“Five-step Authorship Framework” to Improve Transparency in Disclosing Contributors to Industry-Sponsored Publications

LaVerne Mooney, DrPH
Disclaimer

• Information presented reflects my personal knowledge and opinions and does not represent the position of my current or past employers or CSE.
Today’s Objectives

• At the conclusion of this presentation, attendees should understand:

  – The rationale behind the Medical Publishing Insights and Practice (MPIP) Authorship Research Initiative

  – The key findings of the survey and qualitative editor discussions

  – The principles behind the Five-step Authorship Framework

  – How the Framework can improve transparency in disclosing contributors to industry-sponsored trial publications
Building Trust

“A lack of transparency results in distrust and a deep sense of insecurity”

-Dalai Lama
MPIP Vision

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

MPIP 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 research results
Background

• MPIP - founded in 2008 by members of the pharmaceutical industry and International Society for Medical Publication Professionals (ISMPP) and Leerink Swann Healthcare

• Engaged stakeholders in the U.S. and Europe to achieve MPIP vision and objectives

• 4 publications to-date:
  • Enhancing Transparency
  • Authorship Submission Toolkit
  • 10 Recommendations
  • Five-step Authorship Framework
### TABLE: Top 10 Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research

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 end ghostwriting 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 in accordance with journal policies
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

---

**A collaboration between MPIP and journal editors**
5. Improve disclosure of authorship contributions
Defining the Role of Authors and Contributors

Good Publication Practice (GPP2)

International Society for Medical Publication Professionals (ISMPP) position papers

Council of Science Editors (CSE) White Paper

European Medical Writers Association (EMWA) guidelines
2010 ICMJE guidelines stated authorship credit should be based on:

1. *Substantial contributions to the 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*

*Survey conducted in 2010, a 4th criteria has been added since*
Background

What is the Unmet Need

1. Low awareness, variable interpretation, and inconsistent application of authorship guidelines can lead to confusion and a lack of transparency when recognizing those who merit authorship

2. Need to close the gap between authorship guidelines and practical decision-making when determining authorship

Objectives for Authorship Initiative

• Identify authorship scenarios not well addressed by current guidelines

• In collaboration with journal editors, develop a standardized approach that can be used prospectively to facilitate more transparent and consistent authorship decision-making

• Embed use of the “Five-step Authorship Framework” to further transparency in authorship decisions
Study Methods

1. Outline case scenarios
   • Collaborated with various stakeholder groups to identify most challenging, real-life authorship scenarios

2. Develop and distribute survey
   • Partnered with academic collaborators to develop survey of editors, clinical investigators, publication planners and medical writers

3. Editor discussions
   • Reviewed data and aligned on key themes and recommendations

4. Finalize authorship framework
   • Developed standardized approach to facilitate more transparent and consistent authorship decision-making
**Methods: Survey Design**

### Sample design
- Journal editors, clinical investigators, publication professionals and medical writers
- Responses were collected in a blinded and confidential fashion

### Survey design

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>How to adjudicate case study (authorship, acknowledgement, no recognition)?</td>
<td>What guidelines are you aware of?</td>
</tr>
<tr>
<td>What rationale did you use?</td>
<td>Which guidelines do you use most?</td>
</tr>
<tr>
<td>How confident are you?</td>
<td>In a given clinical study, when are authorship criteria determined?</td>
</tr>
<tr>
<td>How frequently does this occur?</td>
<td>In a given clinical study, when are authors determined?</td>
</tr>
</tbody>
</table>
## Methods: Case Scenarios

<table>
<thead>
<tr>
<th>Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Whether patient recruitment and daily site management are substantial contribution</td>
</tr>
<tr>
<td>2</td>
<td>Addition of an author while finalizing a manuscript for first submission</td>
</tr>
<tr>
<td>3</td>
<td>Recognition of the contributions of a medical writer</td>
</tr>
<tr>
<td>4</td>
<td>Removal of an author due to disagreement about interpretation of data</td>
</tr>
<tr>
<td>5</td>
<td>Recognition of the contribution of a contract research scientist</td>
</tr>
<tr>
<td>6</td>
<td>Lack of final approval from an author for submission despite repeated inquiries</td>
</tr>
<tr>
<td>7</td>
<td>Protection of proprietary information when clinician leaves a trial sponsor company for a competitor</td>
</tr>
</tbody>
</table>
Methods: Survey

The survey was sent via an email link to the four respondent groups

<table>
<thead>
<tr>
<th>Final Sample</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical investigator</td>
<td>145</td>
</tr>
<tr>
<td>Journal editor</td>
<td>108</td>
</tr>
<tr>
<td>Publication professional</td>
<td>132</td>
</tr>
<tr>
<td>Medical writer</td>
<td>113</td>
</tr>
</tbody>
</table>

Total of 498 respondents with at least 96 respondents per group enabled estimates with a 10% margin of error
Results: Respondents were Diverse and Experienced

**Professional Affiliation**

- Medical Writer: 23% (n = 113)
- Clinical Investigator: 29% (n = 145)
- Publication Professional: 26% (n = 132)
- Journal Editor: 22% (n = 108)
- Total Respondents = 498

**Geographic Distribution**

- North America: 44%
- Europe: 39%
- Asia Pacific: 13%
- Other: 4%

**Industry-Sponsored Clinical Trial Experience**

- 20+ years: 24%
- 6-10 years: 23%
- 11-20 years: 35%
- 3-5 years: 18%
- Total: 498
Familiarity with Guidelines

Clinical investigators had the lowest awareness of and reliance on authorship guidelines.
Audience Poll for Case 1

<table>
<thead>
<tr>
<th>Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A clinical investigator involved with an industry-sponsored clinical trial enrolled the most patients from dozens of investigators. This investigator did not contribute to trial design, and claims recruiting the most patients and daily trial management merits an invitation for authorship</td>
</tr>
</tbody>
</table>

In your opinion, what would be the most appropriate way to recognize the contribution of the investigator in question?

1. Authorship
2. Acknowledgement
3. No Recognition
4. Other
Results of Case 1

Case #1 - Description

A clinical investigator claims recruiting the most patients and daily site management meets “substantial contribution” criteria for authorship.

Survey Results

- **Clinical Investigator**
  - Authorship: 68%
  - Acknowledgement: 25%
  - No Recognition: 3%
  - Other: 4%

- **Journal Editor**
  - Authorship: 55%
  - Acknowledgement: 30%
  - No Recognition: 5%
  - Other: 10%

- **Publication Professional**
  - Authorship: 53%
  - Acknowledgement: 32%
  - No Recognition: 7%
  - Other: 8%

- **Medical Writer**
  - Authorship: 49%
  - Acknowledgement: 32%
  - No Recognition: 5%
  - Other: 9%

- **Mean**
  - Authorship: 57%
  - Acknowledgement: 29%
  - No Recognition: 5%
  - Other: 5%
## Audience Poll for Case 3

<table>
<thead>
<tr>
<th>Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>A medical writer drafts and helps with revisions for a manuscript from an initial trial report through acceptance</td>
</tr>
</tbody>
</table>

In your opinion, what would be the most appropriate way to recognize the contribution of the medical writer?

1. Authorship
2. Acknowledgement
3. No Recognition
4. Other
Results of Case 3

Case #3 - Description

A medical writer drafts and helps with revisions for a manuscript from an initial trial report through acceptance.
### Audience Poll for Case 6

<table>
<thead>
<tr>
<th>Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>A clinical investigator contributes substantially to trial design, interpretation, and drafting and revision of several drafts of the manuscript. Prior to submission of the manuscript, the lead author makes multiple attempts to contact and secure final manuscript approval, with no response.</td>
</tr>
</tbody>
</table>

In your opinion, what would be the most appropriate way to recognize the contribution of the unresponsive clinical investigator?

1. Authorship
2. Acknowledgement
3. No Recognition
4. Authorship + Letter to editor
5. Other
Results of Case 6

Case #6 - Description

Multiple attempts to secure final manuscript approval with author prior to submission – with no response
Key Takeaways from Survey

- Wide variability existed for awareness/reliance on guidelines
- Authorship decisions on scenarios varied both within and across groups
- When guidance is lacking, respondents tended to use judgment
- Despite the variation in decisions, respondents were uniformly confident in their answers
- Clinical investigators appeared to be most concerned with the importance of the contribution rather than external guidelines
Editor Input Regarding Survey Results

Summary of Editor Feedback

- Authorship is a “unique intellectual contribution”
- Establish criteria a priori and document contributions
- Changes require group approval and rationale/evidence
- Educate investigators and other potential authors
Following qualitative research, the authorship survey, and the editor feedback, a **Five-Step Authorship framework** was developed and published.
## Five-step Authorship Framework

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Establish an authorship working group of core trial contributors as close as possible to trial commencement</td>
<td>PRIOR TO INVITING AUTHORS AND BEFORE MANUSCRIPT WRITING BEGINS</td>
</tr>
<tr>
<td>2</td>
<td>Determine, in the context of the ICMJE authorship criteria and the specific trial, which authorship contributions are ‘substantial’</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Implement a process to track and document contributions</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Assess documented contributions to invite authors (from the defined list of criteria (from step 2) e.g., protocol development, enrollment, meetings, AE management etc.)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Ensure invited authors meet remaining ICMJE authorship criteria</td>
<td>INVITE AUTHORS AND WRITE MANUSCRIPT</td>
</tr>
</tbody>
</table>
Five-step Authorship Framework - Step 1

**Step 1**
Form authorship working group

- Include broad representation from key internal and external stakeholders
- Where possible, engage working group members throughout study
- Working group participation does not guarantee authorship

**Step 2**
Define substantial contributions

**Step 3**
Track & document contributions

**Step 4**
Invite authors

**Step 5**
Meet remaining ICMJE criteria
Five-step Authorship Framework - Step 2

**Step 1**
Form authorship working group

**Step 2**
Define substantial contributions

“See where I’m coming from?”

**Step 3**
Track & document contributions

**Step 4**
Invite authors

**Step 5**
Meet remaining ICMJE criteria

Removing the ambiguity from the definition of ‘substantial contributions’ for authorship
### Five-step Authorship Framework - Step 2

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Form authorship working group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 2</strong></td>
<td>Define substantial contributions</td>
</tr>
<tr>
<td>Step 3</td>
<td>Track &amp; document contributions</td>
</tr>
<tr>
<td>Step 4</td>
<td>Invite authors</td>
</tr>
<tr>
<td>Step 5</td>
<td>Meet remaining ICMJE criteria</td>
</tr>
</tbody>
</table>

- **Working group defines “substantial” contributions that are aligned with internal policies / external guidelines**

- **Timing**: Early, finalized after completion of trial protocol but prior to patient enrollment

- **Scope**: Agreed to by all trial contributors prior to trial initiation

- **Consideration**: Trial activities that impact the broader trial/outcome rather than a specific niche function
**Five-step Authorship Framework - Step 3**

- **Step 1**
  Form authorship working group

- **Step 2**
  Define substantial contributions

- **Step 3**
  Track & document contributions

- **Step 4**
  Invite authors

- **Step 5**
  Meet remaining ICMJE criteria

**Working group** creates and implements a plan to catalogue all relevant trial contributions.

- **Consideration**: Process should be transparent and leverage trial activities to avoid creating new tasks.

- **Consideration**: Plan shared and agreed to by all trial contributors.
### Five-step Authorship Framework - Step 4

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Form authorship working group</td>
</tr>
<tr>
<td>2.</td>
<td>Define substantial contributions</td>
</tr>
<tr>
<td>3.</td>
<td>Track &amp; document contributions</td>
</tr>
<tr>
<td><strong>4.</strong></td>
<td>Invite authors</td>
</tr>
<tr>
<td>5.</td>
<td>Meet remaining ICMJE criteria</td>
</tr>
</tbody>
</table>

- Trial contributors meeting criteria for substantial contribution should be invited to draft/revise manuscript
- All contributors should be treated equally, regardless of affiliation
- Those deemed to have made a substantial contribution must be invited for authorship
- Invitation to serve as an author may be declined
## Five-step Authorship Framework - Step 5

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Form authorship working group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Define substantial contributions</td>
</tr>
<tr>
<td>Step 3</td>
<td>Track &amp; document contributions</td>
</tr>
<tr>
<td>Step 4</td>
<td>Invite authors</td>
</tr>
<tr>
<td>Step 5</td>
<td>Meet remaining ICMJE criteria</td>
</tr>
</tbody>
</table>

- Those accepting authorship invitation serve as the initial author list
- Author list members must fulfill the remaining authorship criteria
- Changes to the author list must be agreed to by the entire author list
- Summary table of contributions can be supplied, in line with journal policy
Strengths of Five-step Framework

✓ Addresses need for more transparent and objective authorship determination for clinical trial manuscripts

✓ Aligns with current approaches for conducting clinical trials and publication planning

✓ Developed in collaboration with editors and other key stakeholders (e.g., clinical investigators, publication planners, and medical writers)

✓ Brings together multiple stakeholders and perspectives to ensure broad representation

✓ Incorporates authorship criteria based on current guidelines early in the trial process prior to initiation of patient recruitment

✓ Flexible to include most relevant trial activities and any updates to external authorship guidelines
<table>
<thead>
<tr>
<th>Scenario</th>
<th>Suggested Guidance by Editors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does patient recruitment count as substantial contribution?</td>
<td>• Recruiting alone should not qualify as a substantial contribution unless clear intellectual insight is involved</td>
</tr>
<tr>
<td>2. Can an author be added after drafting has begun?</td>
<td>• Timing of substantial contribution should not play a role&lt;br&gt;• Must be agreed upon by entire author list prior to submission</td>
</tr>
<tr>
<td>3. Can an author remove his/her name from recognition?</td>
<td>• Authorship cannot be compelled, but acknowledgement is encouraged&lt;br&gt;• All contributions should be included in documentation&lt;br&gt;• Agreed upon by entire author list prior to submission</td>
</tr>
<tr>
<td>4. How should contributions from a medical writer be recognized?</td>
<td>• Medical writers should be treated as trial contributors&lt;br&gt;• All relevant contributions documented and those making substantial contribution warrant invitation for authorship</td>
</tr>
<tr>
<td>5. How should external contracted work be evaluated for authorship?</td>
<td>• External contracted work should be cataloged and evaluated for potential substantial contribution equally with other work</td>
</tr>
<tr>
<td>6. What can be done when an author does not provide final approval?</td>
<td>• Lead investigator should be empowered to ensure approval&lt;br&gt;• Any change to the byline or acknowledgements must be agreed upon by entire author list prior to submission&lt;br&gt;• Unresponsive authors should be removed and acknowledged</td>
</tr>
<tr>
<td>7. What happens when a contributor leaves prior to trial completion?</td>
<td>• Data confidentiality does not trump transparency of recognition&lt;br&gt;• Departing contributors should not be cut off from study&lt;br&gt;• Contributions must be evaluated through authorship criteria&lt;br&gt;• Authorship decision needs to be made prior to submission</td>
</tr>
</tbody>
</table>
Considerations for Implementation

More important will be to develop plans based on appropriately developed approaches to implement the framework. This is likely to be most effective when pharmaceutical companies modify their authorship practices and polices when conducting any clinical trial.

- Dr. David Moher, member of CONSORT and EQUATOR

To enhance uptake of the framework it will be important for the team, or others, to develop a bank of worked examples for each step in the five-step process. Using worked examples from specific trials will likely facilitate implementation.

- Dr. David Moher, member of CONSORT and EQUATOR
Case Study – Patient Recruitment

Description: Recruiting alone should not qualify as a substantial contribution unless clear intellectual insight is involved

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Form authorship working group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Define substantial contributions</td>
</tr>
<tr>
<td>Step 3</td>
<td>Track &amp; document contributions</td>
</tr>
<tr>
<td>Step 4</td>
<td>Invite authors</td>
</tr>
<tr>
<td>Step 5</td>
<td>Meet remaining ICMJE criteria</td>
</tr>
</tbody>
</table>

- Working group determines if recruitment and site management meet the criteria for substantial contribution (trial specific)
- Criteria agreed to by all trial contributors
- Document role in recruitment and other intellectual contributions
- Trial contributors who meet predefined criteria are invited to serve as authors
- Invited authors meet remaining authorship criteria to serve as an author on the manuscript
## Next Steps

<table>
<thead>
<tr>
<th>MPIP</th>
<th>Beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Implementation of process in MPIP Steering Committee member companies’ best practice</td>
<td>• Continue to build awareness of industry tools for authorship</td>
</tr>
<tr>
<td>• Collaborations with additional organizations to drive outreach and education</td>
<td>• Gather additional feedback on the framework</td>
</tr>
</tbody>
</table>
Collaborators / Acknowledgements

• Ana Marusic and Darko Hren - University of Split, Croatia

• The MPIP Steering Committee

• ISMPP, AMWA, EMWA, and various publishers who helped recruit survey respondents

• Journal editors, clinical investigators, publication professionals, and medical writers who participated in the survey and follow-up discussions

• Liz Wager - Sideview Consulting

Please contact MPIP for additional information or to provide your examples of authorship scenarios at: info@mpip-initiative.org