THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

October 21, 2015
ISMPP WOULD LIKE TO THANK . . .

. . . the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

- Amgen
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- Caudex Medical
- Complete Health
- Complete Health Vizion
- CMC
- MedErgy
- MedThink
- Pfizer
• This program qualifies for 1.5 credits towards recertification

• Call for abstracts now open for the 12th Annual Meeting of ISMPP. Deadline is Friday, January 8, 2016

• Registration for the 2016 European Meeting of ISMPP is now open!
2016 EUROPEAN MEETING OF ISMPP
19-20 January, London

• A focus on practical skills that drive successful publication delivery

• GPP3, RWE, data & financial transparency, guidelines & regulations, journal selection and new journal features

• Peer exchange, expert-led roundtables, member presentations, extended Q&As, interactive panel discussions

• Attendees will leave with ideas they can use the day they return to work
Day 1: Tuesday 19 January 2016 - Highlights

- **GPP3 Panel Discussion**
  - GPP3 authors & expert editors answer your questions

- **Real World Evidence and Publications**
  - With Richard White, Oxford PharmaGenesis

- **Roundtables**
  - Attendees can join three different tables, some eligible for CMPP credit

- **Data & Financial Transparency Reporting**
  - Representatives from EMA, EFPIA and industry

- **Evening Poster Presentation & Networking Reception**
Day 2: Wednesday 20 January 2016 - Highlights

- **Publishing & Journals: Practical Considerations in 2016**

- **SPEED Research**
  - Authors have 10 minutes to present their research

- **Parallel sessions: Other Guidelines & Regulations**
  - Attendees select two from three 45-minute sessions:
    1. Copyright
    2. Corporate Integrity Agreements
    3. EQUATOR

- **Keynote Address: Publications Pioneer Vitek Tracz on “The Future of Publications”**
ATTENTION 2010 CMPP’S!

The deadline to apply for recertification is **October 31** to maintain your CMPP™ credential

Visit our website: [http://www.ismpp.org/recertification](http://www.ismpp.org/recertification)

- Recertification Policy
- Recertification Handbook
- Recertification Credit Tracker Application
- Recertification Application

Contact [cmpp@ismpp.org](mailto:cmpp@ismpp.org) with any questions. We’re here to help!
CMPP™: COULD YOU BE A MENTOR?

ISMPP is seeking volunteers to provide mentorship to individuals considering sitting for the exam or who have questions related to recertification

- Must be CMPP™ certified and willing to be listed on the ISMPP website
- Please email cmpp@ismpp.org to register your interest
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• Use a hardwired connection if available

• Use the fastest internet connection available to you

• If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers
QUESTIONS...

• To ask a question, please type your query into the Q&A box
  
  • To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "ALL Panelists"
  Otherwise, all audience members will be able to see your submitted question
  
  • We will make every effort to respond to all questions

NOTE: Make sure you send your question to “ALL Panelists”
GPP3: STRENGTHENING THE PRINCIPLES AND PRACTICES FOR COMMUNICATING COMPANY-SPONSORED RESEARCH
INTRODUCTIONS

• **FACULTY:** Wendy Battisti has nearly 30 years of experience in the medical sciences and scientific writing. Her Ph.D. is in neuroscience, from the Medical College of Pennsylvania, where she also worked for many years as an NIH-supported researcher, faculty member, and neuroscience course director for the medical school. She also led graduate courses in scientific writing and presentation. Her academic career was followed by several years at a medical communication agency before joining Merck & Co., where she worked in various aspects of medical communications and scientific writing. She was at Janssen Research & Development, LLC, (Johnson & Johnson) for ten years working in scientific and medical publications. She has coauthored or assisted with numerous publications and presentations in the areas of neuroscience, neurology, pain, arthritis, respiratory, and cardiovascular, and was a coauthor of the updated good publication practices guidelines known as “GPP2”. Most recently she was the steering committee chair and lead author for GPP3.
FACULTY: Leslie Citrome is Clinical Professor of Psychiatry & Behavioral Sciences at New York Medical College in Valhalla, NY, and has a private practice in Pomona, NY. He is a member of the Board of Directors of the American Society of Clinical Psychopharmacology. He graduated from the McGill University Faculty of Medicine and completed a Residency and Chief Residency in Psychiatry at the New York University School of Medicine, and went on to complete a Masters in Public Health at Columbia University. He is editor in chief of the International Journal of Clinical Practice and the author/co-author of over 400 published research reports, reviews, and book chapters in the biomedical literature.
• **FACULTY: LaVerne Mooney** obtained her BSc degree from Galway University, Ireland and was awarded her Masters and Doctor of Public Health from the Mailman School of Public Health at Columbia University, New York, where she researched genetic and environmental influences on cancer causation. For the last 8 years LaVerne has been at Pfizer; she is a Director and Team Leader of Publications in Pfizer Medical. She has represented Pfizer as a Steering Committee and Founding Member of the Medical Publication Insights and Practice (MPIP) collaboration, and is a co-author of the Good Publication Practice Guidelines (GPP3). She has extensive publishing experience from the academic, agency, and industry perspective. Her current research focus is transparency and best-practices in medical publications. LaVerne has been the ISMPP Treasurer and Board Member since 2013.
INTRODUCTIONS

• **FACULTY: Yvonne Yarker** has over 20 years of experience in medical communications, and has worked in the US, UK, and the Asia-Pacific region. Since 2010 Yvonne has managed her own business (Medicite LLC), offering medical communications services, compliance guidance, and training. She was a coauthor of “Good Publication Practice for Communicating Company Sponsored Medical Research: the GPP2 Guidelines” (Graf et al. BMJ, 2009) and is a coauthor of the more recent “Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3” (Battisti et al. Ann Intern Med 2015), and has presented at professional conferences on authorship, medical writing, and ethical best practices. She is the current Chair Elect of the Board of Trustees of the International Society of Medical Publication Professionals (ISMPP).
INTRODUCTIONS

• **MODERATOR: Brian Scheckner**, PharmD, BCPP, CMPP, is Head, Publication Policy and Education, at BMS. He has worked in the pharmaceutical industry since 1999, serving primarily in publication and medical communication leadership roles. Prior to BMS, Brian's pharmaceutical industry work included positions at Shire (Head of Publications, US), Wyeth, and Interlink Healthcare Communications. Brian attended the University of the Sciences in Philadelphia (PharmD) and Rutgers University (BS, Pharmacy), and has licenses/certifications in pharmacy, psychiatric pharmacy (BCPP), and publications planning (CMPP). Brian is currently serving as the Chair of the ISMPP U Committee, and was a previous member of the ISMPP Standards Committee. He has been a speaker at ISMPP, TIPPA, and CBI publication planning meetings.
DISCLAIMER

- Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or the position of ISMPP.
OBJECTIVES

At the end of this presentation, attendees should be able to:

• Be familiar with the evolution of the GPP guidelines and the process used to try and ensure their broad and relevant applicability

• Understand the updated GPP3 guidance on authorship requirements and recommendations for common authorship issues

• Gain an understanding of the rationale for the new “What Studies to Publish” section

• Know what type(s) of clinical studies should be published, where they should be published and when

• Be familiar with the pharmaceutical association joint position statement

• Be able to appropriately manage the “difficult to publish” studies

• Understand how "disclosure" is a less ambiguous term than "conflict of interest" (or "potential of conflict of interest") and can promote greater transparency

• Understand how GPP3 allows for compensation at fair market value for activities related to medical publishing
INTRODUCTION TO GPP3 AND KEY HIGHLIGHTS

Wendy P Battisti, PhD
GPP3 Lead Author
Former Director, Scientific & Medical Publications
Janssen Research & Development, LLC (Johnson & Johnson)
WHY ALL THE GUIDELINES?

Publications are intended to advance:

- Scientific and medical research;
- Healthcare practice standards; and
- Patient quality of life

Guidelines help establish or reinforce best practices for companies to achieve these goals:

- Develop unbiased, data-driven publications
- Provide full transparency (data, as well as authorship and contributors)
- Document that all activities are to the highest standard
GPP EVOLUTION

GPP (2003)
Current Medical Research Opinion
- First to describe standards for industry-based manuscripts
- Initiated at a meeting of academics, journal editors, and industry affiliates
- Five years in planning and development

GPP2 (2009)
British Medical Journal
- More comprehensive than GPP
- More diverse input (reviewers)
- Additional topics since GPP

GPP3 (2015)
Annals of Internal Medicine
- Expanded focus of GPP, GPP2 core values:
  - Integrity
  - Completeness
  - Transparency
  - Accountability
  - Responsibility
- New elements include:
  - Data sharing
  - Expanded information on authorship; role of medical writers; publication planning
<table>
<thead>
<tr>
<th>Member</th>
<th>Affiliation</th>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>Veitch, Keith</td>
<td>Freelancer, The Netherlands</td>
</tr>
<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>
</tr>
</tbody>
</table>

*ISMPP Certified Medical Publication Professional
GPP3 PARTICIPANTS

- Steering Committee
  - 18 participants
  - Globally diverse group and perspectives from across the profession, seven countries, representing:
    - Industry (Pharma and device)
    - Medical communication agencies
    - Freelance writers
    - Journal editors
    - Publishers
  - Breakdown by country: US (9); 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 Key Process 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 comments (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 reviewer panel comments (Sept-Oct) by:
  - Frequency,
  - Rating, and
  - Individual judgment
- SC reviewed all comments and identified top issues and resolution needed
- Subcommittees address comments; guidelines finalized, submitted to *Annals of Internal Medicine* (Jan 2015)
- Revisions requested (March 2015)
- Accepted June 2015
WHAT’S NEW IN GPP3?

• Reorganized for increased clarity and to reduce redundancy. Additional examples provided throughout to help clarify ‘grey’ areas

• No sections deleted from what was in GPP2, but several new sections added.

• Restructured - Main text and appendices
## Section & Summary

<table>
<thead>
<tr>
<th>Principles of Publications: Summary of ‘top ten’ principles of good publication practice – for quick access and to support details included throughout GPP3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aims &amp; Scope: Consistent with GPP2 - To maintain ethical practices in the development and communication of scientific and clinical research, in particular for industry-sponsored studies</td>
</tr>
<tr>
<td>Methods: Demonstrates the global and diverse perspective, and rigor used in developing the guidelines</td>
</tr>
<tr>
<td>Future Directions: Recognize need for continued research, training and education on best practices, and encourages journals, congresses, and academic institutions to endorse the guidelines and disseminate them throughout the research community</td>
</tr>
</tbody>
</table>
# APPENDICES – GUIDELINES AND RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Section</th>
<th>Key messages</th>
</tr>
</thead>
</table>
| **1.0 Publication Processes**  
• 1.1 Publication planning  
• 1.2 Publication steering committees  
• 1.3 Studies that should be published (including timing)  
• 1.4 Premature publication  
• 1.5 Redundant (or duplicate) publication  
• 1.6 Plagiarism  
• 1.7 Trial registration and public posting of data  
• 1.8 Documentation | • All clinical trials, including noninterventional studies involving humans, ideally in peer-reviewed journal, regardless of whether finding is positive or negative  
• Composition of steering committee and authorship working group clarified, aligned with MPIP recommendations  
• Generally, manuscript submission within 12 months (latest 18 months) of study completion (licensed products) or product approval/study termination (investigational products)  
• Guidance for publication of studies that do not yield medically important results, with multiple journal rejections – option of posting results on publically-accessible website/repository  
• Clarification on duplication publication; Avoidance of plagiarism, including self-plagiarism.  
• Type of documentation to maintain in project file |
| **2.0 Roles and responsibilities**  
• 2.1 Written agreement  
• 2.2 Authors access to data  
• 2.3 Authorship  
• 2.3.1 Qualifications  
• 2.3.2 Application and guidance  
• 2.3.3 Author payment and reimbursement | • Role of sponsor and author outlined in agreement  
• Level and type of data access to be granted to author (respecting patient confidentiality)  
• Guidance on common issues regarding authorship  
• Updated with revised ICMJE criteria  
• Author access to data cannot compromise patient confidentiality  
• Clarity around ‘guest’ & ‘ghost’ authorship  
• Clarity on appropriate authorship payment & reimbursement |
### 2.4 Professional medical writers
- **2.4.1 Role of the writer**
- **2.4.2 Working with authors**
- **2.4.3 As authors**

- Peer reviewed evidence included to support benefits of involving professional writers, and their role in developing a quality publication

### 2.5 Contributorship and acknowledgments

- Continued support for use of contributorship model, even if not required by journal
- Sample language provided
- Maintain the information in project file, if journal or congress does not allow inclusion

### 2.6 Disclosures

- Previously “Conflicts of Interest” section
- Financial and nonfinancial relationships; recommend 36 months disclosure window

### 3.0 Recommendations for specific types of articles and presentations
- **3.1 Primary and secondary publications**
- **3.2 Presentations at scientific congresses**
- **3.3 Review articles**

- Define primary and secondary publications
- Primary publications should be published before secondary publications, recommend at least one author is common to both primary and secondary publications from the same study
- Authorship criteria for posters should follow ICMJE; encores should share authorship with original congress presentation
## APPENDICES – GUIDELINES AND RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Section</th>
<th>Key points</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0 Reporting standards</td>
<td>• Authors should follow applicable standards (eg. CONSORT) for the data set</td>
</tr>
</tbody>
</table>
| 5.0 Data sharing      | • Sponsors should provide access to patient-level data to ‘qualified researchers’ upon request and respect journal requests  
                        • Access to data cannot compromise patient confidentiality                              |
WHAT STUDIES SHOULD BE PUBLISHED?

LaVerne A. Mooney, DrPH
Publications Management Team Leader, Pfizer
GPP3 Author
“Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject”

“Researchers have a duty to make publicly available the results of their research ... Negative and inconclusive as well as positive results must be published or otherwise made publicly available”

– Declaration of Helsinki

“It’s time all clinical trial results are reported… All trials past and present should be registered, and the full methods and the results reported. We call on governments, regulators and research bodies to implement measures to achieve this”

– Alltrials

http://www.up.ac.za/media/shared/Legacy/sitefiles/file/45/2875/declarationofhelsinki_fortaleza_brazil2013.pdf
http://www.alltrials.net/
Studies of NIH and industry-funded trials have reported selective or delayed publications\textsuperscript{1-2}

- 50\% of trials remained unpublished 30 months after study completion\textsuperscript{1,2} and about one third were still unpublished after median of 51 months\textsuperscript{1}

- For published studies the median time from study completion to publication was 23 - 27 months\textsuperscript{1-3}

\textsuperscript{1}Ross JS, Tse T, Zarin DA, Xu H, Zhou L, Krumholz HM. Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis. BMJ 2012;344:d7292

EFPIA / PhRMA JOINT POSITION ON PUBLICATION OF CLINICAL TRIAL RESULTS - 2010

**Which trials:**

"All industry sponsored clinical trials should be considered for publication in the scientific literature irrespective of whether the results of the sponsors medicine(s) are positive or negative. At a minimum, results **from all phase 3 clinical trials** and any clinical trial results **of significant medical importance** should be submitted for publication. This **includes investigational clinical products** whose development programs are discontinued."

**When:** “in a timely manner” and prioritize results of high medical or scientific importance

- Within 12 and by 18 months of:
  - Study completion for marketed products
  - Product approval for investigational products
  - Decision to discontinue

• Ideally all clinical trials published in peer-reviewed journal
• Regardless of whether positive, negative or inconclusive, or
• Whether intervention is investigational, is licensed, or has been discontinued or withdrawn from market
WHEN TO PUBLISH?

• GPP3 recommendations are aligned with the EFPIA

• Submit for publication by 12 and at the latest 18 months:
  — After study completion for approved products
  — After approval for investigational products
  — And after discontinuation decision
DIFFICULT TO PUBLISH STUDIES

• Not every publication will be readily accepted at the journal of the authors’ choice
  — Negative or equivocal results may be more difficult to publish (although there are now journals that state that they publish negative results)
  — Studies that do not change clinical practice or are confirmatory in nature may be more difficult to publish

• After multiple submissions and rejections from appropriate journals
  — Authors may consider posting on a registry e.g., clinicaltrials.gov or EudraCT to ensure the data in the public domain
When a study is terminated - often fewer subjects than planned:

- Studies that have recruitment problems or are terminated by the sponsor for business reasons, might not have sufficient data to test the hypotheses. In this case, posting on a public registry may be a good way to share the information with the public.

- Studies terminated for safety should always be made public; small numbers should not be used as an excuse for not publishing.
Per GPP3, which of the following types of studies should be published in the peer-reviewed literature?

A. Phase 3 studies and studies of medical importance
B. Only those that are properly powered to assess efficacy
C. Studies that are changing clinical practice
D. Ideally, all clinical trials (including non-interventional studies involving human participants)
E. Not sure
AUDIENCE QUESTION #2

According to GPP3 and the EFPIA Joint statement, how long after an investigational product is approved should the manuscript be submitted for publication?

A. Within 12 months after study completion
B. Between 12 months and 18 months after study completion
C. Not until the investigational compound is discontinued
D. Between 12 and 18 months after product approval
E. I don’t have a clue
A U T H O R S H I P

Yvonne E. Yarker, PhD, ISMPP CMPP™
President, Medicite LLC
GPP3 Author
GPP3 AUTHORSHIP GUIDANCE

- Provision of 10 Principles, 5 of which relate to authorship
- Substantial revisions including interpretation of ICMJE criteria
- Two new tables to provide guidance on common authorship issues
- Additional clarity on what constitutes guest or ghost authorship
- Clarification of appropriate payment for authorship
5. The rights, roles, requirements, and responsibilities of all contributors (ie, authors and any nonauthor contributors) should be confirmed in writing, ideally at the start of the research and, in all cases, before publication preparation begins.

6. All authors should have access to relevant aggregated study data and other information (eg, the study protocol) required to understand and report research findings.

7. The authors should take responsibility for the way in which research findings are presented and published, be fully involved at all stages of publication and presentation development, and be willing to take public responsibility for all aspects of the work.

8. Author lists and contributorship statements should accurately reflect all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors should also be disclosed.

10. All authors and contributors should disclose any relationships or potential competing interests relating to the research and its publication or presentation.
**GPP3 provides guidance on interpreting ICMJE authorship criteria to help authors better understand authorship requirements and responsibilities**

<table>
<thead>
<tr>
<th>ICMJE criteria (2014)</th>
<th>GPP3 guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Substantial contributions to the conception or design of the work; or the</td>
<td>Defines what is and is not a substantial contribution and provides examples:</td>
</tr>
<tr>
<td>acquisition, analysis or interpretation of data for the work</td>
<td>“A substantial contribution is an important intellectual contribution, rather</td>
</tr>
<tr>
<td></td>
<td>than technical assistance, without which the work, or an important part of the</td>
</tr>
<tr>
<td></td>
<td>work, could not have been completed or the manuscript could not have been</td>
</tr>
<tr>
<td></td>
<td>written and submitted for publication.”(19). Simply collecting data (eg,</td>
</tr>
<tr>
<td></td>
<td>enrolling a large number of patients) would not necessarily be considered a</td>
</tr>
<tr>
<td></td>
<td>qualifying criterion for authorship.</td>
</tr>
<tr>
<td></td>
<td>Some examples of what might represent a substantial intellectual contribution</td>
</tr>
<tr>
<td></td>
<td>include: actively guiding the scientific or medical content of the publication</td>
</tr>
<tr>
<td></td>
<td>or presentation; statistical analysis and interpretation; crafting of the</td>
</tr>
<tr>
<td></td>
<td>discussion; and developing the protocol.</td>
</tr>
<tr>
<td>ICMJE Criteria (2014)</td>
<td>GPP3 guidance</td>
</tr>
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<td>-----------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>2. Drafting the article or revising it critically for important intellectual content</td>
<td>Provides clarity on what constitutes a critical revision: This refers to revisions beyond minor corrections for grammar, language, formatting, or layout. The key is ongoing intellectual contribution, the provision of substantial comments, and approval of the final version. Although preferred, it is not always feasible or necessary for authors to comment on every stage of manuscript development.</td>
</tr>
<tr>
<td>3. Final approval of the version to be published</td>
<td>Important for the author to read the entire manuscript: To give final approval it is necessary to have carefully read the entire paper from start to finish.</td>
</tr>
<tr>
<td>4. Agreement to be accountable for all aspects of the work in ensuring questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved</td>
<td>Each author is accountable for the work and should have confidence in the integrity of other authors’ contributions: Each author is accountable for the work and should have confidence in the integrity of the other authors’ contributions. Each author should be able to identify who wrote each section.</td>
</tr>
</tbody>
</table>
COMMON AUTHORSHIP ISSUES

- GPP3 provides guidance to help authors navigate common authorship issues, including:
  - Number of authors
  - Author sequence
  - Addition or removal of authors
  - Death or incapacity of an author
  - Change of affiliation
  - Company- or sponsor-employed authors
  - Professional medical writers as authors
### APPENDIX TABLE 2. COMMON ISSUES ABOUT AUTHORSHIP

<table>
<thead>
<tr>
<th>Issue</th>
<th>GPP3 guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of authors</td>
<td>Consideration should be given to the number of qualified authors needed to take responsibility for the publication … it would be unusual in biomedical research …to require more than ten authors to meet this need. A high number of authors calls into question whether they could all have provided ‘substantial intellectual contribution’. Fewer authors are often preferable.</td>
</tr>
<tr>
<td>Author Sequence</td>
<td>Authors should decide how this will be determined at the initiation of the work…Final order, however, should be based on authors’ actual roles and contributions in the development of the publication (and therefore cannot be agreed until this is complete). Those who made the greatest contribution are generally listed first, but alphabetical order may also be used. It may be useful to describe, in the contributorship section of the publication whether alphabetical order or some other convention was used to determine author order.</td>
</tr>
</tbody>
</table>
## APPENDIX TABLE 2. COMMON ISSUES ABOUT AUTHORSHIP

<table>
<thead>
<tr>
<th>Issue</th>
<th>GPP3 guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition or removal of author</td>
<td>…it may be necessary to add or remove an author (eg, if an author fails to provide a substantial contribution or approve the final version of the work). In such cases, all authors should agree to the change. Only in very rare cases, such as substantial changes to the work in response to reviewer comments, should addition or removal of an author be considered after submission. For encore presentations of abstracts at local language congresses where presenters are required to be an author, an additional name may be added to the author list (with all authors’ permission) for the purpose of presenting on behalf of the group in the local language.</td>
</tr>
<tr>
<td>Death or incapacity of an author</td>
<td>Should an author die after completing a major part of the work (ie, fulfilling criteria 1 and 2 in the Table) posthumous authorship can be considered if agreed to by all other authors. We suggest, as a first step, seeking advice regarding correct attribution and process from journal instructions or the editorial office. If the journal agrees to posthumous authorship, but requires submission forms to be signed, then in the case of a sponsor-employed author or a contractor, a supervisor may be the most appropriate proxy. Otherwise, a family member or person with power of attorney should be approached (19). In all cases, efforts should be made to contact the family of the deceased author to inform them of the intention and request their consent to the listing or acknowledgment.</td>
</tr>
</tbody>
</table>
## APPENDIX TABLE 2. COMMON ISSUES ABOUT AUTHORSHIP

<table>
<thead>
<tr>
<th>Issue</th>
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<tr>
<td>Change of affiliation</td>
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<td>Company- or sponsor-employed authors</td>
<td>Sponsor-employed scientists and clinicians are often qualified to participate as authors of company-sponsored research publications and should have that opportunity. Such authors should not be denied authorship because of concerns regarding perception of bias. Whatever criteria are used to determine authorship should be applied equally to company employees, contractors, and others.</td>
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<td>Professional writers as authors</td>
<td>Professional medical writers who meet applicable authorship criteria should be listed as authors. If writers do not meet authorship criteria their contribution should be disclosed (eg, as a nonauthor contributor, in the acknowledgments section). Writers who were not involved with study design, data collection, or data analysis and interpretation (eg, those developing a primary publication from a clinical study report) generally do not meet ICMJE authorship criteria. However, professional writers working on other types of publication (eg, literature reviews) may qualify as authors. For guidance on professional writers as authors please see section 2.4</td>
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</table>
SECTION 2.3.2. AUTHORSHIP APPLICATION AND GUIDANCE

- **Guidance on guest and ghost authorship**
  - Authorship criteria should be applied consistently; all listed authors must fulfill the authorship criteria (ie, no guest authors)
  - All those who fulfill the criteria must be listed as authors, including company- or sponsor-employed authors and contractors (ie, no ghost authors)

- **Authorship must not be used as a reward or gift for services rendered; the following activities alone are not sufficient**
  - Trial enrollment or technical assistance (eg, laboratory assistance, data acquisition, statistical programming, clinical trial management, or editing services).
  - Acquisition of funding or supervision of a research group or department
CONFLICTS OF INTEREST, DISCLOSURES & FAIR MARKET COMPENSATION

Leslie Citrome, MD, MPH
Clinical Professor of Psychiatry & Behavioral Sciences,
New York Medical College, Valhalla, NY
Editor-in-chief, The International Journal of Clinical Practice
GPP3 Author
Conflicts of interest
We recommend that authors disclose financial relationships (for example, any financial relationships or obligation to the research sponsor or other companies, including contractual relations or consultancy fees for scientific, government, or legal services, or equity in the company) and non-financial relationships (for example, personal relationships, including those of immediate family members, and participation in litigation) that could inappropriately influence or seem to influence professional judgment. We recommend that these disclosures are made in all articles submitted for publication in peer reviewed journals, as well as in abstracts and posters submitted to congresses at the time of submission, if space requirements allow, and that they are included in oral presentations and posters at the time of presentation, regardless of whether disclosure is requested by the journal or congress.

For example: “A is a member of a speakers’ bureau, has been a consultant for, and has received research grants from YZ Pharmaceuticals. C is an employee of YZ Pharmaceuticals. B has stated that she has no conflicts of interest.”

There is no universal standard applied by journals and congresses for disclosure of potential conflicts of interest. Until discussions about how to address conflicts of interest are resolved, we recommend authors favour greater, rather than lesser, disclosure.

2.6: Disclosures
When discussing relevant relationships authors may have with commercial (or noncommercial) entities, the term “disclosures” may be preferable to “conflicts of interest” or “competing interests” because these latter terms may imply actual (rather than perceived or potential) conflicts and may inadvertently prevent full disclosure if the authors interpret them narrowly or fail to consider other relationships that may affect the manuscript.

Authors should disclose financial and nonfinancial relationships that could be perceived to bias their work or influence professional judgment. In general, this means disclosing the names of, and relationship with, all pharmaceutical, biologics, medical device, and diagnostics manufacturers in which an author (or close family member) is employed, is a contractor, provides services, or has otherwise collaborated in commercial or scientific pursuits—even in the absence of direct monetary remuneration. The stock holdings and issued or pending patents of an author or family member may also be relevant. Any institutional, company, and journal disclosure requirements should also be followed. If no time frame for disclosure is specified, we recommend following the ICMJE disclosure form and using a 36-month disclosure window. Disclosure statements should be provided (on submission) for each author of a publication (31) or congress abstract (if space requirements allow). Disclosure statements should also be included in slides for oral presentations and on posters.
Disclosures (Formerly ‘Conflict of Interest’)

- Renamed ‘Conflicts of Interest’ to ‘Disclosures’, along with the rationale for this:
  - ‘Disclosures’ may be preferable to ‘conflicts of interest’ or ‘competing interests’ because these latter terms may imply actual (rather than perceived or potential) conflicts and may inadvertently prevent full disclosure if the authors interpret them narrowly or fail to consider other relationships that may affect the manuscript.
  - In some cultures and in some locales, the term ‘conflicts of interest’ implies wrongdoing or corruption.
- The extent of the recommended disclosures is now made explicit.
FROM ‘NEVER PAY’ IN GPP2 TO ‘CAN SOMETIMES PAY’ IN GPP3

**Reimbursement**

It may be appropriate for companies to reimburse reasonable out of pocket expenses (for example, travel expenses) incurred by contributors or pay for specialised services such as statistical analysis. Details of this reimbursement must be disclosed. We recommend that no honorariums are paid for authorship of peer reviewed articles or presentations.


2.3.3: Author Payment and Reimbursement. Companies may reimburse reasonable publication- or presentation-related out-of-pocket expenses (for example, travel and accommodation) incurred by authors and other contributors and pay for publication activities (for example, statistical analysis, medical writing, editing, or similar services) to assist authors in the development of publications and presentations. Any such payments should reflect the services provided and be at fair market value. Details of any payments (or other forms of compensation) to authors and contributors must be fully disclosed and comply with applicable regulations and company, institutional, journal, and congress policies. 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.
PAYMENTS TO AUTHORS: GPP3 ALLOWS FOR COMPENSATION AT FAIR MARKET VALUE FOR ACTIVITIES RELATED TO MEDICAL PUBLISHING

• Clarification on appropriate payment for authorship
  — Never for the ‘name’
  — Never to influence an author’s opinion
  — Never to persons employed by an institution/organization/company where such activities are part of their job and the reason why they get paid a salary
  • GPP3 contains the specific wording that ‘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’
  — However payment can be made for publication activities (for example, statistical analysis, medical writing, editing, or similar services) to assist authors in the development of publications and presentations; payments should reflect the services provided and be at fair market value
  • Examples:
    — The self-employed medical writer who qualifies for and should be a named author
    — The self-employed HCP consultant/author engaged in the data analysis and preparation of the report
    — The self-employed HEOR consultant engaged in the project and a named author
  — Difficult to prove specific intent, thus sponsors may choose to adopt policies that prohibit compensation for time spent authoring a publication or presentation
WHAT'S NEXT?

Wendy P Battisti, PhD
NEXT STEPS FOR GPP3

• Global training and presentations
  – Steering committee presentations at local and national meetings
  – GPP3 sessions at ISMPP Meetings
    • September 2015; Tokyo and Beijing

• GPP3 Website
  – Established GPP3 subcommittee:
    • Will lead effort to monitor and respond to FAQs
    • Develop additional training materials
• GPP3 Website (cont)
  – Update GPP ISMPP website to include GPP3
    • Steering committee and website member list
    • GPP3 for authors’ checklist – practical tool
    • FAQ document
    • GPP3 process summary

• Post acceptance
  – EMWA, AMWA, The European Association of Science Editors (EASE) and the Japan Medical and Scientific Communicators Association (JMCA) have endorsed GPP3; EQUATOR has included the guidelines on their website
  – GPP3 translations into Japanese and Chinese
NEXT STEPS FOR GPP3 (CONT)

- GPP3 Reprints
  - The *Annals of Internal Medicine* will offer all requestors nonprofit pricing for reprints of GPP3
  - Refer to ISMPP website for request/contact information:
    [http://www.ismpp.org/gpp3-reprint-info](http://www.ismpp.org/gpp3-reprint-info)
• Alison Brown - Springer (publisher)
• Kimberly Cash - independent consultant, academic affiliation
• Sarah Feeney - Complete Medical Communications
• John Gonzalez - Astrazeneca
• Tom Grant - Complete HealthVizion
• Kim Pepitone - Cactus
• Suzann Schiller - MedErgy
• Donna Simcoe - independent consultant
• Danita Sutton - independent consultant
• Ryan Woodrow - Aspire Scientific
IN THE END, WHAT’S IT ALL ABOUT?

Our goal must remain excellence in all of our publications: Advances in healthcare, and patient lives and safety depend on it.
THANK YOU!
QUESTIONS . . .

• To ask a question, please type your query into the Q&A box
• To ensure anonymity, before sending please choose the drop-down box option, "ALL PANELISTS." Otherwise, ALL audience members will be able to see your submitted question
UPCOMING ISMPP U'S

- **Nov 9, 2015 at 9pm-EST** (check the ISMPP website for local times)
  - APET ISMPP U Topic: Highlights from the 2015 Asia Pacific Meetings of ISMPP

- **Nov 18, 2015**
  - Topic: Biostats Primer and Working Collaboratively with Statisticians
  - Presenters:
    - Meg Franklin, PharmD, PhD, President, Franklin Pharmaceutical Consulting, LLC
    - Jay Hsu, PhD, Executive Director of Biostatistics, Sunovion Pharma Inc.

- **December 2015**
  - Topic: Medical Devices

- **January 2016**
  - Topic: Manuscript Development
THANK YOU FOR ATTENDING!

- We hope you enjoyed today’s presentation. Please take a few moments to complete the survey that will appear on your screen immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings.