the date of licensing/discontinuation (for investigational products)

IFPMA/EFPIA/JPMA/PhRMA & GPP3

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Outline of content

Writers must receive direction from the authors at the earliest possible stage (e.g., before the outline is prepared)

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Subsequent drafts

The authors should be fully involved at all stages of publication

GPP3

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

GPP3

Authors should have sufficient time to comment on the drafts of an article

EMWA

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Final draft

Authors are responsible for all final decisions on publication content and for final approval of the version for submission

GPP3

Nonauthor contributors should not be expected to approve the final manuscript but a courtesy copy may be provided before submission

GPP3

Commercial functions should not be involved in publication review or approval

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Figures and tables

Permission should be obtained from the copyright holder to reproduce any previously published figures or tables

ICMJE

Copyright of published content may be held by the publisher, so authors may need permission to reuse their own work

GPP3

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Acknowledgments

Ensure that all meaningful contributions to the research and publication by individuals and organizations are acknowledged

GPP3

Each person named in the Acknowledgments should review the wording and provide written permission to be included

GPP3

Those persons who are acknowledged must provide their written permission

ICMJE

The precise role and affiliations of professional medical writers must be disclosed

WAME

Vague acknowledgment of a professional medical writer's role (e.g., for providing 'editorial assistance') must be avoided

EMWA

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Conflicts of interest

Authors and sponsors should disclose relevant financial and nonfinancial relationships that could be perceived to bias their work or influence professional judgment

GPP3

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 study design, collection, analysis and interpretation of data, writing the report, and decision to publish

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Disclosures

Authors and sponsors should disclose all sources of funding and other types of support for the study

GPP3

If a medical writer helps to develop a publication, the authors should disclose the writer's name, professional qualifications, affiliation and funding source

GPP3

The role (if any) of the sponsor in the research and publication should always be clearly disclosed (e.g., involvement in study design, data collection or analysis, writing support, manuscript review)

GPP3

Any involvement by persons or organizations with an interest in the findings (financial or nonfinancial) should be disclosed

GPP3

Authors should declare whether they had access to the study data

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Journal submission

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

Authors should not submit the same manuscript, in the same or different languages, simultaneously to more than one journal

ICMJE

If the corresponding author agrees, and the journal allows this, a medical writer (or appropriate delegate) may complete the administrative tasks associated with submitting the publication to the journal

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Responding to peer reviewers' comments

All reviewer and 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)

GRP

The corresponding author should act as a point of contact between the journal and the other authors and should keep co-authors informed and involve them in decisions about the publication (e.g., responding to reviewers' comments)

WCRI

Authors should approve the version to be published

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Acceptance / rejection

Once an article has received final acceptance it may be cited as being 'in press'

GRP

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

Embargoes

Many journals embargo content before publication

ICMJE

Publication

Authors and sponsors should work together to avoid premature release of study information

GPP3

Embargoes must be respected, e.g., authors, sponsors, and institutions should not issue press releases about accepted articles without consulting the journal

GPP3