Welcome to the 10th Annual Meeting of ISMPP!

Leading Through Collaboration
GPP: Evolution and expansion of guidelines for good publication practices

Wendy P Battisti, PhD, CMPP
Director/Janssen Research & Development, LLC
Objectives

• Understand the need for guidelines on good publication practice and some of the challenges that medical publication professionals face.

• Understand how GPP2 is currently used in practice to help promote integrity, transparency, and best practices and the rationale for updating these guidelines.

• Become aware of the breadth of activities occurring in developing GPP3, the current status, and development timelines.
Outline

• Why all of the guidelines?
• Responding to the changing industry
  – Evolution of GPP1 and GPP2
• Developing GPP2
  – How are they perceived and used (audience survey)
• Developing GPP3
• Summary
Why all the guidelines?

• Peer reviewed publications remain the gold standard for meaningful impact on research as well as our healthcare communities and patients.

• The goals of publications are to help advance scientific and medical research, healthcare practice standards, and ultimately the quality of patients’ lives.

• Good publication practice guidelines (“GPP”) help establish or reinforce best practices for companies to achieve these goals.
  – The aim of these guidelines is to ensure that publications are produced in a responsible and ethical manner. (GPP1)
  – The authors, collaborators, and organizations share responsibility for developing articles and presentations in a responsible and ethical manner. (GPP2)
Good Publication Practice Guidelines “GPP” – The evolution


**GPP3**
Goal of GPP guidelines

- Integrity
- Completeness
- Transparency
- Accountability
- Responsibility

Bullet points from GPP2 checklist

Ethical
‘Good publication practice embraces all the procedures and practices that are necessary for planning, publishing and communicating research and scholarship supported by pharmaceutical, medical device and biotechnology companies within a framework of scientific integrity.’

It’s not all black and white…

Who is eligible to participate in a publication?
How do you choose potential authors?
Is there value in publication planning?

Is there value in medical writing support?

Individual journal criteria that may differ from ICMJE?

ICMJE authorship criteria

“Grey Zones”

Should the sponsor have any role in review/approval of the publication?

Should authors ever receive payment for authorship?

What is a substantial contribution?
What is drafting?
What is revising?
What defines approval?
Responding to the changing industry

• Nearly 10 years between development of GPP1 and GPP2
  – GPP1 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
  – Much changed in the field of publications

• Public scrutiny of pharma
  – Conflict of interest
  – Hiding data
  – Influencing clinicians
  – “Noise” and marketing messages versus good science in publications

• GPP2 is more comprehensive vs. GPP1
  – More diverse input (reviewers)
  – Additional topics
Audience Question

In the last 5 years, the increased number of guidelines and good publication practice initiatives by pharmaceutical companies has resulted in improved trust in our data by public and healthcare providers:

Yes: 68%
No: 32%

N = 107
Responding (still) to the changing industry

- Four years between GPP2 publication and initiation of GPP3 end of 2013
  - Goal: updated guidelines submitted to journal by end of 2014
- What has stayed the same and what continues to change, often with global implications
  - Increased pressure for greater access to clinical trial data
  - Expansion of trial registration requirements and data sharing
  - ICMJE recommendations continue to evolve
  - Open payment legislation evolving worldwide
  - Public trust continues to erode
GPP2 Guidelines and Recommendations

GPP2 is for...individuals and organizations that contribute to the communication (specific to peer reviewed articles and congress presentations) of medical research sponsored by companies (pharmaceutical, medical device, and biotechnology).
**Process – Four Key Steps**

**Step 1**
ISMPP Invitations June 2008
ISMPP initiated update
Steering Committee recruited from membership

**Step 2**
Steering Committee Convened Aug 2008
Reviewed original GPP guidelines
Considered new literature
Wrote first draft for new guidelines
Recruited the consultation panel

**Step 3**
Consultation panel Dec 08 - Feb 09
Reviewed first draft
Invited: N=289;
(Academic centers, journal editors/publishers, medical agencies, pharma, device and biotech companies. Professional organizations)
Responded: n= 116

**Step 4**
Steering committee June 09 – submit BMJ
Ranked panel’s comments
Finalized guidelines
• Submit – June
• Revisions – July
• Resubmitted – Sept
• Acceptance – Oct, 2009

Are you primarily affiliated with:

- Communications agency: 52%
- Industry: 41%
- Academic institution: 1%
- Journal (editor, publisher): 2%
- Other: 4%

N = 113
Are you familiar with or did you use the first set of good publication practice guidelines developed for industry? (Wager et al)

YES: 82%

NO: 18%

N = 117
Are you familiar with or do you use the second set of good publication practice guidelines: “GPP2” (Graf et al)?

YES: 97%

NO: 3%

N = 114
Does your company or institution refer to or cite GPP2 in their policy or standards of practices for publications?

YES: 90%

NO: 7%

DON’T KNOW: 3%
How would you rate the current GPP2 guidelines in terms of usefulness?

Gold standard: 74%

Useful, but not my preferred information source: 25%

Not useful or not relevant to my role: 1%

N = 115
In your opinion, has the use of the good publication practices guidelines (GPP1 and 2) improved standards at your company or institution?

YES: 83%
NO: 3%
DON’T KNOW: 9%
NOT APPLICABLE TO ME: 5%

N = 119
Developing GPP3
GPP3 Steering Committee

• Affiliated with ISMPP
• Diversity of roles, experience, and global representation (as best we could)
• Current affiliations:
  – Publisher
  – Editor
  – Industry
  – Agency
  – Freelance
• Many have worked in more than one of listed affiliations, and some have academic backgrounds.
• Highly experienced, many with 15-20 years in publications
• Representatives of the profession – and, we hope, you
GPP3 Steering Committee

- Baltzer, Lise
  - Novo Nordisk A/S, Denmark
- Battisti, Wendy (2) *
  - Janssen Research & Development LLC, USA
- Bridges, Dan (2) *
  - Apothecom scopemedical, UK
- Cairns, Ange *
  - KnowledgePoint360 Group, UK
- Carswell, Chris
  - *Pharmacoeconomics, Springer Int’l Publishing AG., New Zealand
- Citrome, Les
  - *Int’l Journal Clinical Practice, Wiley-Blackwell, USA
- Graf, Chris (2)
  - Wiley Blackwell, Australia (now UK)
- Gurr, Jim (2) *
  - MedImmune, USA
- Marx, Mary Ellen (2) *
  - PharmaWrite, USA
- Mooney, Laverne
  - Pfizer Inc., USA
- Moore, Jane (2) *
  - Medtronic, USA
- Patel, Mina (2)
  - Vertex Pharmaceuticals, Inc, USA
- Pena, Teresa
  - AstraZeneca, USA
- Sanes-Miller, Carol (2) *
  - Vision2Voice, USA
- Tokaji, Aya *
  - Statcom Co Ltd, Japan
- Veitch, Keith
  - Amsterdam, The Netherlands
- Wager, Liz (1)
  - Sideview, UK
- Woolley, Karen *
  - ProScribe-Envision Pharma Group, Australia
- Yarker, Yvonne (2) *
  - Medicite LLC, USA

(1) GPP1 author; (2) GPP2 steering committee; *CMPP
GPP3

• TITLE: Good publication practice for communicating company-sponsored medical research: GPP3

• SCOPE: The communication of medical research sponsored by companies (GPP2 wording) – to include planning and preparation of publications as did GPP2

• FORMAT: Well defined, high-level principles at the front. Followed by more specific content – now in development.

• REVIEW PROCESS: First draft during the summer?
  – 150 agreed to participate as reviewers
  – Seeking more journal editors as reviewers; stay tuned
Questions?
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