Ashfield
Healthcare Communications

GPP3 Guidelines: What's new and implications for publication planners

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Disclosure

- *Angela Cairns is an employee of Ashfield Healthcare Communications, an author of the GPP3 Guidelines, and a member of the ISMPP Sunshine Act Task Force*
- *The presented content, opinion and discussion comments are my own, and do not necessarily represent the opinion and views of my employer or of ISMPP*

Objectives

- Recognise the key changes in GPP3 vs GPP2
- Understand the implications of the changes on publication planners
- Know what to do next to comply with GPP3
- Know how to access GPP3 and the associated ISMPP resources

GPP3 – free to access online

- The GPP3 guidelines were sponsored by the International Society for Medical Publication Professionals (ISMPP)
- Published in Annals of Internal Medicine, 2015

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

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

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This updated Good Publication Practice (GPP) guideline, known as GPP3, builds on earlier versions and provides recommendations for individuals and organizations that contribute to the publication of research results sponsored or supported by phar-

comments on the second draft, which steering committee members incorporated after discussion and consensus.

The resulting guideline includes new sections (Principles of Good Publication Practice for Company-Sponsored Medical Re-

- Available at: http://annals.org/article.aspx?articleid=2424869
  or
  www.ismpp.org/GPP3

ISMPP resources

Supporting materials

SAVE THE DATE! GPP3 APET ISMPP U coming in December
Click here for more information on ISMPP U

GPP3 presentation by Teresa Peña, PhD
Click here to view

Presentation by Liz Wager offering her perspective on the evolution of GPP and key changes in GPP3
Click here to view

Editorial from *International Journal of Clinical Practice* by Leslie Citrome, MD MPH
Click here to view

***Overview of Good Publication Practice Guidelines, Including GPP3: Why should medical writers care?* Presented by Teresa Peña at AMWA 2015**
Click here to view

GPP3 Checklist
COMING SOON!!

Frequently Asked Questions
COMING SOON!!

Endorsements & Support

The following organisations support and encourage the use of the GPP3 guidelines

Walkthrough of key changes and implications

What's changed?

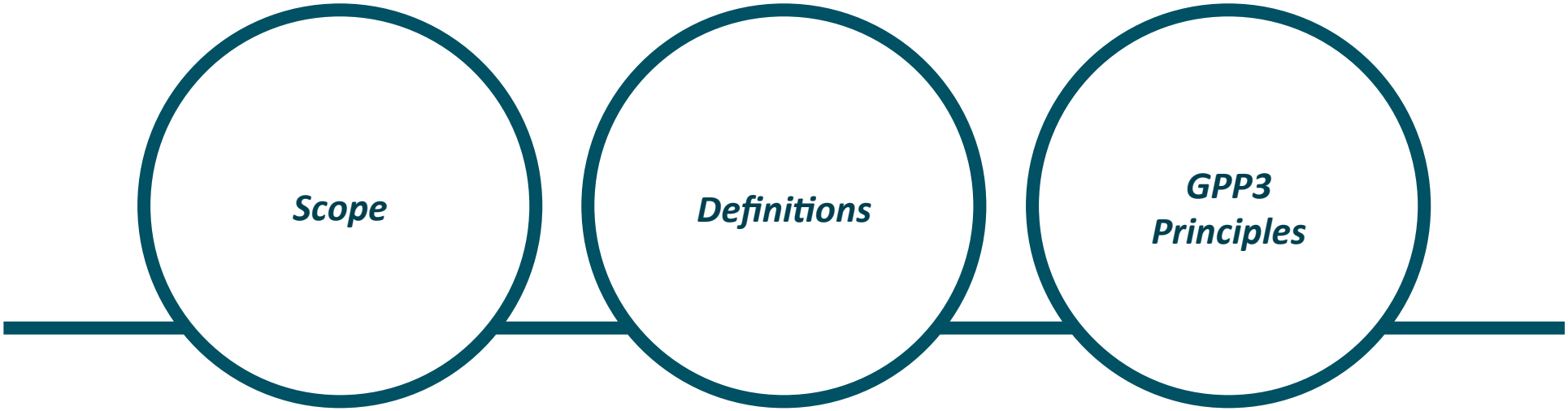
General

- Order of sections changed to reflect typical process
- Improved description of scope, clearer definitions
- Simplification of language and more assured tone

New sections

- Principles of GPP
- Studies that should be published
- Plagiarism
- Appropriate data sharing
- Guidance on interpreting updated ICMJE authorship criteria
- Guidance on some common authorship issues

Scope, definitions and principles



- Applies to all research
- All medical and healthcare professionals
- Explains what is not covered

- Pubs = all types of peer-reviewed articles
- Presentations = congress abstracts, posters, slides
- Pub professional = all key

- Overarching principles
- 'Spirit' of the guidelines

How does this impact?

- Do definitions need updating in internal documents/training?
- Are you meeting the 'spirit' and not just the 'letter' of the guidelines?

1.1 Publication planning

- Focus on 'responsible, ethical, complete, and timely' publications
- Clarity on author roles

- Pub plans are an ethical approach – they are not about 'industry control'
- +ve and –ve studies, timelines, additional pubs only if scientific/clinical value

- Need for cross-functional team
- Commercial functions not to direct pub plans, pubs development or review/approve pubs

Publication planning – how does this impact?

- What is your current approach to establishing a publication planning team?
  - Are all relevant stakeholders represented?
  - Which role is leading/directing?
  - What is the role of commercial?

- Review any internal SOPs on publication planning, especially sections on:
  - Publication plan objectives
  - Publication plan team and management

1.2 Publication Steering Committees

- New – how to establish a committee
- When to form a committee – more flexible than GPP2 (before database lock)

- To describe Committee roles & responsibilities
- Especially recommended for international and multi-institutional research

- Formed by members of the Steering Committee
- To ensure appropriate and transparent authorship decisions

http://www.biomedcentral.com/1741-7015/12/197

Publication Steering Committees – how does this impact?

- Check your current approach to using Publication Steering Committees
- Review internal guidelines/SOPs that mention Publication Steering Committees
  - Do they describe how to establish a Committee?
  - Update wording (if necessary) on when to establish a Committee
- Develop a template for Publication Steering Committee charter/ guidance document (if used)
- Develop generic roles/responsibilities for authorship working group (or include in above charter/guidance) based on MPIP

http://www.biomedcentral.com/1741-7015/12/197

1.3 Studies that should be published
1.6 Plagiarism

- Studies that should be published
  - All trials, positive or negative, design and results
  - Post 'non-publishable' data on public site, registry/repository
  - Follow existing guidance on timing of publication
- Plagiarism – new section; unethical and unacceptable

How does this impact?

- Reflects existing guidance (WMA Dec of Helsinki 2013; Joint Position on the Publication of Clinical Trial Results, 2010)
- Minimal impact – should already be standard practice

1.7 Trial registration/results posting
1.8 Documentation

- Follow latest legislation/ standards
- Include trial identifier in all publications of registered studies or state why trial not

- Maintain data in shareable format in case requested
- Auditable document trail
- Inform external authors of process and types of documents to be retained

- Author approvals of version to be published (not just version to submit)
- Decision on who will submit
- Author disclosures/COIs
- Peer-review comments

Impact? Document management and filing systems, pub planning tools

2.1 Written agreement

- GPP2 'earliest opportunity e.g. when protocol finalised'; GPP3 'before work on a publication begins'
- Author acknowledge receipt

- Agree order of authors
- Control publication content
- Agree to any writing/ editorial support
- Journal/congress decision

- Inform authors of publication process
- Advise authors of any transparency reporting obligations

Impact? Revise author agreement templates where required

2.2 Authors' access to data

- Provide 'full access to relevant aggregated study data' before publication work begins
- Provide any missing or final data as soon as available
- Provide all information necessary to 'correctly appraise the quality and robustness of the [study] findings'
- Provide 'reasonable' additional analyses on request
- Different from GPP2 'full access to study data'?
  - Provision of 'full data' implies entire database – not practicable
  - Simply starting with aggregated data then drill down as required
  - Access to certain areas of 'raw' data may still be justified or required

Impact? Check SOPs re statements on providing access to data; check wording of author standard agreements/letters

2.3 Authorship

- Updated to reflect revised ICMJE authorship criteria
- Large trials: priority given to key contributors with expertise to analyse and interpret study findings
- Clear statement – no ghosts, no guests
- “Authorship must represent a substantial intellectual contribution to both the research being reported and the development of the publication”

Interpreting ICMJE authorship criteria

ICMJE		GPP3
1	Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of the data for the work	***Defines what is substantial contribution and what is not, with examples***
2	Drafting the work or revising it critically for important intellectual content	***Provides clarity on what constitutes a critical revision***
3	Final approval of the version to be published	***Important for the author to read the entire manuscript***
4	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	***Each author is accountable for the work and should have confidence in the integrity of the other authors' contributions***

Table 2 – common authorship issues

- Many common issues related to authorship

No. of authors • Preferably <10	**Change of affiliation** • Where major part of work was done
Author sequence • Final order based on actual contribution	**Company/sponsor-employed authors** • Standard authorship criteria apply
Addition/removal of author • All authors should agree to the change	**Professional medical writers as authors** • Author if meet authorship criteria
Death/incapacity of an author • Posthumous authorship possible; needs proxy approval; family consent	***Impact? Consider whether any of these points should be included in the standard author agreement***

2.2.3 Author payment and reimbursement

GPP2	GPP3
May reimburse reasonable out-of-pocket expenses	No change
Company may 'pay for specialised services such as statistical analysis'	May pay for 'publication activities (e.g. statistical analysis, medical writing, editing or similar services) to assist authors . . ' 'Payment should reflect the services provided and be at fair market value.'
'We recommend no honorariums are paid for authorship of peer-reviewed articles or presentations.'	'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. Payments should not be made to authors who are employed by an institution or organization that is already in receipt of funding to undertake and publish the research.'

Author payment and reimbursement – how does this impact?

- Review internal policies on author payment
- What is in your research contracts?
  - Is it considered that publications are ‘part and parcel’ of the research agreement so no further payment should be provided? (GPP3 position)

2.4 Professional medical writers

- More information on value of professional medical writers
- Generally do not meet authorship criteria, but some exceptions

Before beginning work, a professional writer should confirm the following in writing	
1	The authors will control and direct the content of the publication or presentation. The writer must receive direction from the authors at the earliest possible stage (for example, before the outline is prepared)
2	All authors have agreed to the writer's involvement
3	All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities
4	The authors will disclose, at a minimum, the writer's name, professional qualifications, affiliation, funding source, and any other information required by the journal or congress
5	Good publication practices will be followed

5.0 Data sharing

- New section in GPP3
- Regulations, recommendations and journal requirements are evolving rapidly
  - Some journals require original data to be provided on request
  - Some require inclusion of a ‘data sharing’ statement
- GPP3
  - Follow applicable rules, legislation and guidelines (including journal requirements)
  - Recommends that sponsors grant access to patient-level data to qualified researchers on request (reports redacted to protect patient confidentiality)

Summary

- Download GPP3 and review carefully
- Distribute GPP3 to employees working on publications
- Review existing policies and SOPs and update where necessary
- Review & update standard templates, author agreements, training materials and references to GPP (including website)
- Identify where training on changes in GPP3 may be required, e.g. internal and external stakeholders, affiliates
- Check new pubs against revised policies/SOPs