GPP2: What's new?

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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] → debate → evolution

1. Wager E et al. Good publication practice for pharmaceutical companies. CMRO 2003;19:149-54
2. Graf C et al. The GPP2 guidelines. BMJ 2009;339:b4330

The differences

Public regardless of outcome

- GPP1: endeavour to publish the results from all of their clinical trials of marketed products[1]
- 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?

BMJ. Submitting an article to the BMJ. http://resources.bmj.com/bmj/authors/article-submission

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

BMJ editorial

- "although the ICMJE authorship criteria and [GPP2] are useful…
- … they currently focus too much on the manuscript rather than the underlying data"

Godlee F, Clarke M. Why don't we have all the evidence on oseltamivir? BMJ 2009;339:b5351

BMJ.com ‘Rapid Response’

- Do the GPP2 authors agree that it is still important to publish the results of all trials?

From EMWA by Jacobs and Baldwin http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#227612

In reply

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

- Sponsors should endeavour to publish

BMJ.com ‘Rapid Response’

- 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?

From EMWA by Jacobs and Baldwin http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#227612

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

BMJ.com ‘Rapid Response’

- 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?

From Roy M Poses http://www.bmj.com/cgi/eletters/339/nov27_1/b4330#226987

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”

BMJ.com ‘Rapid Response’

- 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

In reply

- 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

An editor

- 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

An editor

- Poses on Health Care Renewal Blog makes some good points
  http://hcrenewal.blogspot.com/2009/11/how-industry-views-research-it-sponsors.html

- However, for Pharma research there is usually no one “PI” that can take responsibility as with academic research

An editor

- 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”

http://hcrenewal.blogspot.com/2009/11/how-industry-views-research-it-sponsors.html

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