



Building Trust in Industry-Sponsored Research

LaVerne Mooney DrPH

Director, Publication Management

Pfizer External Medical Communications

Disclosure

- LaVerne Mooney is an employee of Pfizer, a sponsor-company of MPIP
- The views and opinions presented here during discussion are her own and may not represent those of her employer

Introduction

MPIP Vision

To develop a culture of **mutual respect, understanding, and trust** between journals and pharma that will support more **transparent and effective** dissemination of results from industry-sponsored trials



MPIP activities supported by Leerink Swann LLC

About MPIP

Our Organization

- Founded in 2008 by pharmaceutical co-sponsors and International Society for Medical Publication Professionals (ISMPP)

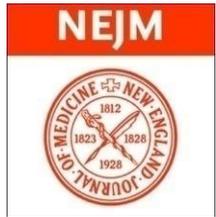


Our Objectives

- Understand issues and challenges in publishing industry-sponsored research
- Identify potential solutions to increase transparency and trust
- Promote more effective partnership between sponsors and journals to raise standards in medical publishing and expand access to data

Introduction

MPIP participants to date



THE LANCET



Annals of Internal Medicine



Clinical Therapeutics



THE JOURNAL OF CLINICAL PSYCHIATRY



PHARMACOTHERAPY

The Journal of Infectious Diseases

Journal of Opioid Management

Clinical Cancer Research



Introduction

Major activities – 2008-2010

Editor Research

- Combination of interviews, surveys, and focus groups to obtain editors' feedback on key issues

Collaborative Meetings

- Initial meeting of editors and industry to exchange ideas on key issues and brainstorm solutions in 2009
- Follow-up Roundtable meeting in 2010 discussed ways to enhance the quality and credibility of industry-sponsored clinical research

Peer Reviewed Publications

- Summary of key outputs from 2009 Roundtable published in *International Journal of Clinical Practice*¹
- Guide to submission “best practices”, co-authored by editors, publishers, and pharma publication planners in *Current Medical Research & Opinion*²

Outreach

- MPIP presentations at professional society meetings
- Creation of a MPIP website to distribute resources

¹ Clark J, et al. *International Journal of Clinical Practice* 2010; 64(8): 1028-33.

² Chipperfield L, et al. *Current Medical Research and Opinion* 2010; 26(8): 1967-82.

Progress in the past year

- “Ten Recommendations for Closing the Credibility Gap” ***published by Mayo Clinic Proceedings*** in May 2012
- An accompanying ***video produced by MPIP and press release from Mayo*** generated multiple press articles and discussion
- MPIP hosted a ***presentation of the “Top 10 Recommendations” and current activities*** at the 2012 ISMPP meeting
- MPIP ***launched a new website*** (<http://www.mpip-initiative.org/>) to more broadly communicate its mission, provide a link with external stakeholders, and serve as a repository for past materials
- Hosted the 4th annual journal editor meeting in New York City – “Who is an Author? Perspectives from Editors, Investigators, and Publication Professionals”

MPIP is using insights to drive joint activities with editors



- Surveyed editors for barriers to transparent publication
- Convened editor workshop to identify and prioritize ways to close the “credibility gap” for industry trials

- Assembled editors and industry co-sponsors to draft whitepaper
- Peer-reviewed article published by *Mayo Clinic Proceedings*¹

- Authorship a key area for focus of joint activities in 2012
- Working with editors and other stakeholders to develop authorship guidance from case study analysis

¹Mansi B, et al. Mayo Clinic Proceedings 2012 87(5):424.

Introduction

Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research

- Co-authored by members of MPIP Steering Committee and:
 - Dan Haller, Editor-in-Chief emeritus, *Journal of Clinical Oncology*
 - Christine Laine, Editor-in-Chief, *Annals of Internal Medicine*
 - Maja Zecevic, former North American Senior Editor, *The Lancet*
- Collaborative brainstorming, writing, and editing process over several months via teleconferences
- Published *Mayo Clinic Proceedings* in May 2012

These “Ten Recommendations” serve as a platform for planning future MPIP activities to support more transparent and effective dissemination of results from industry-sponsored trials

“Ten Recommendations for Closing the Credibility Gap”

1. Ensure clinical studies and publications address clinically important questions
2. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy
3. Improve understanding and disclosure of authors’ potential conflicts of interest
4. Educate authors on how to develop quality manuscripts and meet journal expectations
5. Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to definitively end ghost writing and guest authorship
6. Report adverse event data more transparently and in a more clinically meaningful manner
7. Provide access to more complete protocol information
8. Transparently report statistical methods used in analysis
9. Ensure authors can access complete study data, know how to do so, and can attest to this
10. Support the sharing of prior reviews from other journals

MPIP's focus for 2012 – Authorship

- **Improve disclosure of authorship / writing assistance and education on best publication practices to end “ghost” and “guest” writing**
 - Combat “guest” authorship in academia and industry
 - Determine level of internal and external contribution required for publication needs
 - Continue positive activities in full disclosure of all contributors, including professional medical writers

Why focus on authorship?

**Significant Need
for Editors and
Industry**

**Opportunity to
Make a Valuable
Contribution**

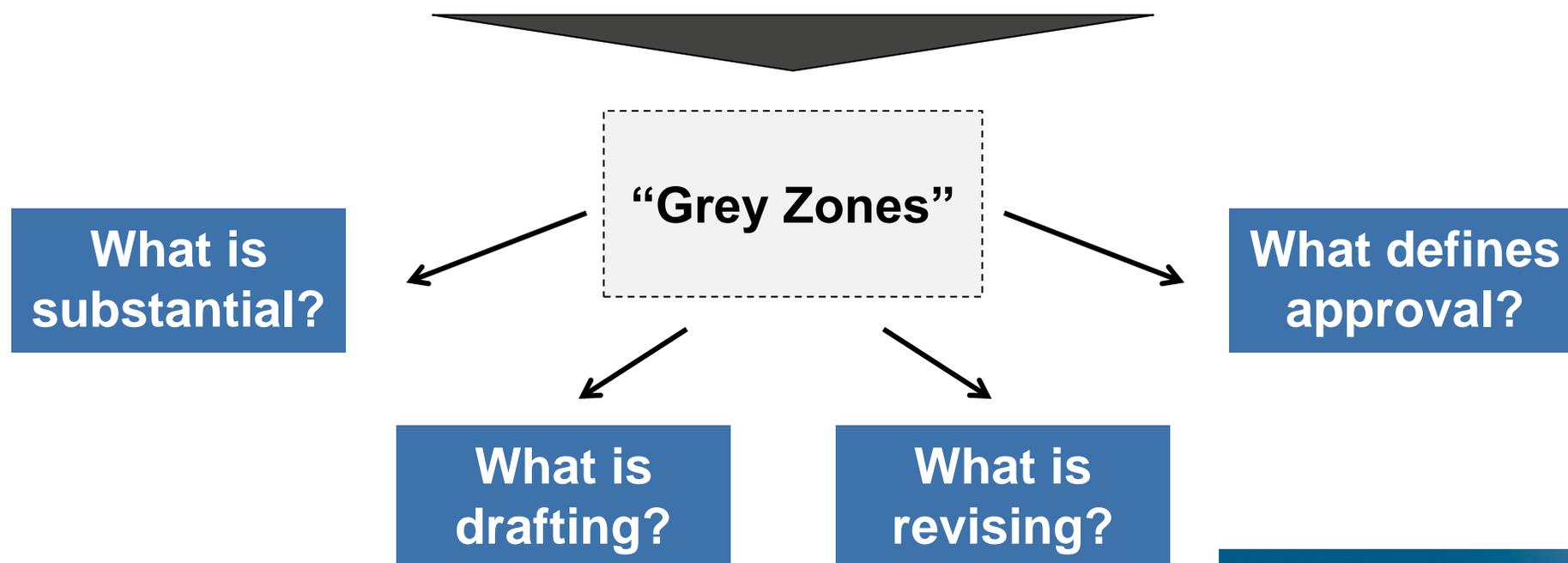
**Aligned with
MPIP's Vision and
Mission**

- Editors have expressed need for action in various MPIP events and activities
- Initial outreach with editors suggests:
 - Persistent and difficult issue
 - Interest in collaborating with industry
 - MPIP activity here would be valuable
- Aligned with MPIP's history and goal of collaborative activities to raise standards – supported by editors

Current challenges in authorship

ICMJE guidelines state authorship credit should be based on:

1. *Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;*
2. *Drafting the article or revising it critically for important intellectual content; and,*
3. *Final approval of the version to be published*



Authorship

MPIP designed a 3-part approach to address authorship needs identified by journal editors and industry co-sponsors

Goals for MPIP's Authorship Activities

- Clarify definitions of authors / contributors that resolve challenging ambiguities in current guidelines for industry-sponsored trial publications
- Inform development and distribution of harmonized definitions / criteria that are accepted by all stakeholders
- Continue to promote further transparency among stakeholders for industry-sponsored clinical trial publications



Authorship

MPIP formed a research team that includes external collaborators with an interest in authorship

MPIP Steering Committee

- Collaborative approach; full transparency
- Assist in initial development of “Grey Zone” case studies
- Identify stakeholders and provide outreach for interviews and survey

**Ana Marusic, MD, PhD &
Darko Hren, PhD
(Academic Collaborators)**

- Facilitate development and analysis of research
- Lead publication development and conference presentations

**Liz Wager (Advisor) &
Journal Editors**

- Provide feedback on case studies and methodology
- Advise post-research journal engagement

Authorship

MPIP's academic collaborators have published previously on authorship and other medical research topics



Ana Marusic, MD, PhD

- Professor of Anatomy and Chair of Research in Biomedicine and Health department at the University of Split
- Research interests in peer review and research integrity
- Editor-in-chief of Croatian Medical Journal and Journal of Global Health



Darko Hren, PhD

- Instructor in educational psychology and research methods at University of Split Faculty of Philosophy
- Research interests in moral development and moral decision making
- Former statistical editor for the Croatian Medical Journal

MPIP developed a case-based, survey approach to answer key authorship questions

Key Questions

- Which authorship problems arise most frequently and are most difficult to adjudicate?
- Is there agreement on who should be an author for these scenarios within and across stakeholders?
- What rules / guidelines do people use to adjudicate authorship and how confident are they in their assessment?

Survey Rationale

- Identify insights from a large sample of key stakeholders
- Case-based format focuses responses on highest priority and most prevalent issues
- Will contribute to the literature by:
 - Highlighting most challenging and frequent “Grey Zones”
 - Understanding how these challenging scenarios are adjudicated across four stakeholder groups
 - Capturing confidence of answers and frequency of cases

Authorship

MPIP implemented a three-part plan to develop, field, and analyze an authorship survey in 2012

Early 2012

Create and refine “Grey Zone” case scenarios

- Develop “Grey Zone” case studies with input from key stakeholders
- Benchmark current industry approaches
- Conduct qualitative research with key stakeholders to refine case studies

Mid-2012

Develop and field survey

- With collaborators, design and refine case based survey
- Build survey respondent lists
- Collaborate with publishers on outreach plan for journal editors

Late 2012-2013

Analyze data and develop outputs

- Analyze / synthesize research project output
- Discuss interpretation with editors to prioritize areas of need and map out next steps
- Reach alignment on and develop guidance to address ambiguities in current guidelines

Current Focus

MPIP set criteria for how to define potential survey respondents from each of four stakeholder groups

Journal Editors

- Indexed on NIH's Abridged Index Medicus list of clinical journals or a top 30 journal by ISI or Page Rank
- Listed on masthead of respective journal as editor-in-chief, associate editor, deputy editor, scientific editor, or positions of similar influence

Clinical Investigators

- Participation in industry-sponsored clinical trials, phase I or above (from Adis database collaboration)

Publication Planners

- Membership in ISMPP

Medical Writers

- Membership in AMWA/EMWA

Authorship survey design overview

Journal
Editors

Clinical
Investigators

Publication
Planners

Medical
Writers

Confidential and blinded responses

Survey design

• “Grey Zone” case studies*:

- How to adjudicate case study (authorship, acknowledgement, no recognition)?
- What rationale did you use?
- How confident are you?
- How frequently does this occur?

• Current authorship practices:

- What guidelines are you aware of?
- Which guidelines do you use most?
- In a given clinical study, when are authorship criteria determined?
- In a given clinical study, when are authors determined?

*Note: Cases were presented in a random order to avoid fatigue bias

Next steps for authorship research project

Early 2013

Continue to refine survey analysis

- Convene meeting of EU editors to broaden MPIP engagement
- Continue to analyze survey results and validate findings
- Layer in additional research with clinical investigators

Mid-2013

Draft and disseminate guidelines

- Collaborate with editors and other stakeholder to craft guidance
- Present full findings at upcoming conferences
- Draft whitepaper submission for peer review

Late 2013

Collaborate with groups to broaden impact

- Obtain buy-in from influential external organizations
- Incorporate authorship recommendations into co-sponsor policies as appropriate
- Leverage MPIP website to disseminate results and broaden reach

Reporting adverse event (AE) data more transparently and in a more clinically meaningful manner is part of the “Top 10” list

• **Rationale for inclusion:**

- Provide practical information that clinicians need to know to safely optimize patient care
 1. Continued need to ensure AE claims made in publications are appropriately balanced and reflect limitations of the trial design
 2. Several common phrases used in reporting adverse events (e.g., "no clinically significant adverse events", "no unexpected adverse events", or overuse of the vague terms “safe and well tolerated”) provide insufficient detail, particularly for agents that may be used chronically in large patient populations

• **Potential recommendations:**

- Journals should consider whether they would prefer additional adverse event information to be present in the body of the paper, and if so, revise their manuscript length policies accordingly

The MPIP collaboration – Keys to success

Joint Activities

- Engage leading editors who shared our goals in small, focused roundtables
- Stress joint communication and understanding

Independent Research

- Obtain open and honest feedback from key stakeholders on barriers to trust and transparency to provide a foundation for successful partnership

Tangible deliverables

- Work alongside editors in the solutions and outreach, including development of papers, presentations, and other educational activities

Track Progress

- Focus on actionable solutions for industry partners that result in advancement against initial barriers and challenges

Thank You

Appendix

'Top 10' Recommendations for Enhancing Credibility of Industry-Sponsored Research

1. Ensure clinical studies and publications address clinically important questions

- Address perception that some industry-sponsored research does not address clinically meaningful questions
- Consider soliciting more public feedback on R&D to enhance credibility

2. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy

- Strive for increased transparency around industry's commitment to promptly publish all results, irrespective of study outcome
- Continue discussion of how / where to disclose studies of specialized interest

3. Improve understanding and disclosure of authors' potential conflicts of interest

- Clarify authors' confusion on what constitutes "relevant" relationship
- Encourage standardization (e.g., ICMJE's form)
- Encourage discussion of how to develop more centralized approach

'Top 10' Recommendations for Enhancing Credibility of Industry-Sponsored Research

- 4. Educate authors on how to develop quality manuscripts and meet journal expectations**
 - Expand author education in both academia and industry
 - Raise awareness beyond “big pharma”, to small companies and vendors
 - Broadly distribute existing resources, e.g., Author’s Submission Toolkit
- 5. Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end “ghost” writing and “guest” authorship**
 - Combat “guest” authorship in academia and industry
 - Educate industry that KOL inclusion not needed to “impress” editors
 - Continue positive activities in full disclosure of all contributors, incl. professional medical writers
- 6. Report adverse event data more transparently and in a more clinically meaningful manner**
 - More completely report all adverse events, even low-incidence ones
 - Support development and dissemination of standard approach

'Top 10' Recommendations for Enhancing Credibility of Industry-Sponsored Research

7. Provide access to more complete protocol information

- Help journals verify eligibility, endpoints and pre-specified analyses
- Inform alignment on most appropriate venue for dissemination, handling of amendments, and how to handle irrelevant information

8. Transparently report statistical methods used in analysis

- Encourage “reproducible results” in academia and industry
- Continue dialogue to address challenges with independent analysis

9. Ensure authors can access complete study data, know how to do so, and can attest to this

- Fully educate authors on rights and responsibilities re. data access

10. Support the sharing of prior reviews from other journals

- Educate authors in academia and industry that sharing submission history, incl. prior reviews and responses, would enhance credibility

MPIP collaborated with a number of publishers to reach editors who publish industry-sponsored clinical trial results

Selection Criteria

Journal Editors

- Affiliated with a journal indexed on NIH's Abridged Index Medicus list of core clinical journals (<http://www.nlm.nih.gov/bsd/aim.html>), supplemented with journals by impact factor and those recommended by publishers
- Listed on masthead of respective journal as editor-in-chief, associate editor, deputy editor, scientific editor, or positions of similar influence

Collaborating Publishers

