Update on the Authors’ Submission Toolkit
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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

- 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

Summary Article

Published in Int’l Journal of Clinical Practice

Perspective

Enhancing transparency and efficiency in reporting industry-sponsored clinical research: report from the Medical Publishing Insights and Practices initiative

Clark J et al.
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
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

[Date]
[Address]
[City, State, Zip Code]

[Paragraph]

First paragraph:
- Introduce the manuscript, including the title, type of article (e.g., original research article, review article, case report, etc.), journal name, journal category (e.g., ‘AIDS’, ‘Pediatrics’), and the fact that the authors are submitting on behalf of a colleague, friend, or other non-affiliated person.
- Include a sentence that indicates the manuscript has been prepared for submission to the journal.

Second paragraph:
- Discuss the purpose, content, findings, and value of the manuscript, which will be consistent with the current state of the field.
- Describe the purpose of the study and what the manuscript reports.
- Discuss the clinical relevance of the findings.
- Discuss the new guidelines that have been published regarding the field.
- Discuss any ethical considerations.

Third paragraph:
- Address the potential conflicts of interest.
- Discuss any financial support or other support provided by any organization.
- Include a statement about the originality of the manuscript.
- Include a statement about the availability of the data set.

Fourth paragraph:
- Provide a brief summary of the manuscript.
- Include any potential conflicts of interest.

Fifth paragraph:
- Provide a detailed explanation of the background of the study.
- Include any necessary references.

Sixth paragraph:
- Thank the editor for considering the manuscript.

Signature

Author’s Name

Author’s Name

Checklist

- Author’s Name
- Mailing Address
- City, State, Zip Code
- Phone Number
- Fax Number
- Email Address

Cover Letter Preparation

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
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
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/mpi/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
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**
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
Questions & Answers