The Medical Publishing Insights and Practices (MPIP) Initiative

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ISMPP — International Society for Medical Publication Professionals

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 MEDICAL PUBLISHING INSIGHTS AND PRACTICES INITIATIVE

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

MPIP participants to date

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.*
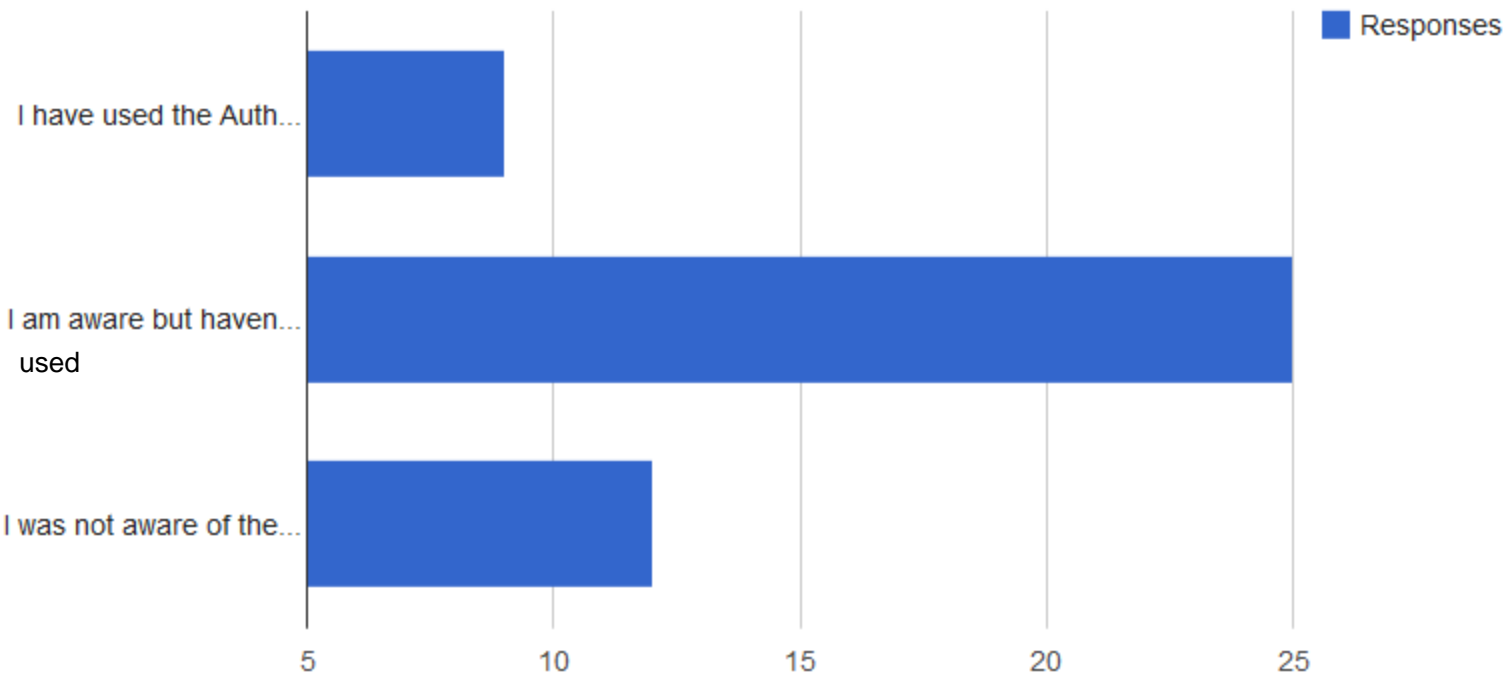
www.mpip-initiative.org

Audience Question #1

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

1. I have <u>used</u> the ***Authors' Submission Toolkit***

2. I am <u>aware but haven't used</u> the ***Authors' Submission Toolkit***

3. I was <u>not aware</u> of the ***Authors' Submission Toolkit***

1. How familiar are you with MPIPs Authors' Submission Toolkit?

Results

Legend: ■ Responses

Categories (top to bottom):
- I have used the Auth… (≈9)
- I am aware but haven… used (≈25)
- I was not aware of the… (≈12)

X-axis: 5, 10, 15, 20, 25

MPIP is using insights to drive joint activities with editors

Obtain Insights
2010

Codify Recommendations
2011

Execute Joint Activities
2012+

- 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.

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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

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Why focus on authorship?

Significant Need for Editors and Industry

- Editors have expressed need for action in various MPIP events and activities

Opportunity to Make a Valuable Contribution

- Initial outreach with editors suggests:
  - Persistent and difficult issue
  - MPIP activity here would be valuable
  - Interest in collaborating with industry

Aligned with MPIP's Vision and Mission

- Aligned with MPIP's history and goal of collaborative activities to raise standards – supported by editors

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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; <u>and</u>,*

3. *Final approval of the version to be published*

"Grey Zones"

What is substantial?

What defines approval?

What is drafting?

What is revising?
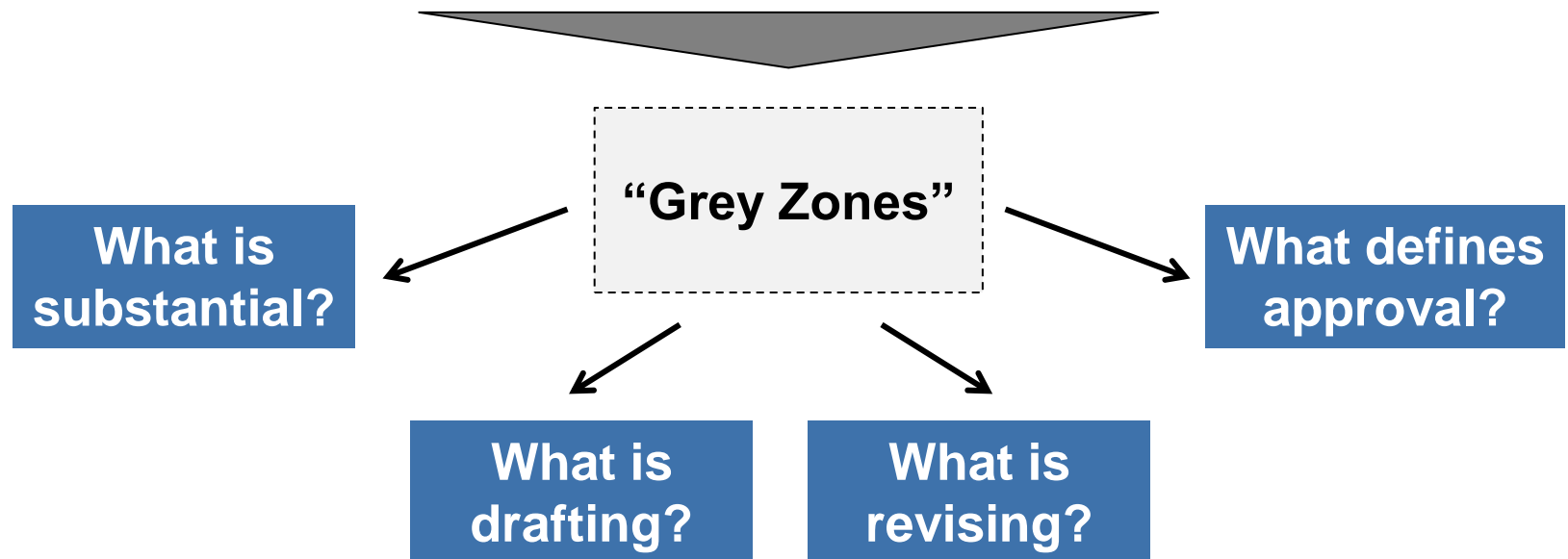
Audience Question #2

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

1. <u>Substantial contributions</u> to conception and design, acquisition of data, or analysis and interpretation of data

2. Drafting the article or revising it critically for <u>important intellectual content</u>

3. <u>Final approval</u> of the version to be published

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

Results

Responses

Substantial contributi...

Drafting the article or ...

Final approval of the ...

2   9   16   23   30

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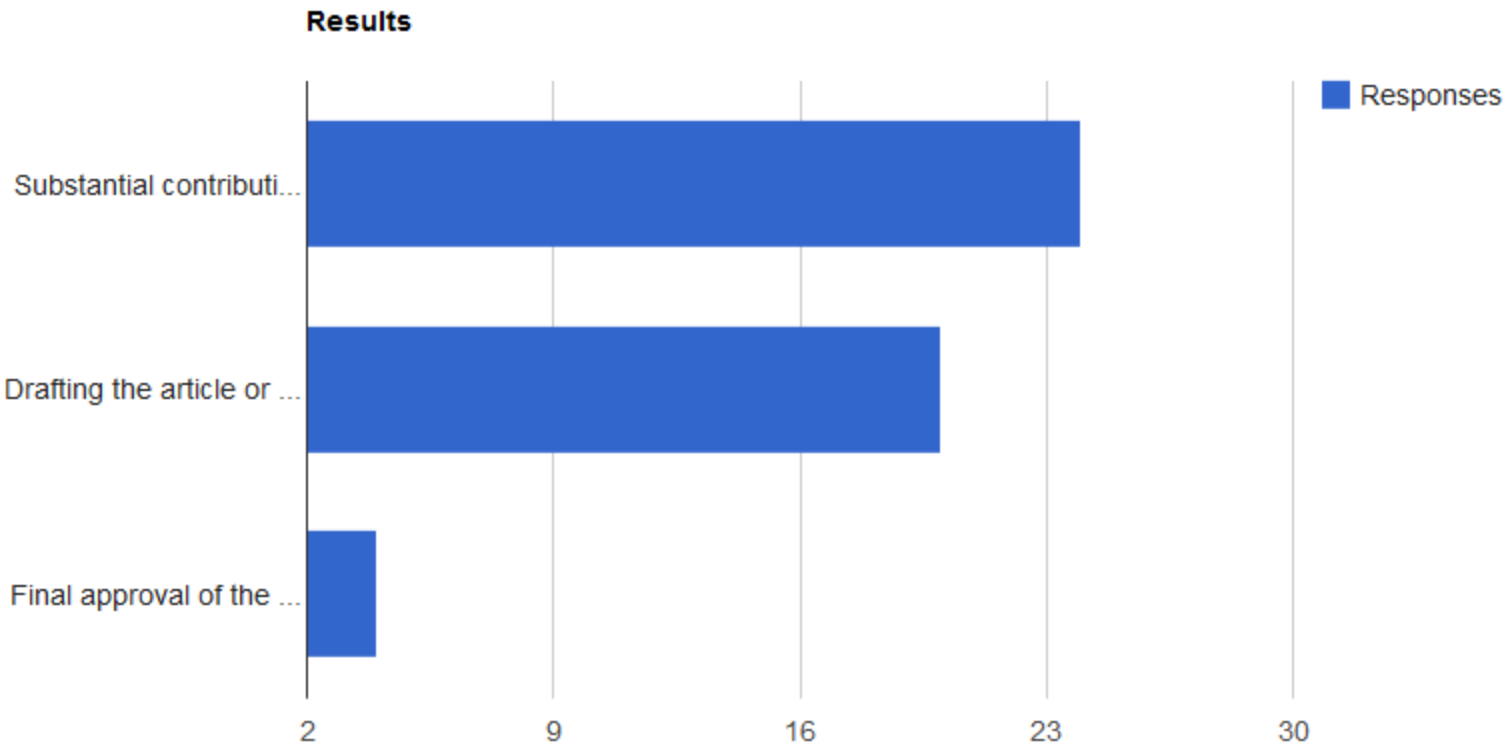
Near term authorship activities

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

Brainstorming, Outreach, and Refinement	Research	Review Outputs

- Develop case studies, with input from editors and other stakeholders
  – Incl. EU editors

- Benchmark current industry approaches to supplement case study development

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

- Analyze/synthesize research findings

- 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

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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

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