The Medical Publishing Insights and Practices (MPIP) Initiative

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Disclosure

• Teresa Peña is an employee of AstraZeneca, 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*
MPIP participants to date
Highlights of MPIP accomplishments since 2008

Raising Standards

• Journal-pharma roundtable reached consensus on “Ten Recommendations” to close the credibility gap in industry-sponsored research, published in 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 >26,000 times

Engaging Key Stakeholders

• Executed research project to understand challenges to determining authorship for industry-sponsored clinical trials
• Awarded 2010 Communiqué Trust and Reputation Award
• Presented at CSE, ISMPP, and other forums

MPIP uses insights to drive joint activities with editors

**Obtain Insights**
- Surveyed editors
- Convened workshop with editors and industry co-sponsors
- Brainstormed and prioritized ways to close the “credibility gap” for industry trials

**Codify Recommendations**
- Assembled editors and industry co-sponsors to draft whitepaper
- Peer-reviewed article published by *Mayo Clinic Proceedings* in May 2012*

**Execute Joint Activities**
- Aligned on authorship as key area for focus of joint activities
- Worked with editors and other stakeholders to develop and implement activities

MPIP developed a 3-part approach for its authorship activities

Goals for MPIP’s Authorship Activities

• Clarify definitions of authorship that resolve challenging ambiguities for industry-sponsored trial publications

• Inform development of harmonized definitions / criteria

• Continue to promote further transparency among stakeholders for industry-sponsored clinical trial publications

1. Identify authorship ambiguities
2. Collaborate to create new approaches
3. Support dissemination of outputs
MPIP formed an external research team to execute this plan

MPIP Steering Committee

Academic Collaborators

• Ana Marusic, MD/PhD & Darko Hren, PhD
  • Facilitate development and analysis of research

Additional Advisors

• Liz Wager, PhD and select journal editors
  • Provided feedback on case studies and methodology
Initial qualitative research uncovered multiple “Grey Zones” with current authorship guidelines

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*

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What defines approval?

What is substantial?

What is drafting?

What is revising?

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“Grey Zones”
MPIP and its collaborators created a case-based survey to further test these “Grey Zones”

- Grey Zone 1
- Grey Zone 2
- Grey Zone 3

Case Study 1
Case Study 2
Case Study 3

- Is there agreement on who should be an author for these scenarios within and across stakeholders?
- What rules / guidelines do key stakeholders use to adjudicate authorship?
Audience Question #1

A clinical investigator for a multi-center trial enrolled the most patients from dozens of investigators but did not contribute to trial design or data analysis/interpretation.

What is the most appropriate way to recognize the contribution of this clinical investigator?

a. I would invite the investigator to help draft the manuscript as an author listed on the byline

b. I would list the investigator’s contribution in the acknowledgement section

c. I would not invite the investigator to be an author nor recognize the investigator in the manuscript
Authorship survey overview

- Journal Editors
- Clinical Investigators
- Publication Professionals
- Medical Writers

Confidential and blinded responses

- “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 scenario occur?

- Current authorship practices:
  - What current guidelines are you aware of?
  - Which current guidelines do you use most?
  - In a given clinical study, when are authorship criteria determined?
  - In a given clinical study, when are authors determined?
Survey demographics (1)

Professional Affiliation

- Medical Writer: 22% (n = 113)
- Clinical Investigator: 29% (n = 145)
- Publication Professional: 27% (n = 132)
- Journal Editor: 22% (n = 108)

Total Respondents = 498
Survey demographics (2)

Geographic Distribution

North America - 44%
Europe - 39%
Asia Pacific - 12%
Other - 5%

Industry-Sponsored Clinical Trial Experience

3-5 years - 18%
6-10 years - 23%
11-20 years - 35%
20+ years - 24%
Roundtable discussions about the survey results with journal editors provided valuable feedback

1. Prospectively set authorship criteria
   - Set authorship criteria early in the trial, ensure all understand the responsibilities of authorship, and document agreement

2. Systematically document contributions
   - Document relevant contributions from trial participants in a consistent and transparent way

3. Authorship changes approved by entire group
   - Any changes to byline must be discussed and agreed to by entire author list on publication
MPIP worked with journal editors to develop outputs to supplement current authorship guidance

**Key Inputs**
- Authorship survey results
- Journal editor discussions

**Key Outputs**

**Supplemental Authorship Guidance**
- Framework and supporting detail to transparently disclose all contributors and their contributions

**Lessons from Challenging Scenarios**
- Recommendations for how to adjudicate the seven authorship scenarios included in the survey
For the rest of 2013, MPIP will broaden its outreach to refine and disseminate outputs from the Authorship project.

- **Ongoing discussions**
- **Congress presentations**

Publication of survey findings, supplemental guidance, and editor insights.

Outreach with stakeholders to build awareness.
Audience Question #2

What activity from the “Ten Recommendations” list would you like to see MPIP focus on next?

a. Further work in authorship in other regions (e.g., Asia)
b. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy
c. Educate authors on how to develop quality manuscripts and meet journal expectations
d. Report adverse event data more transparently and in a more clinically meaningful manner
Thank You
Appendix
“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
## Criteria to define survey respondents

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<th>Role</th>
<th>Criteria</th>
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| Journal Editors        | • Indexed on NIH’s Abridged Index Medicus or a top 30 journal by ISI or Page Rank  
                        | • Serves in an editorial capacity                                          |
| Clinical Investigators | • Participation in industry-sponsored clinical trials, phase I or above (from Adis database collaboration) |