

The Medical Publishing Insights and Practices (MPIP) Initiative

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Disclosure

- Mary-Margaret Lannon is an employee of Takeda, a sponsor-company of MPIP. The views and opinions presented here during discussion are her own and may not represent those of her employer.

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

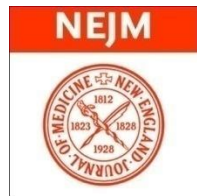


MPIP activities supported by Leerink Swann LLC



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MPIP participants to date



THE LANCET



Clinical Therapeutics
The International Peer-Reviewed Journal of Drug Therapy

Annals of Internal Medicine

Diabetes, Obesity and Metabolism



JOURNAL OF CLINICAL ONCOLOGY

Neurology



The Journal of Infectious Diseases

PHARMACOTHERAPY

THE JOURNAL OF CLINICAL PSYCHIATRY



Clinical Cancer Research



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Highlights of MPIP accomplishments since 2008

Raising Standards

- Journal-pharma roundtable in 2010 reached consensus on recommendations to close credibility gap in industry-sponsored research – in press at *Mayo Clinic Proceedings**
- Collaborated with journals on publication to raise standards and streamline publication process**



Driving Best Practices

- Developed **Authors' Submission Toolkit** collaboratively with editors and publishers
- Published in *Current Medical Research and Opinion****, and downloaded >15,000 times



Engaging Key Stakeholders

- Awarded 2010 Communiqué Trust and Reputation Award by enhancing industry's trust and reputation
- Presented at CSE, ISMPP, and other forums
- Ongoing outreach via publications and research



* Mansi B, et al. *Mayo Clinic Proceedings* 2012; in press.

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

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



Audience Question #1

**How familiar are you with MPIPs
Authors' Submission Toolkit?**

- a. I have used the ***Authors' Submission Toolkit***
- b. I am aware but haven't used the ***Authors' Submission Toolkit***
- c. I was not aware of the ***Authors' Submission Toolkit***

MPIP is using insights to drive joint activities with editors



- Surveyed editors for barriers to transparent publication
- Convened workshop with editors and industry co-sponsors
- Brainstormed and prioritized ways to close the “credibility gap” for industry trials
- Assembled editors and industry co-sponsors to draft whitepaper
- Peer-reviewed article accepted by *Mayo Clinic Proceedings* (in press)*
- Aligned on authorship as key area for focus of joint activities in 2012
- Working with editors to develop authorship guidance and case studies analysis

* Mansi B, et al. *Mayo Clinic Proceedings* 2012; in press.

Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research: A Joint Journal / Pharmaceutical Industry Perspective

- 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, North American Senior Editor, *The Lancet*
- Collaborative brainstorming, writing, and editing process over several months via teleconferences
- In press at *Mayo Clinic Proceedings*

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

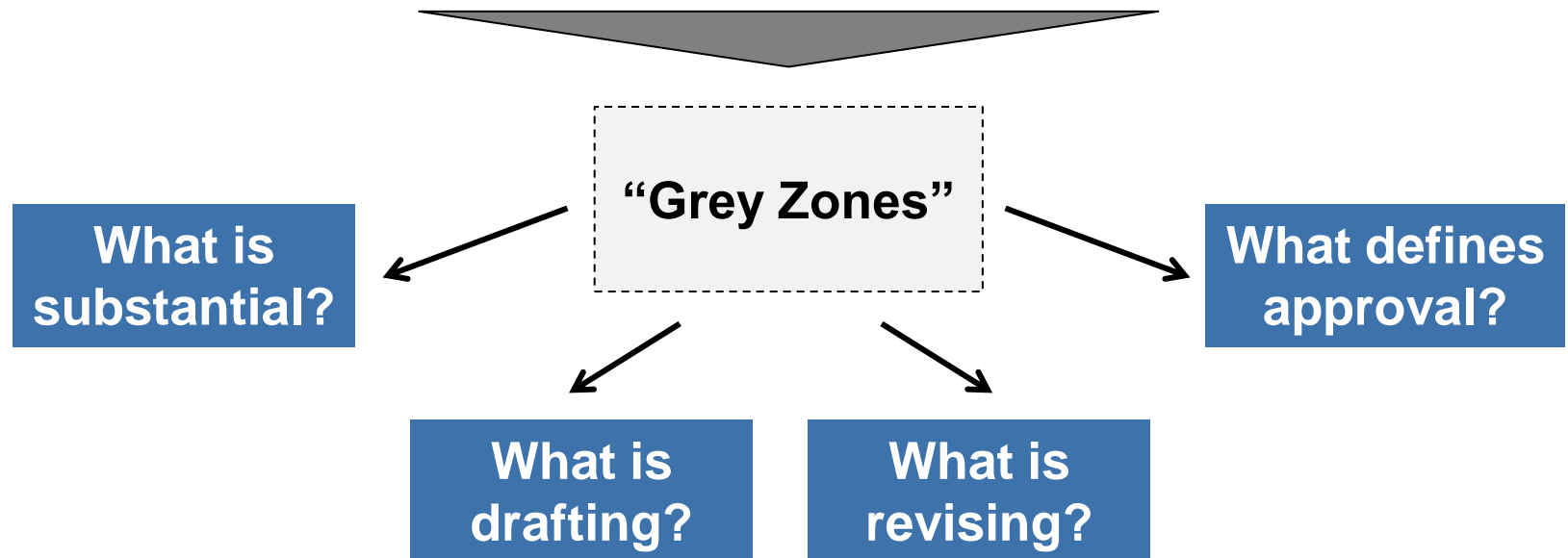
Aligned with MPIP's Vision and Mission

- Editors have expressed need for action in various MPIP events and activities
- Initial outreach with editors suggests:
 - Persistent and difficult issue
 - MPIP activity here would be valuable
 - Interest in collaborating with industry
- 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*



Audience Question #2

Which of the following ICMJE criteria for authorship can be most challenging to interpret and would benefit from further clarification?

- a. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- b. Drafting the article or revising it critically for important intellectual content
- c. Final approval of the version to be published

Near term authorship activities

MPIP will work with editors and other stakeholders to define authorship “Grey Zones”, to be the focus of further efforts

Brainstorming, Outreach, and Refinement

- Develop case studies, with input from editors and other stakeholders
 - Incl. EU editors
- Benchmark current industry approaches to supplement case study development

Research

- With editor input, design survey to test case studies with key stakeholders (editors, authors, etc.)
- Analyze/synthesize research findings

Review Outputs

- Review cases and data with editors to identify next steps – e.g., joint development of guidance in “grey zones”
- Develop publication, conference presentation, etc. to enhance outreach

The MPIP collaboration – Key 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 on barriers to trust and transparency from editors 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

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

2010 MPIP workshop participants

- Vito Brusasco, Editor-in-Chief, *European Respiratory Journal*
- Tad Champion, Online Editor and Senior Deputy Editor, *New England Journal of Medicine*
- Juli Clark, Director, Global Medical Writing, Amgen
- Finbarr Cotter, Editor-in-Chief, *British Journal of Hematology*
- Cynthia Dunbar, Editor-in-Chief, *Blood*
- Robert Enck, Editor-in-Chief, *American Journal of Hospice and Palliative Medicine*
- Lorna Fay, Director, Team Leader – Publications, Pfizer
- Rollin Gallagher, Editor-in-Chief, *Pain Medicine*
- John Gonzalez, Global Skills Lead – Publications, AstraZeneca
- Daniel Haller, Editor-in-Chief, *Journal of Clinical Oncology*
- Brian S. Jenkins, Executive Supplements Editor, Elsevier (for *Osteoporosis International*)
- Christine Laine, Editor-in-Chief, *Annals of Internal Medicine*
- Delong Liu, Editor-in-Chief, *Journal of Hematology and Oncology*
- Elizabeth Loder, Section Editor, *British Medical Journal*
- Bernadette Mansi, Director, Medical Communications Quality and Practices, GlaxoSmithKline
- Robert Matheis, President-Elect, ISMPP
- Charles Miller, Director, Medical Governance Information, GlaxoSmithKline
- LaVerne Mooney, Director, Publications Management, Pfizer
- Maja Zecevic, North American Senior Editor, *The Lancet*

2011 MPIP workshop participants

- Patricia Baskin, Executive Editor, *Neurology*
- Matthew Cahill, Executive Director, Global Scientific & Medical Publications, Merck
- Tad Campion, Online Editor and Senior Deputy Editor, *New England Journal of Medicine*
- Juli Clark, Director, Global Medical Writing, Amgen
- Anthony DeMaria, Editor-in-Chief, *Journal of the American College of Cardiology*
- Robert Enck, Editor-in-Chief, *American Journal of Hospice and Palliative Medicine*
- Lorna Fay, Director, Team Leader – Publications, Pfizer
- Thomas Gesell, Board of Directors, International Society for Medical Publication Professionals
- Susan Glasser, Senior Director, Scientific & Medical Publications, J&J Pharmaceutical R&D
- John Gonzalez, Global Skills Lead – Publications, AstraZeneca
- Samantha Gothelf, Executive Director, Global Medical Publications, Bristol-Myers Squibb
- Daniel Haller, Editor-in-Chief emeritus, *Journal of Clinical Oncology*
- Carolyn Hustad, Director, Publication Services , Global Scientific and Medical Publications, Merck
- Christine Laine, Editor-in-Chief, *Annals of Internal Medicine*
- Mary-Margaret Lannon, Director, Medical / Scientific Publications, Takeda Pharmaceuticals International
- Elizabeth Loder, Section Editor, *British Medical Journal*
- Juan-Carlos López, Editor, *Nature Medicine*
- Bernadette Mansi, Director, Medical Communications Quality and Practices, GlaxoSmithKline
- Charles Miller, Director, Medical Governance Information, GlaxoSmithKline
- LaVerne Mooney, Director, Publications Management, Pfizer
- Ann Murphy, Managing Editor, *The Oncologist*
- Maja Zecevic, North American Senior Editor, *The Lancet*

Leerink Swann attendees: Frank S. David, Timothy Lee and Kraig Schulz



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