

The Authors' Submission Toolkit: A Practical Guide to Getting Your Research Published

Medical Publishing Insights
and Practices Initiative

April 21st, 2010



Introductions

Presenters

- LaVerne Mooney, DrPH, Pfizer
- Robert Enck, MD, *The American Journal of Hospice and Palliative Medicine*
- Ann Murphy, PhD, *The Oncologist*
- Jay Magrann, *Current Medical Research & Opinion*

Q&A Panelists

- Bernadette Mansi, GlaxoSmithKline
- Juli Clark, PharmD, Amgen
- Leighton Chipperfield, Elsevier

Moderator: Al Weigel, ISMPP

Agenda

Introduction

- Overview & Panel Introductions
- MPIP Initiative Background
- Authors' Submission Toolkit:
Rationale and Structure

Al Weigel
LaVerne Mooney
Robert Enck

Authors' Toolkit Section Highlights

Ann Murphy &
Jay Magrann

Q&A Session

Working Group
Members

Wrap-Up

Al Weigel



MPIP Initiative Background

LaVerne Mooney, DrPH
Director, Publications Management, Pfizer

Our 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

Objectives

- Understand issues and challenges in publishing industry-sponsored research
- Identify potential solutions to increase transparency and trust
- Promote more effective partnership between sponsors and journals to raise standards in medical publishing and expand access to data

Organization

Co-Sponsors



Project Management



LEERINK SWANN



Participants to Date



Since its inception, the MPIP has engaged editors and publishers from 35+ organizations.

MPIP Accomplishments

- Identified issues and challenges perceived as barriers to transparency and trust by journals
- Collaborated with journals to identify and implement solutions to enhance mutual understanding and improve medical publishing standards
- Demonstrated industry's commitment to transparency and restoring trust

Completed Activities, 2008 – 2009

Editor-Publisher Roundtables

July – Dec. 2008

- 25 U.S. and E.U. editors / publishers
- Discussed key challenges for pharma-sponsored studies
- Output presented at 2009 ISMPP annual meeting
- Findings informed planning for journal-pharma workshop

Joint Journal-Pharma Workshop

Sept. 2009

- 15 U.S. and E.U. editors / publishers, plus co-sponsor representatives
- Explored shared concerns and potential solutions
- Brainstormed actionable next steps
- Peer-reviewed article on workshop output accepted by *IJCP*

Workshop Topics

- Increased manuscript volume
 - Trends in industry submissions
 - Journals' resource constraints
 - Sponsors' challenges
- Innovative solutions to handling increased volume
- Streamlining the submission process
- Charting the way forward for the MPIP

Proposed Solutions

- Streamlining the submission process
 - Help reduce the editorial and administrative burden on authors, journals, and reviewers, especially as submission volumes continue to rise
- Promoting journal-industry collaboration to identify “best practices”
 - Provide additional clarity for industry-sponsored research, an area where medical publication practices and guidelines are undergoing frequent refinement and evolution

The Authors' Submission Toolkit was identified as a key next step coming out of the follow-up workshop.

MPIP Plans in 2010

- Facilitate development of the Authors' Submission Toolkit
- Disseminate the authors' toolkit to promote best practices among authors, sponsors, and editors / publishers
- Continue journal outreach to enhance cooperation with industry
- Expand industry involvement in MPIP activities

To provide suggestions for the MPIP initiative, please contact Frank David at Leerink Swann:

Phone: 617.918.4038

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The Authors' Submission Toolkit: Rationale and Structure

Robert Enck, MD

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

Purpose

The Authors' Submission Toolkit was created to:

- Facilitate dynamic discussions between authors and journal editors
- Facilitate dissemination of good research that needs publishing but may be awkward to place
- Summarize tips and best practices on journal selection and demystify “black box” aspects of submission, peer review and transparency requirements
- Combine insights from journals and industry through a uniquely collaborative process

Educating Authors

- Authors* and journals can benefit from collegial and open dialogue during the manuscript preparation and submission process
- Authors' Submission Toolkit provides a comprehensive overview of best practices
- “Demystifying” journals' editorial policies can help authors navigate the journey to publication

** and medical writers, publication planners*

Publish Good Work in the Right Place

- Authors, medical writers, and publication planners may struggle to find the appropriate “home” for some types of work, e.g., early phase industry-sponsored studies
- Authors’ Submission Toolkit aims to ensure that:
 - Manuscript submissions are better targeted and more effective for authors, sponsors, and journals
 - Research findings reach the most suitable audiences

Combining Insights

- Developed through unique collaboration between MPIP co-sponsors, journal editors, and publishers
- Reflects perspectives of both journals and industry on how to raise standards in publishing industry-sponsored studies
- Should help to increase trust between journal editors and the teams who produce industry sponsored research: industry investigators, authors, publication planners and medical writers

Intended Use

- Authors: “How to” guide for getting research published
- Journals: Resource to supplement journals’ existing instructions to authors
- Industry: Best practices that can be recommended to authors to maximize likelihood of acceptance

Impact

- ✓ Aid in streamlining journal selection and submission
- ✓ Enable open communication between authors, journals, and industry
- ✓ Provide support for policies encouraging greater transparency



The Authors' Submission Toolkit: Section Highlights

Ann Murphy, PhD
Managing Editor, The Oncologist

Jay Magrann
Publisher, Current Medical Research & Opinion

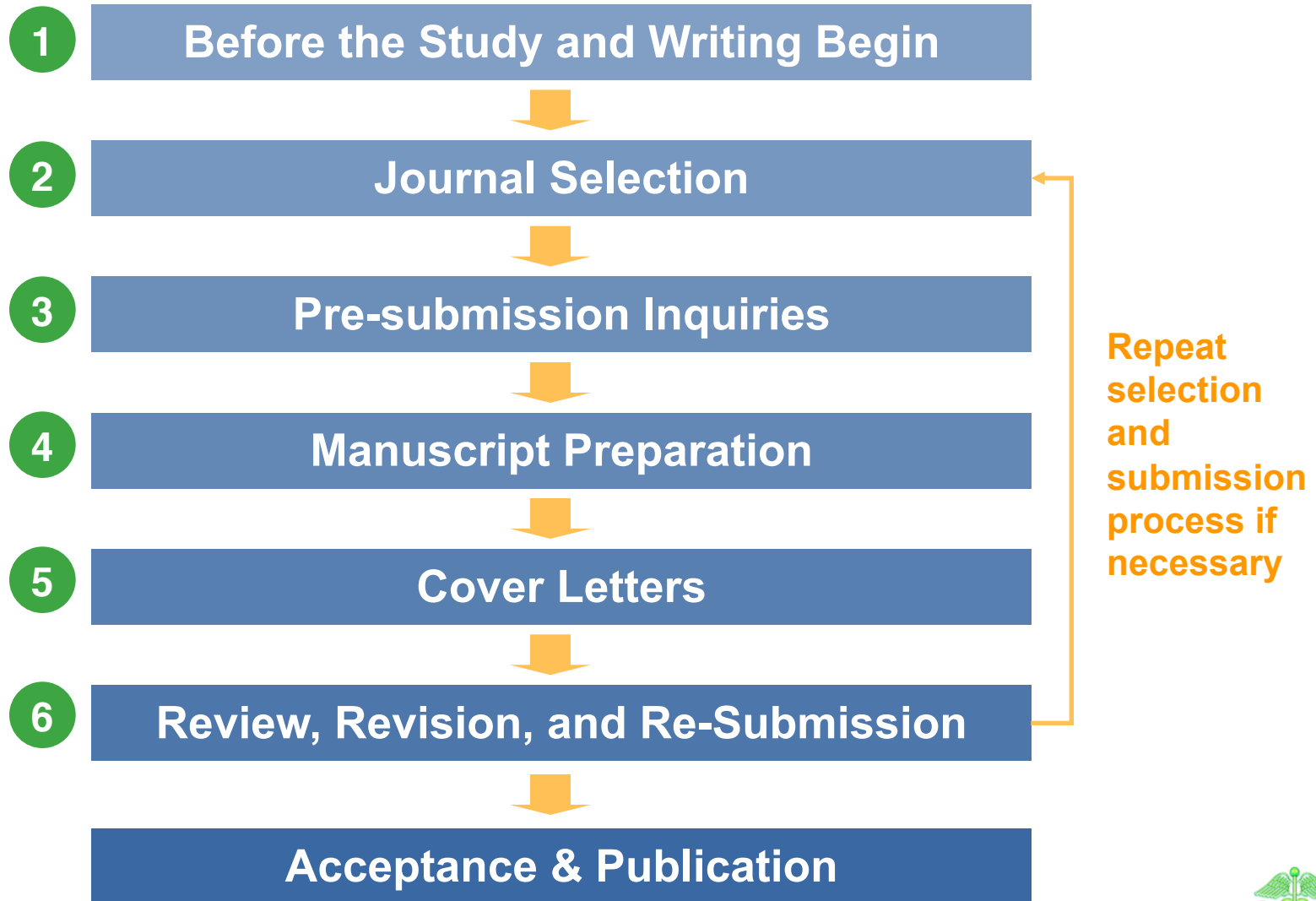
Structure

- Compilation of “best practices” walking through the stages of planning, preparation, and submission
- Reflects perspectives from a unique collaboration between journals and industry
- Intended for all authors of medical research publications and provides valuable resources on how to navigate the manuscript preparation and submission process
- Particular focus on industry-sponsored research

Working Group Members

- Leighton Chipperfield, Elsevier
- Leslie Citrome, MD, PhD, *The International Journal of Clinical Practice*
- Juli Clark, PharmD, Amgen
- Frank S. David, MD, PhD, Leerink Swann
- Robert Enck, MD, *The American Journal of Hospice and Palliative Medicine*
- Michelle Evangelista, Leerink Swann
- John Gonzalez, AstraZeneca
- Trish Groves, MRCPsych, *BMJ*
- Jay Magrann, *Current Medical Research & Opinion*
- Bernadette Mansi, GlaxoSmithKline
- Charles Miller, GlaxoSmithKline
- LaVerne Mooney, PharmD, Pfizer
- Ann Murphy, PhD, *The Oncologist*
- John Shelton, PhD, *The Journal of Clinical Psychiatry*
- Philip Walson, MD, *Clinical Therapeutics*
- Al Weigel, International Society for Medical Publication Professionals

Submission Flowchart



1 Before the Study and Writing Begin

Topics Covered

- *What should I be aware of prior to beginning a study?*
 - Journals' instructions to authors
 - Study design resources

- *What should I be aware of after completing a study?*
 - Determining authorship and contributorship
 - Understanding conflict of interest disclosures

- *What do I need to know about the publication plan?*
 - Determining when it can be used
 - Identifying key questions to ask about it

2 Journal Selection

Topics Covered

- *What are the important questions to consider as I begin my journal search?*
 - Answering key questions to provide “guideposts” for journal selection

- *How do I compile a list of potential journals?*
 - Identifying strategies for selecting the right journal
 - Understanding best practices for researching journals

- *How do I identify my top choices?*
 - Clarifying strategies for narrowing a long list of journals to one top choice

3 Pre-Submission Inquiries

Topics Covered

- *Why is a pre-submission inquiry important?*
 - Understanding the value and benefits of submitting a pre-submission inquiry

- *How do I complete a pre-submission inquiry?*
 - Clarifying situations where it may be appropriate to submit a pre-submission inquiry
 - Understanding how to complete a pre-submission inquiry
 - Summarizing “best practices” for completing a pre-submission inquiry

4 Manuscript Preparation

Topics Covered

- *What are important considerations for manuscript preparations?*
 - Clarifying priorities when beginning to prepare a manuscript
- *What are best practices for each section of the manuscript?*
 - Avoiding common pitfalls
 - Ensuring adherence to journal instructions

Title and abstract

Acknowledgements

Introduction

Methods

Results

Discussion

Conclusion

References

5 Cover Letters

Topics Covered

- *What are the key elements of a good cover letter?*
 - Identifying key points of information to convey
 - Employing a cover letter template that includes recommendations from Working Group editors / publishers

Appendix

Cover letter template

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

[Date] Month Day, 20XX

Journal Editor-in-Chief [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 – for submission to journal (repeat journal name).
- If you are the principal author and are submitting on behalf of yourself and colleagues, this is nice to mention up front (e.g., 'On behalf of my colleagues, I would like to submit to The Journal of Clinical XXXX this manuscript of original clinical research entitled...').

Second paragraph:

- This paragraph is usually a 3–5 sentence synopsis of the Introduction, and should hit on 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:
 - (1) This disease/condition has no current standard of care and this manuscript reports the first randomized clinical findings for this disease, etc.
 - (2) New guidelines have recently been published describing updated standard therapies for XX disease/condition
 - (3) Disease/condition is lacking in data and this manuscript provides clinical data
 - (4) Discuss current hot topics/controversies in the field and how this manuscript addresses these topics
- Include at least one sentence of the key, high level 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 (Helsinki, EMEA, FDA, etc.).
- Often, this paragraph ends with 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 are to forestall the participation of

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6 Review, Revision, and Re-Submission

Topics Covered

- *How does the review process work?*
 - Clarifying the rationale and organization of the review process from an editors' perspective

- *What are best practices in revision and re-submission?*
 - Understanding useful strategies for dealing with revision and re-submission

- *What should I do if my submission is rejected?*
 - Distinguishing between situations where it may be appropriate to appeal and when to re-submit



Q&A Panel

Al Weigel

Immediate Past President, ISMPP

MPIP Resources

Being distributed at the ISMPP meeting

- **MPIP 2009 Roundtable Report**
 - In press in the *International Journal of Clinical Practice*

Coming soon

- **Authors' Submission Toolkit Publication**
 - Under revision at *Current Medical Research & Opinion*
- **MPIP landing page – www.MPIP-initiative.org**
 - Anticipated launch in a few weeks
 - Check back for more useful resources and updates