



MAKING SCIENCE MATTER

CSE 2011
ANNUAL MEETING



29 APRIL – 3 MAY 2011
HILTON BALTIMORE, BALTIMORE, MARYLAND

Update on the Authors' Submission Toolkit





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Update on the Authors' Submission Toolkit

Dr. Robert Enck

Editor-in-Chief, *American Journal of Hospice and Palliative Medicine*.

Dr. Ann Murphy

Managing Editor, *The Oncologist*.

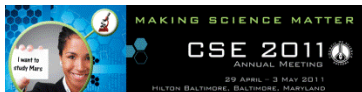
Dr. Frank David

Director, Leerink Swann Strategic Advisors

MPIP has brought together editors and pharma publication professionals to advance best practices in industry-sponsored research, as exemplified by the “Authors’ Submission Toolkit”, published in 2010.

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

- ◆ Focus groups, surveys and interviews to identify unmet needs

◆ Collaborative Meetings

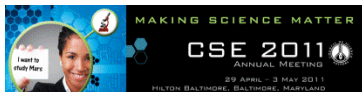
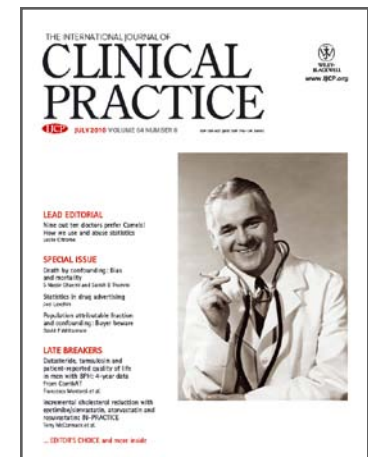
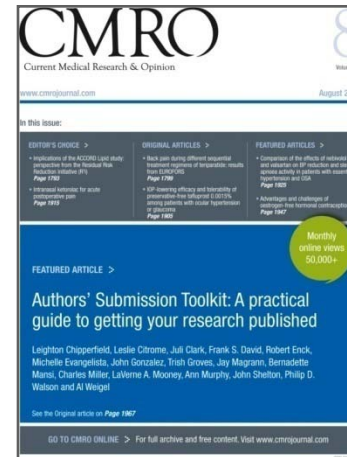
- ◆ Two joint journal-pharma workshops to exchange ideas and explore opportunities

◆ Authors' Submission Toolkit

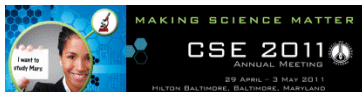
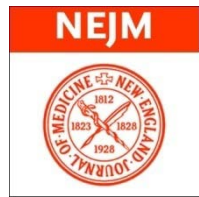
- ◆ Presentations to industry, journals, medical writing agencies, authors, etc.

◆ Website / outreach

- ◆ Collaborative activities to advance and disseminate best practices



Participants in MPIP Activities to Date



2009 MPIP Journal-Industry Workshop

MPIP Journal-Industry Workshop

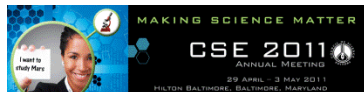
- ◆ Half-day workshop, Sep 9, 2009
- ◆ 15 journal/publisher reps. and 9 industry co-sponsor reps.



Key Outputs

- ◆ Focused on shared concern of journals and sponsors
- ◆ Brainstormed potential solutions:
 - ◆ Continued industry transparency
 - ◆ Author education
 - ◆ Future joint journal-industry activities

<p>Summary Article Published in <i>Int'l Journal of Clinical Practice</i></p>	<p>PERSPECTIVE Enhancing transparency and efficiency in reporting industry-sponsored clinical research: report from the Medical Publishing Insights and Practices initiative Clark J et al.</p> <p>THE INTERNATIONAL JOURNAL OF CLINICAL PRACTICE Published online May 7th, 2010</p>
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MPIP Vancouver Workshop (Sep '09) Output

- ◆ **MPIP Vancouver Workshop findings**
 - ◆ Shared interests expressed by journals and pharma
 - ◆ Streamlining journal submission
 - ◆ Enhancing transparency
 - ◆ Proposed “Authors’ Submission Toolkit” to codify best practices with consolidated insights from journals and sponsors



Toolkit Goals

◆ Educate authors

- ◆ Encourage dialogue with editors
- ◆ Demystify journals' editorial policies
- ◆ Capture best practices

◆ Publish good work in the right place

- ◆ Increase awareness about venues for all study types
- ◆ Help authors reach the most suitable audiences
- ◆ Provide tools for selecting the right journals

◆ Combine insights

- ◆ Advance dialogue between editors/publishers and pharma
- ◆ Increase trust between journals and publication teams



Intended Uses

◆ Authors

- ◆ Compilation of editors and sponsors' suggestions on how to get research published

◆ Journals

- ◆ Deployment of a resource to supplement journals' existing instructions for authors

◆ Industry

- ◆ Dissemination of “best practices” for authors to maximize likelihood of acceptance



Toolkit Summary

- ◆ **Before the Study and Writing Begin**
 - ◆ Authorship, medical writer acknowledgement, conflict of interest
 - ◆ Study registration and reporting requirements
- ◆ **Journal Selection**
 - ◆ Identifying suitable journals (esp. “specialized interest” results)
- ◆ **Pre-submission Inquiries**
 - ◆ Why, when and how to conduct them
- ◆ **Manuscript Preparation**
 - ◆ “Best practices” for each manuscript section
- ◆ **Cover Letters**
 - ◆ Key elements of a good cover letter, incl. model template
- ◆ **Review, Revision, and Re-Submission**
 - ◆ Overview of what to expect during revision and re-submission
 - ◆ “Best practices” for revision and re-submission



Content for Discussion Today

- ◆ **Acknowledging medical writers**
- ◆ **Pre-submission inquiries**
- ◆ **Cover letters**
- ◆ **Review, revision, and resubmission**



Acknowledging Medical Writers

◆ Why is this important?

- ◆ Ensure transparency around all contributions
- ◆ Misconceptions about acceptability of medical writing assistance
- ◆ Confusion about how to acknowledge medical writing assistance



Acknowledging Medical Writers

◆ Recommendations

- ◆ Remember medical writing assistance is acceptable and can raise quality of publications
- ◆ Adhere to established authorship criteria
- ◆ Always disclose contributions of medical writers
- ◆ Do not be afraid to ask questions of journals and sponsors



Pre-submission Inquiries

◆ Why is this important?

- ◆ High submission volume strains journal resources
- ◆ Publish results in appropriate venue
- ◆ Seek clarification where journal guidance incomplete



Pre-submission Inquiries

◆ Recommendations

- ◆ Provide sufficient study information, esp.:
 - ◆ Perceived value to a journal's audience
 - ◆ Relationship to existing work on specific topic
 - ◆ Prior submissions
- ◆ Be concise in communications – editors are time constrained
- ◆ Request suggestions for more suitable journals (if not accepted)



Cover Letter Preparation

◆ Why is this important?

- ◆ Streamlines editorial process
 - ◆ Demonstration of why article would be appropriate for a particular journal
 - ◆ Additional context to inform decision-making
- ◆ Provides key context for submission
 - ◆ Establishes useful journal-author dialogue
 - ◆ Provides continuity between review and resubmission



Cover Letter Preparation

◆ Recommendations

- ◆ Articulate the study's research purpose clearly – investing time in this area will pay dividends
- ◆ Remind editors of previous communications
- ◆ Mention prior submissions to help editors evaluate improvements to a manuscript
- ◆ Ensure cover letter is easy to read – see the Toolkit cover letter template for suggestions



Cover Letter Preparation

Appendix

Cover Letter Template

Author's Name
Mailing Address (Suite #)
City, State, Zip Code
Phone Number
Fax Number
Email Address

[Date]
Journal Editor-in-Chief (or the editor who has been the journal contact during previous correspondence) [including title]
Journal Name
Mailing Address (Suite #)
City, State, Zip Code

Dear Dr. / Mr. / Ms. XXX:

First paragraph:

- Introduce the manuscript, including the title, type of article (e.g., original research article, review article, case report, etc.), journal category (depending on the type of journal) – mention that you intend to submit to [insert journal name].
- If you are the principal author and are submitting on behalf of yourself and colleagues, this should be declared (e.g., “On behalf of my colleagues, I would like to submit to [insert journal name] this manuscript of original clinical research entitled “[insert article name]”).

Second paragraph:

- This paragraph is usually a 3-5 sentence synopsis of the Introduction, and should address key points that are of likely interest to the editor and the reviewers.
- Describe the purpose, content, findings, and value of the manuscript, which will often relate to the current state of the field, for example:
 - This disease/condition has no current standard of care and this manuscript reports the first randomized clinical findings for this disease, etc.
 - New guidelines have recently been published describing updated standard therapies for disease/condition “X”
 - Disease/condition “X” is lacking in data and this manuscript provides clinical data.
- Discuss current hot topics/ controversies in the field and how this manuscript addresses these topics
- Include at least 1 sentence summarizing the key findings of the research study.
- If original research has been conducted, denote whether all national and international regulatory guidelines for clinical trial research have been met (Declaration of Helsinki, EMEA, FDA, etc.).
- Often, this paragraph ends with addressing the value of the information in this manuscript to the specific readership of the journal.

Third paragraph:

- Indicate that the manuscript has been read and approved by all authors. Stipulate that all persons listed as authors have contributed to preparing the manuscript and/or that International Committee of Medical Journal Editors (ICMJE) criteria for authorship have been met, and that no person or persons other than the authors listed have contributed significantly to its preparation. The intent of these statements is to forestall the participation of outside parties (“ghostwriters”) who may stand to benefit by attempting to influence the content of a study or its results.
- Specify whether the manuscript or any significant part of it is under consideration for publication, has been published or was submitted for publication elsewhere, or has appeared elsewhere in a manner that could be construed as a prior or duplicate publication of the same, or very similar, work. For example, including a statement such as the following can

be useful: “The contents of this manuscript are my/our original work and have not been published, in whole or in part, prior to or simultaneous with my/our submission of the manuscript to [journal name].”

- Also describe any NIH/Wellcome Trust funding and any issues regarding copyright transfer/open access requirements.

Fourth paragraph:

- Detail any funding of the work reported, as well as financial or other support in the preparation of the manuscript (including editorial/writing assistance). For example (from GPP2), “The study was funded by YZ Pharmaceuticals, the manufacturer of Drug F. Medical writing services from WX Medical Writing were funded by YZ Pharmaceuticals.”
- When appropriate, the cover letter should contain a brief summary of any potential conflict of interest (both financial or otherwise) arising from relationships with commercial or corporate interest in connection with the work submitted and attestation that these relationships have been addressed in the appropriate section of the manuscript. For example, “This study was funded by a grant from [company]. Authors AA, BB, and CC are or were employees of [company] when this study was conducted and own stock in [company #2], of which [company] is a subsidiary. Authors DD, EE, and FF received research funding from [company]. Author GG has no conflict of interest to report. We attest that we have herein disclosed any and all financial or other relationships that could be construed as a conflict of interest and that all sources of financial support for this study have been disclosed and are indicated in the acknowledgments.”

Fifth paragraph:

- Describe the contents of the submission package, usually per journal instructions (e.g., “per journal’s instructions, 3 hard copies of the manuscript and figures, study protocol, author checklist, journal submission form, are included”).
- Depending on the journal, if color figures are included, some journals may request a statement indicating that the authors are willing to assume the cost of color separations and reproduction is requested. Denote if there has been any prior publication of figures or tables in the manuscript, in which case documentation of written permission from the publisher should be included.
- Journals may accept suggestions for included and excluded reviewers, which can either be listed here or indicate that this list is also provided on a separate sheet. Provide the name, title, institution, address, contact telephone number, and email of all mentioned reviewers.

Sixth paragraph:

- Graciously thank the editor for his/her time in reviewing this submission. Remind him/her of your interest in the journal’s review of your manuscript. Provide the editor with contact information if any questions should arise regarding this submission or during the review process.

Salutation

Signature

Author’s name [title]

Toolkit Appendix, Pages 16-17



Review, Revision, and Resubmission

◆ Why is this important?

- ◆ “Black box” to many authors
- ◆ Uncertainty about how to interpret and address reviewers’ comments
- ◆ Indecision about when to resubmit vs. submit elsewhere



Review, Revision, and Resubmission

◆ Recommendations

- ◆ Remember reviewers' feedback is meant to help
- ◆ Address all comments—if one seems incorrect or unjustified, explain why with references
- ◆ Avoid “easy fixes” – often transparent to editors
- ◆ For submission to new journals, disclose prior submissions and responses to prior comments





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Ongoing MPIP Activities

Toolkit Dissemination

- ◆ Encouraging journals to link to the toolkit from their 'Instructions to Authors' on website



- ◆ *“Prospective authors are encouraged to read the Authors' Submission Toolkit: A practical guide to getting your research published (available at <http://www.cmrojournal.com/ipi/ih/MPIP-author-toolkit.jsp>). The toolkit summarizes tips and "best practices" to increase awareness of editorial requirements, journal selection, submission processes, publication ethics, peer review, and effective communication with editors.”*

- ◆ Translating toolkit into Chinese



“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?



Attendees

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

Also representatives from Amgen, AstraZeneca, GlaxoSmithKline, ISMPP and Pfizer



'Top 10' Recommendations

- 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**



'Top 10' Recommendations

- 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**



Next Steps

◆ 'Top Ten' Whitepaper

- ◆ MPIP collaborating with editors to write whitepaper on 'Top Ten' Recommendations
 - ◆ Dan Haller, Editor-in-Chief, *Journal of Clinical Oncology*
 - ◆ Christine Laine, Editor-in-Chief, *Annals of Internal Medicine*
 - ◆ Maja Zecevic, NA Senior Editor, *The Lancet*



Additional Resources

- ◆ **Summary of best practices in manuscript preparation**
 - ◆ Table 1 of the Toolkit
- ◆ **Supplemental list of journals for “specialized interest” manuscripts**
 - ◆ [http://mpip-initiative.org/PDF/Options_specialized-interest data MPIP 8.19.10.pdf](http://mpip-initiative.org/PDF/Options_specialized-interest_data_MPIP_8.19.10.pdf)



For More Information...

- ◆ For more information about MPIP activities:
 - ◆ MPIP initiative landing page
 - ◆ www.mpip-initiative.org
 - ◆ Frank S. David, M.D., Ph.D., Leerink Swann, 617.918.4038, frank.david@leerink.com





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Questions & Answers