GPP2: What's new?

Chris Graf
Associate Editorial Director, Wiley-Blackwell
Publisher, IJCP, International Journal of Clinical Practice
chris.graf@wiley.com
This is all about

- Differences between GPP1 and GPP2
- Critiques and comments
- Hearing what you’ve got to say
GPP2

- Big consultation (116)
- Born of GPP1\(^1\) and more (Table 1)
- Practical (and long)
- Checklists (2 plus 1)
- Prominent publication\(^2\) $\rightarrow$ debate $\rightarrow$ evolution

1. Wager E et al. Good publication practice for pharmaceutical companies. CMRO 2003;19:149-54
The differences
Public regardless of outcome

- GPP1: endeavour to publish the results from all of their clinical trials of marketed products¹

- GPP2: register, post all applicable clinical trials according to legislation, guidelines

- GPP2 recommends “Making public or publishing results regardless of outcome”
Full access to data

- GPP1: All authors … should have access to the statistical reports and tables supporting each publication
Full access to data

• GPP2: Authors and contributions should have full access to study data … before writing begins

• Protocols, statistical plans and reports, data tables, clinical study reports, even study database
Reimbursement

- GPP2: It may be appropriate to reimburse reasonable out of pocket expenses

- No ‘honorarium’ simply for putting name on a paper
Primary, secondary papers

• GPP2: articles should indicate whether they are primary articles

• Secondary articles must avoid duplicate publication

• One or more authors of primary article should contribute to secondary articles from the same study
Review articles

• GPP2: Comprehensive, methods stated
• Discussions founded on opinion identified
• Appropriate description of contributions
• BMJ’s “Who prompted this submission?”
BMJ’s questions

• Has anyone (particularly a company or PR agency) prompted or paid you to write this article?

• Did a professional writer contribute to the article, and to what extent?

• Would the BMJ article be original?
Adopt contributorship

• GPP1: Some journals have adopted a system of listing contributors rather than authors

• GPP2 recommends adopting contributorship … with acknowledgements to describe role performed by each author and contributor, and the sponsor
About steering committees

• GPP1: Formation of a writing committee involving the medical writer may facilitate the process

• GPP2: It may be useful to form a publication steering committee of authors and contributors to oversee and produce articles from a research study
About steering committees

- GPP2: Members of the study steering committee, protocol development team
- Investigators, individuals who have expertise and who are willing
- Employees of the sponsor involved in the study (clinicians, statisticians, professional medical writers)
About steering committees

• GPP2: Publication steering committee should be formed early

• All study investigators are informed of the committee’s membership, responsibilities

• Authors, contributors agree to their roles before writing begins
Professional medical writers

- GPP2: Writers directed by the lead author

- Authors may delegate administrative tasks

- All authors aware of writer’s involvement

- Medical writers may qualify for authorship
Conflicts of interest

- GPP2: Disclose financial relationships and non-financial relationships that could inappropriately influence or appear to influence professional judgment
Critiques and comments
“although the ICMJE authorship criteria and [GPP2] are useful…

… they currently focus too much on the manuscript rather than the underlying data”
• Do the GPP2 authors agree that it is still important to publish the results of all trials?
In reply

• Particularly for clinical trials GPP2 recommends “Making public or publishing results regardless of outcome”

• Sponsors should endeavour to publish
• Do the GPP2 authors agree that it is important to ensure that sponsor employees should either be named authors of a paper or, if they are not named authors, should have no influence on the content of the publication?
In reply

• GPP2 requires “Honest attribution of authorship”

• Who did the work?

• All those who have had “influence” (i.e. made a significant contribution) should be listed, including those employed by the sponsor
Who appoints the guarantor? Who is responsible for the integrity prior to his or her appointment? When a trial generates more than one manuscript, would they necessarily have the same guarantor? If not, who would ultimately be responsible, and how would disagreements be resolved?
In reply

- One of the PIs would likely be guarantor on at least the primary publication(s)

- “One or more authors of primary article should contribute to secondary articles from the same study”

- “Honest scientific debate as the means to resolve scientific differences”
• Seem to condone ghost authorship

• Only if willing to “take public responsibility” then [a professional writer] may be in a position to meet the ICMJE criteria

• Would allow a professional writer to simply be unwilling to take such responsibility in order to avoid being listed as an author

From Roy M Poses http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#226987
• Guest and ghost authors are unacceptable

• Again, GPP2 requires “Honest attribution of authorship”

• Being “unwilling to take such responsibility in order to avoid being listed as an author” is simply being dishonest
• GPP2 will do little unless accompanied by registration and reporting of all clinical trial results

• The concept of a guarantor is interesting... I am not sure anyone will take this seriously
• Poses on Health Care Renewal Blog makes some good points

• However, for Pharma research there is usually no one “PI” that can take responsibility as with academic research
A blog reader added this comment:

“[Poses] is confusing the person responsible to complete a publication with the role of an investigator – of course the investigator is involved in the collection of trial data – but they are not always interested, or so inclined to participate in the development of publications”

An editor

• The blog reader was being charitable…

• The investigator may not be an academic (and they usually are not), and have NO skills necessary to understand the statistical plan, much less interpret and write
I like these

- “the guidelines contain much good advice that should help to promote high ethical standards”\(^1\)

- “We urge all contributors … to familiarize themselves with and adhere to [GPP2]”\(^2\)

1. From EMWA by Jacobs, Baldwin. http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#227612
2. 2. From AMWA by Gegeny T et al. http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#227162