Closing the Credibility Gap in Industry-Sponsored Clinical Research

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And
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Journal of Clinical Oncology

ISMPP International Society for Medical Publication Professionals

Overview of MPIP Activities

John Gonzalez
AstraZeneca, MPIP

MPIP MEDICAL PUBLISHING INSIGHTS AND PRACTICES INITIATIVE

www.mpip-initiative.org

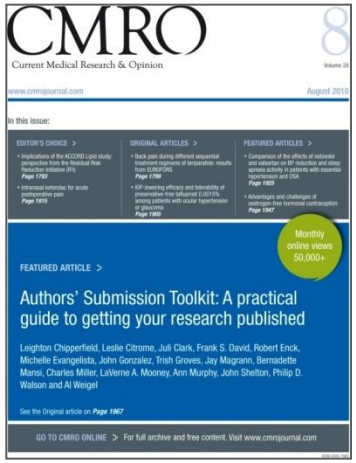
MPIP Vision

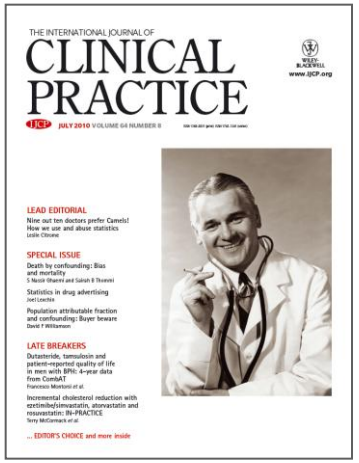
To develop a culture of **mutual respect, understanding and trust** between journals and pharma that will support more **transparent and effective** dissemination of results from industry-sponsored trials

MPIP activities supported by Leerink Swann LLC

MPIP Activities

- **Editor/Publisher Research**
- **Collaborative Meetings**
- ***Authors' Submission Toolkit***
- **Website / outreach**





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"Closing the Credibility Gap in Industry-Sponsored Clinical Research"

November 10th, 2010 • New York City

The workshop convened representatives from industry and journals to accomplish three goals:

- **Define the "Credibility Gap"**
  - Most pressing needs?
  - Progress to date?
- **Brainstorm Solutions**
  - Greatest joint unmet needs?
  - Possible initiatives / activities?
- **Prioritize Activities**
  - Execution: industry, journals or both?
  - MPIP role?

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Editors in Attendance

Annals of Internal Medicine
Christine Laine, Editor-in-Chief

American Journal of Hospice and Palliative Medicine
Robert Enck, Editor-in-Chief

Blood
Cynthia Dunbar, Editor-in-Chief

British Journal of Hematology
Finbarr Cotter, Editor-in-Chief

British Medical Journal
Elizabeth Loder, Section Editor

European Respiratory Journal
Vito Brusasco, Editor-in-Chief

Journal of Clinical Oncology
Daniel Haller, Editor-in-Chief

Journal of Hematology and Oncology
Delong Liu, Editor-in-Chief

The Lancet
Maja Zecevic, NA Senior Editor

New England Journal of Medicine
Tad Campion, Senior Deputy Editor

Osteoporosis International
Brian Jenkins, Executive Supplements Editor, Elsevier

Pain Medicine
Rollin Gallagher, Editor-in-Chief

Industry Representatives in Attendance

Amgen
Juli Clark, Director,
Global Medical Writing

AstraZeneca
John Gonzalez, Global Skills Lead – Publications

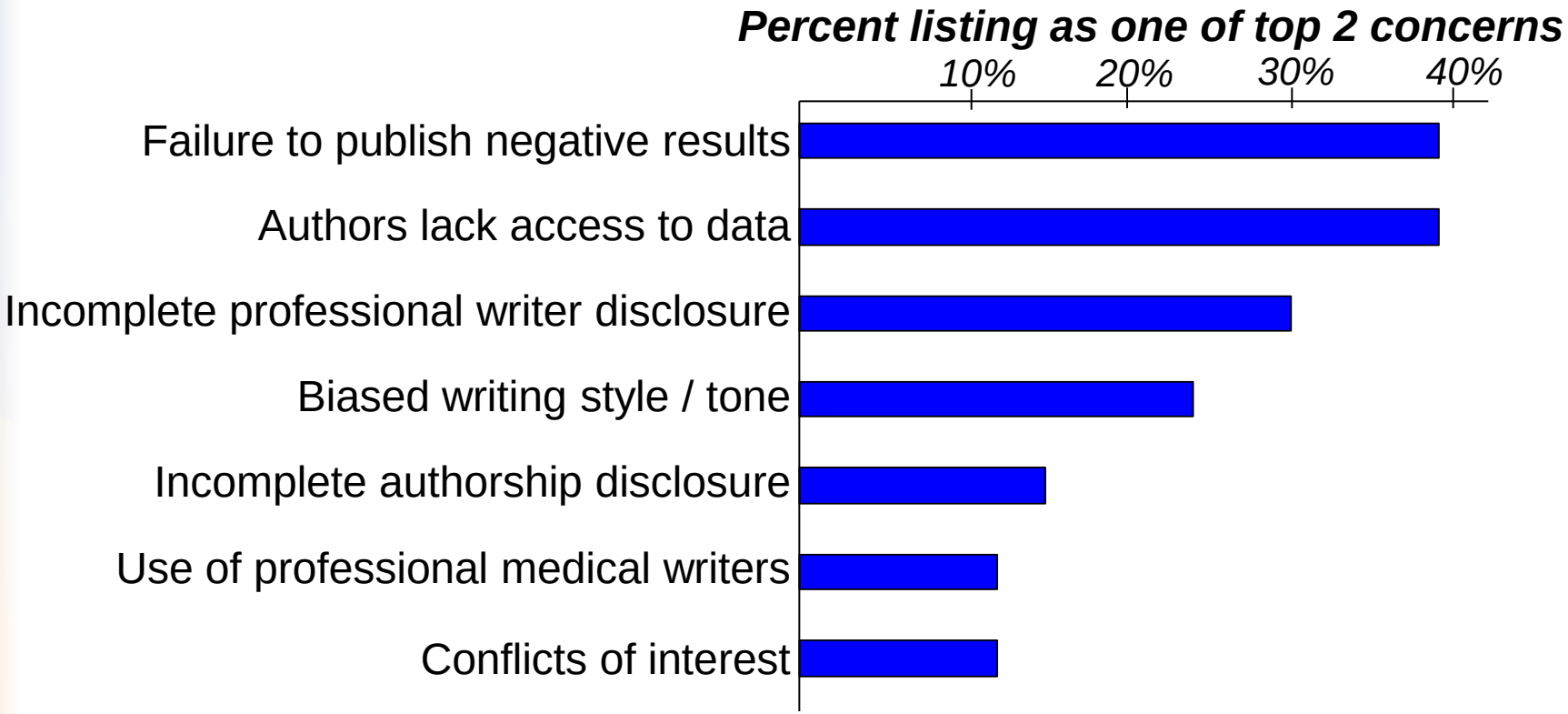
GlaxoSmithKline
Bernadette Mansi, Director, Medical Communications Quality & Practices
Charles Miller, Medical Governance Information Director

International Society for Medical Publishing Professionals
Robert Matheis, President, Credentialing Board of Trustees (Interim)
Publications Manager, Sanofi-Aventis

Pfizer
Lorna Fay, Director, Team Leader – Publishing,
LaVerne Mooney, Director, Publications Management

Pre-Workshop Survey Summary

What are the 2 most important outstanding unmet needs to address in order to improve the credibility of industry-sponsored research?



*Online survey completed by 33 editors (of 302 invitations); Mix of editors-in-chief, deputy editors and other senior editors; ~12% ex-U.S. and ~85% from journals specialized by therapeutic area

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Discussion Summary

- **Many editors believe credibility has increased**
  - Editors split on extent to which industry research credibility affects the credibility of their journals
- **Limited awareness of ongoing initiatives**
- **Several areas of persistent unmet need**
  - Disclosure (authorship / financial)
  - Dissemination of results (esp. of negative studies)
  - Integrity of research design, execution, analysis and reporting

Next Steps Toward Improving Credibility

Dr. Daniel Haller

Journal of Clinical Oncology

‘Top 10’ Recommendations for Enhancing Credibility of Industry-Sponsored Research

1. Ensure clinical studies and publications address clinical questions

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

3. Improve understanding and disclosure of authors’ financial ties and conflicts of interest

4. Educate internal and external authors on how to develop quality manuscripts, meet journal expectations and respond to reviewer comments

5. Improve disclosure of authorship / writing assistance and education on best publication practices to definitively end “ghost” and “guest” writing

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‘Top 10’ Recommendations for Enhancing Credibility of Industry-Sponsored Research

6. Report adverse event data more transparently and in a more clinically meaningful manner

7. Provide access to more complete protocol information

8. Support open dialogue with journals about statistical methods used in analysis

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

10. Share prior reviews from other journals openly, to show how reviewer comments have been addressed

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Protocols: An Editor's Perspective

- **Rationale**
  - Limited space in manuscript for full methods
  - Informs translation of results to 'real world' practice
  - Better information for reviewers

- **Outstanding Questions**
  - Publish them?
  - Definitions – what is a protocol?
  - Version– which to post?
  - Validation?
  - Confidential information?
  - Effect on authors' desire to submit?

The JCO Protocol Experience

- **Original Policy**
  - Redacted or full protocol required for all Ph. 2/3 studies
  - Only for editors and reviewers
  - Key elements:
    - Eligibility criteria
    - Schema / dose modifications
    - Statistical analysis methods
- **Revised Policy**
  - Same scope
  - Published online with article
  - Key elements:
    - Patient selection
    - Schema / treatment plan
    - Rules for dose modification
    - Measurement of Rx effect
    - Definitions / methods of measuring response / survival
    - Reasons for early cessation
    - Objectives
    - Entire statistical section

Key Learnings

- No author pushback
- Journal can't take responsibility for validation
- Applicable to other therapeutic areas?

Educate Internal and External Authors

- **Need more formal author education**
  - Some critical topics, e.g., self-plagiarism
  - Small biotechs
  - Ex-U.S. Authors
- **Role for editors**

Call To Action

- **Education**
  - Authors' Submission Toolkit
  - "Top Ten List"
  - Small companies and ex-U.S. authors
  - "Bring forward the lagging edge"
  - JCO on The Road

- **Collaboration**
  - Joint educational activities
  - Input on journal policy development

Appendix

1. **Ensure clinical studies and publications address clinical 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/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' financial ties and 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

4. **Educate internal and external authors on how to develop quality manuscripts, meet journal expectations and respond to reviewer comments**
   - 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 / writing assistance and education on best publication practices to definitively end “ghost” and “guest” writing**
   - 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. **Ensure more transparent, clinically meaningful reporting of adverse events**
   - More completely report all adverse events, even low-incidence ones
   - Support development and dissemination of standard approach

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. **Support open dialogue with journals about statistical methods used in analysis**
   - Encourage “reproducible results” in academia and industry
   - Continue dialogue to address challenges with independent analysis

9. **Ensure authors can and know how to access complete study data and can attest to this**
   - Fully educate authors on rights and responsibilities re. data access

10. **Share prior reviews from other journals openly, to show how reviewer comments have been addressed**
    - Educate authors in academia and industry that sharing submission history, incl. prior reviews and responses, would enhance credibility

Further Reading on Protocols

- Daniel G. Haller and Stephen A. Cannistra, “Providing Protocol Information for *Journal of Clinical Oncology* Readers: What Practicing Clinicians Need to Know,” *Journal of Clinical Oncology*, vol. 29 (2011).

- Albert Ocana, Eitan Amir, and Bostjan Seruga, “Clinical Research: Show us the Data,” *Journal of Clinical Oncology*, vol. 29 (2011).