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Resources for authors and journals

# Good Publication Practice (GPP3)

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## Background to GPP

- Council of Biology Editors meeting **(Nov 1998)**
- Three-way meeting: **Journal editors / Academics / Pharmaceutical industry**
- Revealed editors' and academics' uneasiness about industry practices

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## Concerns

- Selective publication (non-publication of negative results, over-publication of positive results)
- Failure to disclose conflicts of interest
- Unacknowledged use of medical writers (ghost writers)
- Guest authorship
- Inadequate involvement of named authors

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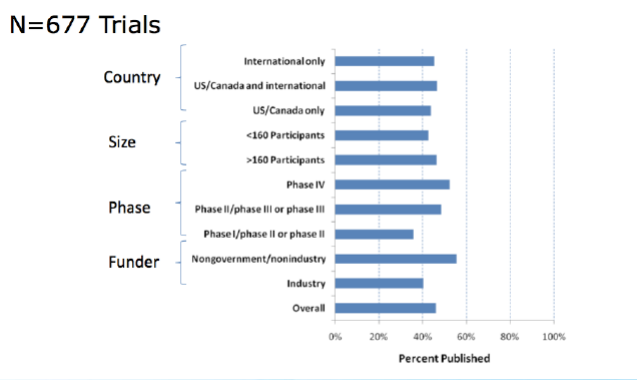
# Why do we need GPP?

## Half of all clinical trials are never published




Ross et al *PLOS Med* 2009;e1000144

Publication rate may be higher for more recent studies but publication bias affects the literature on most prescribed medicines

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# Why do we need GPP?

## Selective reporting

- Comparison of protocols cf publications (N=102)
- Found incomplete reporting of:
  - 50% of efficacy
  - 65% of safety/AE outcomes
- Statistically significant outcomes more likely to be reported
- 62% of trials had at least one **primary outcome** changed, introduced or omitted

Chan *et al JAMA* 2004;**291**:2457-65

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## Why do we need GPP?

### Honorary and ghost authors

- Surveyed 896 corresponding authors of articles published in *Annals Int Med, Lancet, JAMA, Nature Med, NEJM, PLOS Med* in 2008
- Found 21% of articles had guest or ghost authors (decrease from 29% in 1996)
- 17% of articles had guest (honorary) authors
- 8% of articles had ghost authors

Wislar *et al BMJ* 2011;**343**:d6128

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## GPP

The first GPP guidelines came out in 2003


Good publication practice for pharmaceutical companies

Elizabeth Wager[1], Elizabeth A. Field[2] and Leni Grossman[3]

[1]Sideview, Princes Risborough, Buckinghamshire, UK
[2]EMD Pharmaceuticals, Inc., Research Triangle Park, North Carolina, USA
[3]Whitehouse Station, New Jersey, USA

GPP2 published in 2010


RESEARCH METHODS & REPORTING

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

GPP3 published August 2015


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

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## Evolution of GPP

| Version | Date | Title | Published |
|---|---|---|---|
| GPP | 2003 | Good Publication Practice for pharmaceutical companies | *Current Medical Research & Opinion* |
| GPP2 | 2010 | Good publication practice for communicating company sponsored medical research: the GPP2 guidelines | *BMJ* |
| GPP3 | 2015 | Good publication practice for communicating company-sponsored medical research: GPP3 | *Annals of Internal Medicine* |

All available at www.ismpp.org

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## Authors

- GPP: Wager, Field & Grossman
- GPP2: Graf, **Battisti, Bridges**, Bruce-Winkler, Conaty, Ellison, Field, **Gurr**, Marx, Patel, **Sanes-Miller, Yarker**
  for ISMPP
- GPP3: **Battisti**, Wager, Baltzer, **Bridges**, Cairns, Carswell, Citrome, **Gurr**, Mooney, Moore, Pena, **Sanes-Miller**, Veitch, Woolley, **Yarker**

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## International author group

Authors from: US (8), UK (3), Denmark, the Netherlands, Australia, New Zealand & Steering Group member in Japan

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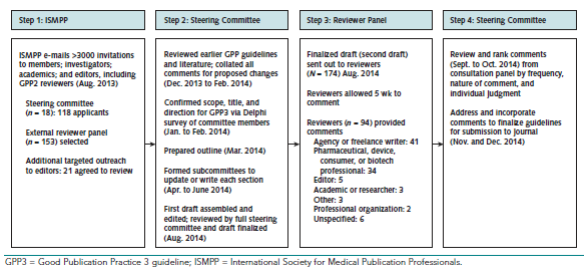
## Development

### GPP2

- 16 Steering cttee members
- 14 authors
- Draft circulated to 193
- 116 sets of comments

### GPP3

- 241 applicants (for author and/or reviewer)
- 18 Steering cttee members
- 15 authors
- Draft circulated to 174
- 94 sets of comments




GPP3 = Good Publication Practice 3 guideline; ISMPP = International Society for Medical Publication Professionals.

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## Key points

- 1st guideline to require drug companies to endeavour to publish results of all trials
- Set out roles and responsibilities of professional medical writers (so they are NOT ghost writers)
- Described relationships between investigators (authors) and companies

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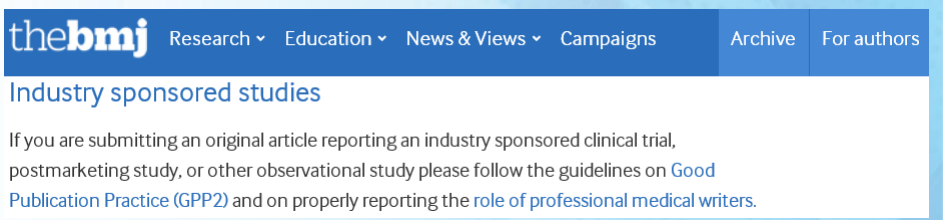
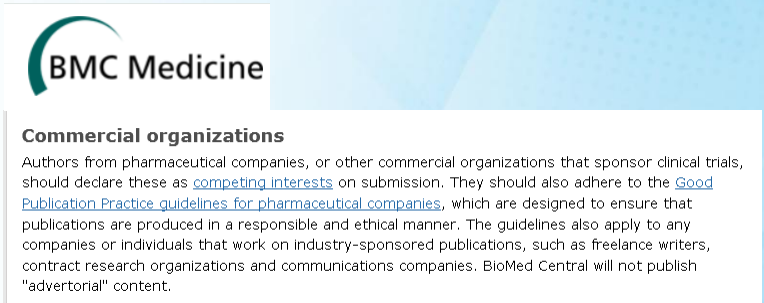
## Endorsed by journals

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# Endorsed by drug companies

Roche

**Alignment with External Standards**—Roche conducts publication activities in alignment with international regulations and industry guidelines, including Good Publications Practice (GPP), Consolidated Standards of Reporting Trials (CONSORT statement), and the ICMJE's "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (URM).

ACTELION

**USE OF PROFESSIONAL MEDICAL WRITERS**

Actelion may offer authors the assistance of professional medical writers to facilitate the development of publications. Such collaborations must follow ethically acceptable practice, as outlined in several internationally recognized guidance documents (GPP; EMWA; AMWA; ISMPP).

Journal Editors (ICMJE), intern
porting guidelines (CONSORT, S
etc.), individual journal guidelin
practice guidelines, such as Good Publication Practice (GPP); and position statements from the European Medical Writers Association (EMWA), American Medical Writers Association (AMWA) and International Society for Medical Publication Professionals (ISMPP), etc.).



# Principles of GPP

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 (eg, FDAA) and guidelines (eg, ICMJE and reporting guidelines on the EQUATOR Network).
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 (eg, 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 (ie, 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.

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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.



## The quick version

1. Publish all trials
2. Follow reporting guidelines and laws
3. Follow journal requirements
4. Involve everybody in publication planning
5. Have a publication agreement
6. Give authors access to study data, etc.
7. Authors are responsible for pub's
8. Authorship should be accurate
9. Disclose role of sponsor
10. Disclose Conflicts of Interest

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## Commitment to publish all trials

- GPP1: Companies should endeavour to publish the results from all of their clinical trials of marketed products
- GPP was the first guideline to call for this

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## GPP3

- "The design and results of all clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner" (1st principle)
- Publication plans should ensure "that both positive and negative findings are published" (1.1)
- "Findings from all clinical trials … should be made public, ideally by publication in a peer-reviewed journal" (1.3)

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- "Findings from all clinical trials … should be made public, ideally by 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." (1.3)

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## Declaration of Helsinki 2013

- **Negative and inconclusive as well as positive results must be published or otherwise made publicly available.**
- Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication. (36)

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## What about trials that are hard to publish?

- "However, not all studies produce publishable data. In such situations (e.g. 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 (e.g. ClinicalTrials.gov), or data repository may be an option for disclosure."

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## When should trials be published?

- GPP2 "timely"
- GPP3 New section (1.3.1) on Timing
- "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".

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## Authorship

- GPP (1&2) has always endorsed ICMJE criteria
- GPP3 recommends ICMJE and gives extra guidance and clarification of what this means in practice

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## Authorship

- "Authorship must not be used as a reward or gift for services rendered… Authorship must represent a **substantial intellectual contribution** to both the research being reported and the development of the publication or presentation, and the willingness and ability to take public responsibility for both" (2.3.2)

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## ICMJE authorship criteria

www.icmje.com

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising 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 parts of the work are appropriately investigated and resolved.

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## ICMJE: the essentials

Authors should:

1. take part in the research
2. take part in the publication
3. agree to be listed / the manuscript
4. take accountability

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## Contributors (ICMJE)

- "Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples include … writing assistance, technical editing, language editing, and proofreading."



## Are medical writers authors?

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

## More detail on authorship

| ICMJE | GPP3 |
|---|---|
| 1. Substantial contributions … | • intellectual contribution rather than technical (eg drafting protocol, crafting discussion, statistical analysis) |
| 2. Drafting or revising | • more than minor corrections for grammar, language, format |
| 3. Final approval | • must read the entire manuscript! |
| 4. Accountability | • each author is accountable for the work, should have confidence in other authors, should be able to identify who wrote each section |

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## Appendix Table 2

- Number of authors
- Author sequence
- Addition or removal of author
- Death or incapacity of an author
- Change of affiliation
- Company-employed authors
- Professional writers as authors

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## Payments to authors (2.3.3)

- Companies may reimburse "reasonable out-of-pocket expenses"
- May "pay for publication activities (eg statistical analysis, medical writing, editing or similar services)"
- "Any such payments should reflect the services provided and be at fair market value"



## Payments to authors (2.3.3)

- "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."

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## Acknowledgments

- Follow journal / congress requirements
- Get written permission for acknowledgments
- "Nonauthor contributors listed in the acknowledgments should not be expected to approve the final manuscript or presentation, but a courtesy copy may be provided before submission." (2.5)

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## Role of medical writers

- "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" (2.4.1)

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- "Professional medical writers have a responsibility to ensure that findings are presented clearly and accurately, and without any intent of misleading readers. Emerging evidence suggests that the use of professional medical writers may enhance publication quality and has been associated with a reduced risk of retractions due to misconduct." (2.4.1)

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## Role of steering committees (1.2)

The publication steering committee:

- is initiated by the sponsor
- may be a subgroup of the trial steering cttee
- members may become authors if the meet ICMJE criteria

- Recommends an authorship working group

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## Authorship working group

- "formed by members of the publication steering committee to ensure appropriate and transparent authorship decisions"
- As described in MPIP authorship framework initiative
- Marusic et al *BMC Med* 2014;**12**:197

## Data sharing (5.0)

- Journal requirements vary but must be respected
- "We recommend that, in addition … sponsors grant access to patient-level data to qualified researchers on request" (redacted to protect confidentiality)

## Trial registration (1.7)

- Trial registration numbers should be included (even if not required by journal / congress)
- Unregistered clinical trials should be declared as such (and the reason for non-registration provided)

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Annals of Internal Medicine RESEARCH AND REPORTING METHODS

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

## Key points

- GPP3 is relevant to any company-sponsored medical research
- It is aimed at companies and researchers
- Principles might apply to all medical research?
- Use GPP3 when planning research (e.g. discussing authorship, preparing agreements) and when publishing research
- We hope journals will endorse GPP3 and add a link in their instructions to authors

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## and there are other guidelines to be aware of:

- Declaration of Helsinki
- ICMJE Recommendations
- EMWA g/l for medical writers
- EFPIA / PhRMA statements
- WAME, CSE statements
- Individual journal requirements

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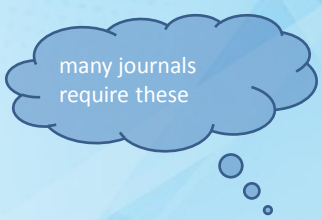
## Reporting guidelines

- CONSORT (RCTs), STROBE (obs/epi), PRISMA, STAR-D, SPIRIT (protocols)
- CHEERS – Consolidated Health Economic Evaluation Reporting Standards
- Check Equator Network www.equator-network.org

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## Reporting guidelines all available on one site:

www.equator-network.org

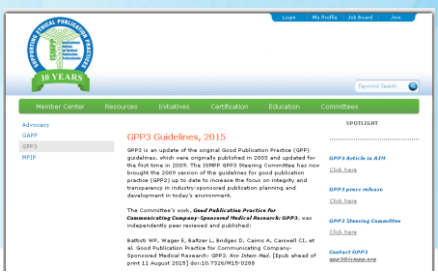



## GPP3 is freely available from *Annals of Internal Medicine*

http://annals.org/article.aspx?articleid=2424869


## Also available on ISMPP website

www.ismpp.org/gpp3



# Questions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