

GPP3: what's new?

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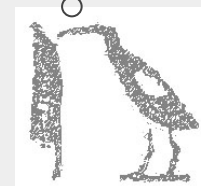


Title

Can you spot the difference?

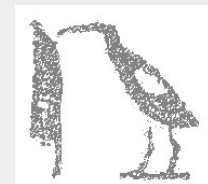
- Good Publication Practice for communicating company sponsored medical research
- Good Publication Practice for communicating company-sponsored medical research

Oh, the joys of journal house styles!



Authors

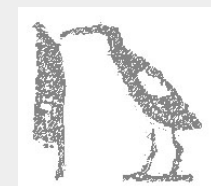
- **GPP**: Wager, Field & Grossman
- **GPP2**: Graf, **Battisti**, **Bridges**, Bruce-Winkler, Conaty, Ellison, Field, **Gurr**, Marx, Patel, **Sanes-Miller**, **Yarker** for ISMPP
- **GPP3**: **Battisti**, Wager, Baltzer, **Bridges**, Cairns, Carswell, Citrome, **Gurr**, Mooney, Moore, Pena, **Sanes-Miller**,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



International author group



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



New features

- Numbered sections
- Different order

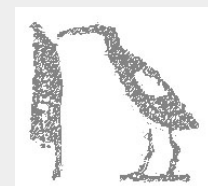
Bolder language

- We recommend → should
- **More concrete**
timely → within 12 months



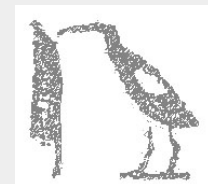
New sections

- Principles
- Studies that should be published
- Plagiarism
- Data sharing
- Tables on authorship



Principles of GPP: 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 CoIs



Why do we need 10 principles?

- Handy document
- Useful for training / promotion
- Won't need such frequent revision
- Should help determine future recommendations (in new situations)

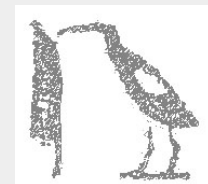


Didn't
somebody else
do this too?



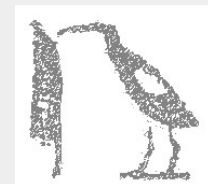
Stronger commitment to publish all trials

- GPP1: Companies should endeavour to publish the results from all of their clinical trials of marketed products
- GPP2: *Nothing specific on this (except something in checklist about publishing in a timely manner)*



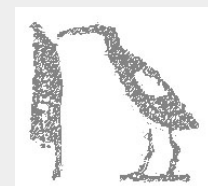
GPP3

- “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)



More specific guidance

- GPP2 “timely”
- 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”.



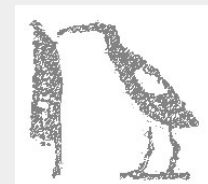
Payments to authors

GPP2

- OK to reimburse “reasonable out-of-pocket expenses”
- Co. can pay for “specialised services (eg statistical analysis)”

GPP3 (2.3.3)

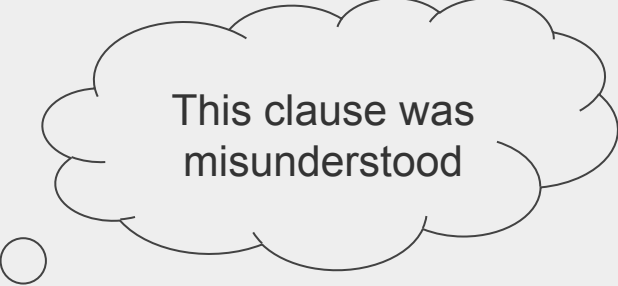
- Unchanged
- May “pay for publication activities (eg statistical analysis, medical writing, editing or similar services)”
- “Any such payments should reflect the services provided and be at fair market value”



Payments to authors

GPP2

- “No honoraria should be paid for authorship of peer-reviewed articles or presentation”



This clause was misunderstood

GPP3 (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.”



Authorship

GPP2

- Use ICMJE
- Table with ICMJE criteria

GPP3

- “Authorship must represent a substantial intellectual contribution to both the research being reported and the ... publication”
- Table with additional guidance (App Table 1)
- & App Table 2 on Common issues about authorship



Appendix Table 1

ICMJE

1. Substantial contributions
...
2. Drafting or revising
3. Final approval
4. Accountability

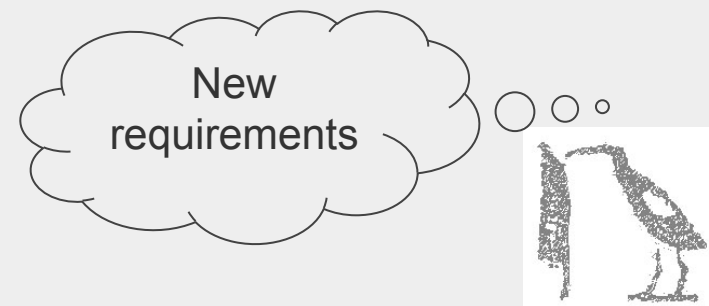
GPP3

- intellectual contribution rather than technical (eg drafting protocol, crafting discussion, statistical analysis)
- more than minor corrections for grammar, language, format
- must read the entire manuscript!
- each author is accountable for the work, should have confidence in other authors, should be able to identify who wrote each section



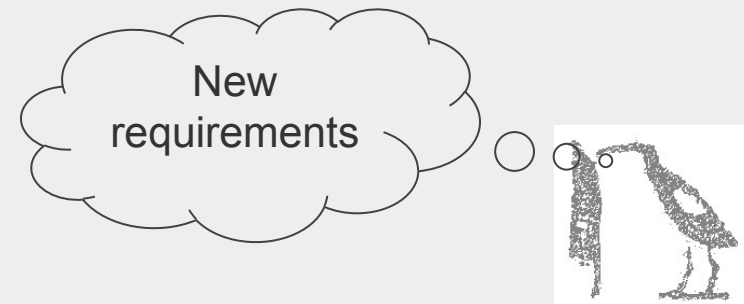
Data sharing (new section 5.0)

- 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)



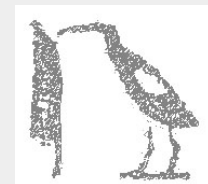
Trial registration (1.7)

- 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)



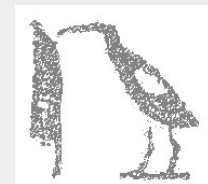
Key points

- Download GPP3 and check it carefully
- Distribute to all involved with publications
- Check wording on company policies and update where necessary
- Update references in company policies / websites



Things you might need to change

- Include trial registration numbers (even if not required by journal / congress)
- Use authorship working groups
- Grant access to patient-level data on request (even if not required by journal)



Conclusions

- Developing GPP3 was a lot of work
- End result = up-to-date, clearer document
- But you are the judges
- Only time will tell

