11TH ANNUAL MEETING OF ISMPP

PRACTICAL IMPLICATIONS OF GPP3: ARE YOU PREPARED?

Teresa Peña, PhD
Executive Director, Medical Publications
Bristol-Myers Squibb
April 29, 2015
Session Goal

- Overview of reviewer input
- Key areas of change in GPP3
- How to prepare your organization for GPP3
Disclaimer

The opinions expressed are my own and do not necessarily reflect those of my individual employer or of ISMPP
GPP3 STEERING COMMITTEE

Meet the faces behind the update
GPP3 Steering Committee

Wendy Battisti, PhD, Lise Baltzer, Dan Bridges, PhD, Angela Cairns, Christopher Carswell, MSc, Leslie Citrome, MD, MPH, Chris Graf, James Gurr, PhD, LaVerne Mooney, DrPH, Carol Sanes-Miller, MS, Jane Moore, MS, Mina Patel, PhD, Terry Peña, PhD, Aya Tokaji, Keith Veitch, PhD, Elizabeth Wager, PhD, Karen Woolley, PhD, Yvonne Yarker, PhD
GPP3 Participants

- **Steering Committee**
  - 19 qualified
  - Globally diverse group and perspectives from across the profession from seven countries representing:
    - Industry (pharma and device)
    - Medical communication companies
    - Freelance writers
    - Journal editors
    - Publishers
  - Breakdown by country: US (10); Netherlands (1); UK (3), Denmark (1); Aus/NZ (3), Japan (1)

- **Reviewer panel**
  - 174 approached and 94 confirmed reviewers, mainly from pharmaceutical/device industries and medical communication agencies; included 21 journal editors
GPP3 process - four key steps

**ISMPP**
- ISMPP emails >3000 invitations to members, editors and previous GPP2 reviewers (Sept 2013)
  - Steering Committee (n=18) selected from applicants (N=118)
  - External reviewer panel (n=153) selected. Additional targeted outreach to editors: 21 agreed

**Steering committee**
- Reviewed earlier GPP guideline and literature; collated all comments for proposed changes (Dec 2013 - Feb 2014)
  - Confirmed scope, title, and direction for GPP3 via repeated survey process of committee members (Jan-Feb 2014)
  - Prepared outline (March 2014)
  - Formed subcommittees to update or write each section (April-June 2014)
  - First draft assembled and edited; reviewed by full SC, and draft finalized (Aug 2014)

**Reviewer panel**
- Finalized draft (2nd draft) sent to reviewers (N=174) Aug 2014
  - Reviewers allowed 5 weeks to comment via Excel spreadsheet.
  - Comments captured by section heading and line number.
  - Reviewers (n=94) provided comments.

**Steering committee**
- Review and rank comments (mid Sept-Oct) from reviewer panel by:
  - Frequency,
  - Rating, and
  - Individual judgment
- SC reviewed all comments and identified top issues and resolution needed
- Subcommittees address comments; guidelines finalized for submission to Annals of Internal Medicine (Jan 2015)
## GPP3 Subcommittees

<table>
<thead>
<tr>
<th>Section</th>
<th>Subcommittee members</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principles of Publications</strong></td>
<td><strong>Liz Wager (Lead)</strong>; <strong>Karen Woolley</strong>; <strong>James Gurr</strong></td>
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<tr>
<td><strong>Aims &amp; Scope</strong></td>
<td><strong>Wendy Battisti</strong></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td><strong>Wendy Battisti</strong></td>
</tr>
<tr>
<td><strong>Section 1. Publication Processes</strong></td>
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<tr>
<td>• <strong>Section 1.1. Publication Planning</strong></td>
<td><strong>Keith Veitch (Lead)</strong>; <strong>Jane Moore</strong>; <strong>Dan Bridges</strong>; <strong>Aya Tokaji</strong></td>
</tr>
<tr>
<td>• <strong>Section 1.2. Publication steering committees and writing groups</strong></td>
<td><strong>Jim Gurr (Lead)</strong>; <strong>Yvonne Yarker</strong>; <strong>Mina Patel</strong>; <strong>Carol Sanes Miller</strong>; <strong>Lise Baltzer</strong>; <strong>Les Citrome</strong>; <strong>Laverne Mooney</strong></td>
</tr>
<tr>
<td><strong>Sections 1.3 - 1.8.</strong></td>
<td><strong>Keith Veitch (Lead)</strong>; <strong>Jane Moore</strong>; <strong>Dan Bridges</strong>; <strong>Aya Tokaji</strong></td>
</tr>
<tr>
<td>(What should be published, Premature publication, Redundant or duplicate publication, Plagiarism, Trial registration and public posting of data, Documentation)</td>
<td>Formerly – “Planning, registering, posting, and documenting”</td>
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</table>
# GPP3 subcommittees

<table>
<thead>
<tr>
<th>Section</th>
<th>Subcommittee members</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 2.0. Roles and responsibilities</strong></td>
<td><strong>Dan Bridges (Lead)</strong>; Jim Gurr; Liz Wager; Angela Caims; Les Citrome</td>
</tr>
<tr>
<td>• 2.1 Written agreement</td>
<td></td>
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<tr>
<td>• 2.2 Authors Access to data</td>
<td></td>
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<tr>
<td><strong>Section 2.3. Authorship</strong></td>
<td><strong>Chris Carswell (Lead)</strong>; Keith Vetch; Liz Wager; Angela Caims; Les Citrome; Wendy Battisti; Carol Sanes-Miller</td>
</tr>
<tr>
<td><strong>Section 2.4. Professional medical writers</strong></td>
<td><strong>Karen Woolley (Lead)</strong>; Keith Vetch; Jim Gurr; Ange Caims; Yvonne Yarker; Jane Moore; Liz Wager</td>
</tr>
<tr>
<td><strong>Section 2.5. Contributorship and acknowledgments</strong></td>
<td><strong>Angela Caims (Lead)</strong>; Jane Moore; Mina Patel; Jim Gurr</td>
</tr>
<tr>
<td><strong>Section 2.6. Disclosures</strong></td>
<td><strong>Les Citrome (Lead)</strong>; Terry Peña; Angela Caims; Carol Sanes Miller</td>
</tr>
<tr>
<td><strong>Section 3.0: Recommendations for specific types of articles and presentations</strong></td>
<td><strong>Lise Baltzer (Lead)</strong>; Yvonne Yarker; Liz Wager</td>
</tr>
<tr>
<td><strong>Sections 4.0 - 5.0. (Reporting standards, Data sharing)</strong></td>
<td><strong>Laverne Mooney (Lead)</strong>; Terry Peña; Aya Tokaji; Chris Carswell; Keith Veitch</td>
</tr>
<tr>
<td><strong>Section 6.0. Future Directions</strong></td>
<td>Liz Wager</td>
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NOTE! GRAB YOUR TECHNOLOGY!

This presentation contains polling questions

PRACTICAL IMPLICATIONS OF GPP3
Question: In your opinion, how well informed are you on the development of GPP3?

• Potential answers
  – **Very informed**, heard updates at several publication meetings 48% (29/60)
  – **Somewhat informed**, heard update at a single publication meeting 30% (18/60)
  – **Not informed**, have not heard a thing 22% (13/60)

60 Respondents
Question: Have you begun to prepare your organization for GPP3?

- **Yes**, have begun preparing publications group and the broader organization on upcoming updates to GPP2  14% (9/65)
- **Somewhat**, have begun preparing publications group, but not the broader organization on upcoming updates to GPP2  11% (7/65)
- **No**, have not prepared anything. Waiting for GPP3 to be published  75% (49/65)

65 Respondents

Progress on core principles
Why the update to GPP2?

- The ISMPP GPP3 Steering Committee has updated the current guidelines for good publication practice (GPP2) to further improve integrity and transparency in industry-sponsored publication planning and development in today’s environment.
GPP Evolution

Current Medical Research Opinion

• First to describe standards for industry-based manuscripts
• Initiated at a meeting of academics, journal editors, and industry affiliates in 1998
• Five years in the planning and development

British Medical Journal

• More comprehensive than GPP
• More diverse input (reviewers)
• Additional topics since GPP

Submitted to Annals of Internal Medicine

• Expand focus of GPP and GPP2 on core values:
  • Integrity
  • Completeness
  • Transparency
  • Accountability
  • Responsibility
• New elements such as:
  • Data sharing
  • Expanded information & evidence base on role of medical writers
What's new in GPP3?

<table>
<thead>
<tr>
<th>New elements include:</th>
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<tbody>
<tr>
<td>1. Guidance on updated ICMJE 2013 authorship criteria</td>
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<tr>
<td>2. Guidance on common issues regarding authorship</td>
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<td>3. Guidance and improved clarity on author payment and</td>
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<td>reimbursement</td>
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<td>authorship</td>
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<td>5. Expanded information on the role and benefit of</td>
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<td>professional medical writers</td>
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<td>6. Guidance for appropriate data sharing</td>
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<tr>
<td>7. Overall simplification of language and format with a</td>
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<tr>
<td>new guiding principles section and quick reference tables</td>
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<tr>
<td>addressing guidance on authorship criteria and common</td>
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<tr>
<td>authorship issues</td>
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# New sections

<table>
<thead>
<tr>
<th>Section</th>
<th>Highlight</th>
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<tbody>
<tr>
<td>Principles of Good Publication Practice For Company-Sponsored Medical Research</td>
<td>• Summary of ‘top ten’ principles of good publication practice – for quick access and to complement more detailed guidelines included throughout GPP3</td>
</tr>
<tr>
<td>Aim and Scope</td>
<td>• To maintain ethical practices in the development and communication of scientific and clinical research</td>
</tr>
<tr>
<td>Disclosures</td>
<td>• Previously known as Conflicts of Interest section</td>
</tr>
<tr>
<td>Data Sharing</td>
<td>• Sponsors should provide access to patient-level data to ‘qualified researchers’ upon request</td>
</tr>
<tr>
<td></td>
<td>• Access to data cannot compromise patient confidentiality</td>
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</table>
### New sections

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| Studies that should be published             | • Clinical trials including non-interventional studies involving human participants  
  • Publication regardless of whether finding is positive or negative  
  • Guidance for publication of studies that do not yield medically important results, with multiple journal rejections… |
| Timing of Publications                       | • Licensed products: manuscript submissions within 12 months (at latest 18 months) of study completion  
  • Investigational products: within 12 months (at latest 18 months) of product approval or within 18 months of study discontinuation |
| Plagiarism                                   | • Definition, including self-plagiarism  
  • Copyright permission                     |
# Key changes in existing sections

<table>
<thead>
<tr>
<th>Section</th>
<th>Highlight</th>
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<tbody>
<tr>
<td>Authorship</td>
<td>• Author access to data cannot compromise patient confidentiality</td>
</tr>
<tr>
<td></td>
<td>• Updated with revised ICMJE criteria</td>
</tr>
<tr>
<td></td>
<td>• Clarity around ‘guest’ &amp; ‘ghost’ authorship</td>
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<tr>
<td></td>
<td>• Clarity on authorship payment &amp; reimbursement</td>
</tr>
<tr>
<td>Professional Medical Writers</td>
<td>• Included peer reviewed published evidence to support benefits of involving professional writers</td>
</tr>
<tr>
<td>Primary and Secondary Publications</td>
<td>• Primary publications should be published before secondary publications</td>
</tr>
<tr>
<td>Review articles</td>
<td>• Added reference to PRISMA guidelines for systematic reviews</td>
</tr>
<tr>
<td>Publications Steering Committees</td>
<td>• Recommend authorship working group from MPIP authorship framework</td>
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GPP3 REVIEWER ANALYSIS

What have we learned?
Reviewer Breakdown

GPP2 vs GPP3

- **Academic**: 45% (GPP2) vs 43% (GPP3)
- **Industry**: 37% (GPP2) vs 35% (GPP3)
- **Journal editor**: 7% (GPP2) vs 1% (GPP3)
- **Professional organization**: 3% (GPP2) vs 3% (GPP3)
- **Agency/freelance**: 2% (GPP2) vs 15% (GPP3)
- **Other/unspecified**: 3% (GPP2) vs 3% (GPP3)

n=116 for GPP2
n=94 for GPP3
Density of reviewer comments

No. of comments per line

- Beneficial
- Critical

Categories:
- Authorship
- GPP principles
- Aims & Scope
- Plan, Reg, Post, Doc
- PSC
- Future res/dir
- Trans/pub access
- Roles & Resp
- Prof Med Writers
- Article-specific recs
- Methods
- Contrib/auth
- Disclosures
- General
Summary from initial data review

• Data show we still have more work to do to engage journal editors in guideline development and review.

• Key areas of interest / debate still boil down to:
  – Authorship
  – GPP Principles
  – Aims and scope of guidelines
Testimonials

- **Clear**, useful guidelines that clarify some ambiguities from GPP
- Content very **comprehensive** and relevant.
- I found the draft guidelines to be **comprehensive** and very **useful**. I commend the steering committee for their excellent work. Thank you for the opportunity to review them.
- I have carefully reviewed the draft and am **delighted** to report that I have no substantive recommendations for changes. I think the authorship team has done an **outstanding job** on this draft! Thank you all.
- I thought this was a **great article**! I just had a few comments.
- Overall it is very well done and thought out. I only have a few points of critique. **Good job** to all the authors and thanks for updating GPP2!
- Overall, I think this is a **excellent guidance document**, building upon the GPP2 to where we are today. Kudos to the team, and I look forward to seeing the final document.
- Overall, the GPP3 document is **thorough, clear** in its guidance, and a **valuable tool** for beginning and experienced professionals in the publication planning field.
- **Very clearly laid out**, and very **concise**. I like the addition of the list of principles at the beginning of the article so that readers are not required to search through the entire paper to discover them.
GPP3 JOURNAL SUBMISSION
Update
Journal submission update

• January 2015: manuscript submitted to Annals of Internal Medicine
  – Manuscript is under review
PREDICTING THE IMPACT OF GPP3

How might GPP3 recommendations affect day-to-day publications activities?
What’s new in GPP3?

New elements include:

1. Guidance on updated ICMJE 2014 authorship criteria
2. Guidance on common issues regarding authorship
3. Guidance and improved clarity on author payment and reimbursement
4. Additional clarity on what constitutes ghost or guest authorship
5. Expanded information on the role and benefit of professional medical writers
6. Guidance for appropriate data sharing
7. Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues
Predicting the impact

New elements include:

1. Guidance on updated ICMJE 2014 authorship criteria
2. Guidance on common issues regarding authorship
3. Guidance and improved clarity on author payment and reimbursement
4. Additional clarity on what constitutes ghost or guest authorship
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PREPARING FOR GPP3

Recommendations for effective communication and roll-out
Where to start?

Think global

Key Steps

1. Prepare
2. Launch
3. Check
4. Mitigate

Where to start?
Step 1

- **Review** current / existing policy and SOPs against new sections & key changes in GPP3

- **Identify** potential areas of ‘global’ impact that will require communication and training of:
  - Internal & external stakeholders
  - Affiliates in regions
  - Country medical staff

- **Plan** updates to global policy, SOPs & training materials

Remember GPP3 is global so think & act globally!
Step 2

• **Develop** customized plans to communicate the right information, at the right level, to the right audience

• **Socialize** potential areas of impact & change with key stakeholders prior to roll-out of communication and training

• **Delay not**.. Inform those who need to know in a timely manner
Step 3

- **Identify** GPP3 requirements to monitor in SOPs and training materials

- **Perform** regular baseline assessments of publications against updated guideline

- **Track & Report** on any impact & change related to GPP3 implementation
Step 4

- **Evaluate** monitoring data & assess need for additional clarification & training

- **Act** on findings to identify root cause & address potential gaps in GPP3 compliance

- **Publish** research on GPP3 use & value

- **Manage change** go back to Step 1

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"The Only Thing That Is Constant Is Change"

Heraclitus
**Education & training pyramid**

- **Focused & customized training**
  - Senior Leaders
    - 1st line communication & education on business impact
  - Authors, agency partners, publication teams, cross-functional stakeholders & partners
    - 2nd line education & training
  - Publication, compliance & legal teams
    - 1st line education & training

GPP3 Education & Training

High detail & depth
THE JOURNEY HOME

Next steps for GPP3
Key Takeaways

• Begin parallel activities
  – Update GPP website on ISMPP site content to include GPP3
    • Steering committee member list
    • ‘GPP3 for authors’ checklist- practical tool
    • FAQ document
    • GPP3 process summary
  – Establish GPP3 sub-committee to monitor and respond to FAQs
  – Explore GPP3 sessions at ISMPP Annual Meetings
    • September 2015; Tokyo & Beijing

• Post acceptance activities
  – Organization outreach for GPP3 endorsement to include AMWA, EMWA, COPE and others...
  – Guideline translations in Japanese and Chinese
  – Download access to GPP3
  – Archive of GPP2 information
CLOSING THOUGHTS
In the end, what's it all about?
11TH ANNUAL MEETING OF ISMPP

OPTIMIZING SCIENTIFIC VALUE:
SMART AND SYSTEMATIC APPROACHES TO MEDICAL PUBLICATIONS

April 27-29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA
BACK-UP SLIDES
## GPP3 Steering Committee

<table>
<thead>
<tr>
<th>Member</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Baltzer, Lise</td>
<td>Novo Nordisk A/S, Denmark</td>
</tr>
<tr>
<td>Battisti, Wendy*</td>
<td>Janssen Research &amp; Development LLC, USA (Chair)</td>
</tr>
<tr>
<td>Bridges, Dan*</td>
<td>Apothecom scopemedical, UK</td>
</tr>
<tr>
<td>Cairns, Angela*</td>
<td>Ashfield Healthcare Communications, UK</td>
</tr>
<tr>
<td>Carswell, Chris</td>
<td>Pharmacoeconomics, Springer Int’l Publishing AG., Switzerland</td>
</tr>
<tr>
<td>Citrome, Les</td>
<td>Int’l Journal Clinical Practice, Wiley-Blackwell, USA</td>
</tr>
<tr>
<td>Graf, Chris</td>
<td>Wiley Blackwell, Australia (now UK)</td>
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<tr>
<td>Gurr, James*</td>
<td>MedImmune, USA</td>
</tr>
<tr>
<td>Mooney, Laverne</td>
<td>Pfizer Inc., USA</td>
</tr>
<tr>
<td>Moore, Jane*</td>
<td>Medtronic, USA</td>
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<tr>
<td>Patel, Mina</td>
<td>Vertex Pharmaceuticals, Inc, USA</td>
</tr>
<tr>
<td>Peña, Teresa</td>
<td>Bristol-Myers Squibb, USA</td>
</tr>
<tr>
<td>Sanes-Miller, Carol*</td>
<td>Baxter Healthcare, USA</td>
</tr>
<tr>
<td>Tokaji, Aya*</td>
<td>McCann Complete Medical, MDS-CMG, Japan</td>
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<tr>
<td>Veitch, Keith</td>
<td>Freelancer, The Netherlands</td>
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<tr>
<td>Wager, Liz</td>
<td>Sideview, UK</td>
</tr>
<tr>
<td>Woolley, Karen*</td>
<td>Proscribe Envision Pharma Group, Australia</td>
</tr>
<tr>
<td>Yarker, Yvonne*</td>
<td>Medicite LLC, USA</td>
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</table>

*ISMPP Certified Medical Publication Professional
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