



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

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Disclaimer

- Information presented reflects my personal knowledge and opinions and does not represent the position of my current or past employers or CSE.

- 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



“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

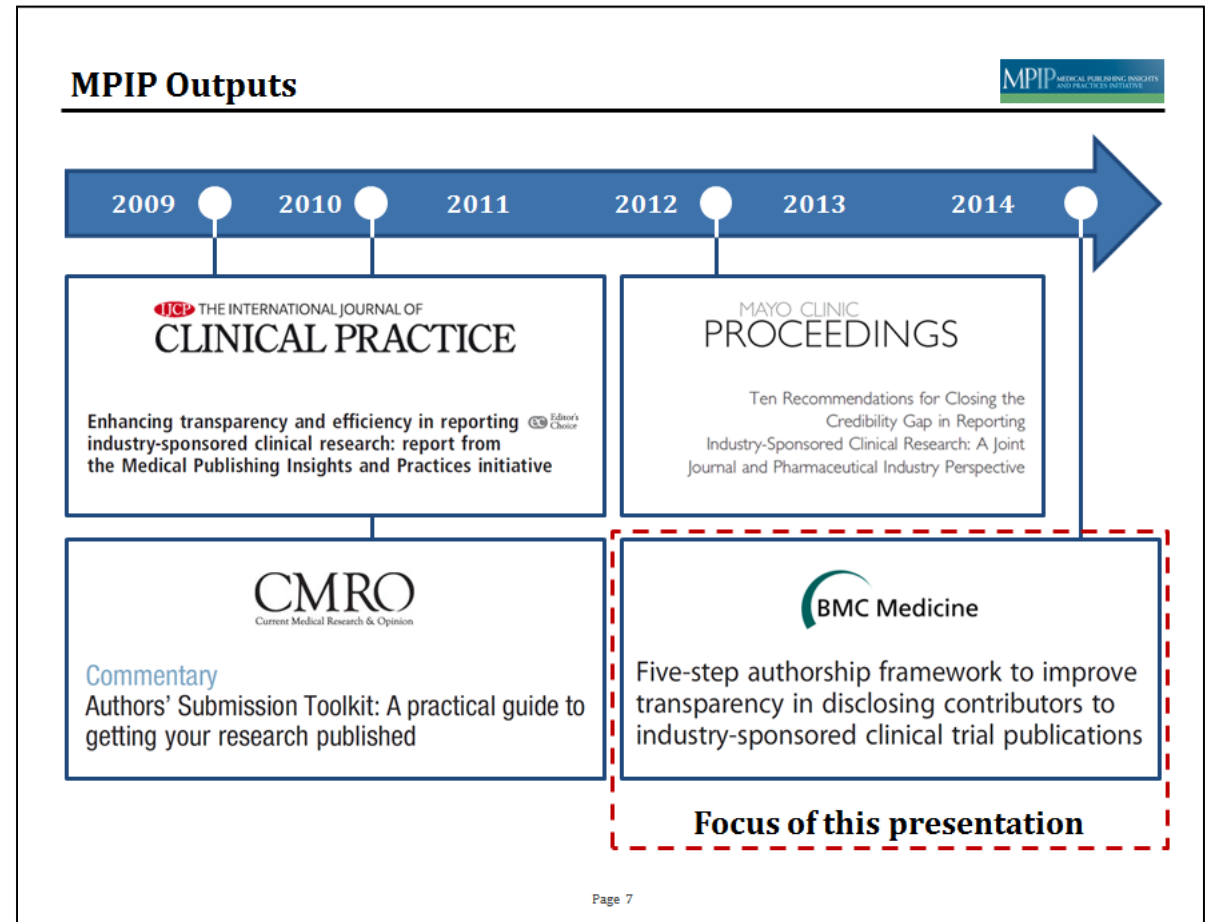


TABLE: Top 10 Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research

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

MPIP Road Map: Ten Recommendations



5.
Improve
disclosure of
authorship
contributions

Background: Available Guidelines and Recommendations



Defining the Role of Authors and Contributors



Good Publication Practice (GPP2)

International Society for Medical Publication Professionals (ISMPP) position papers

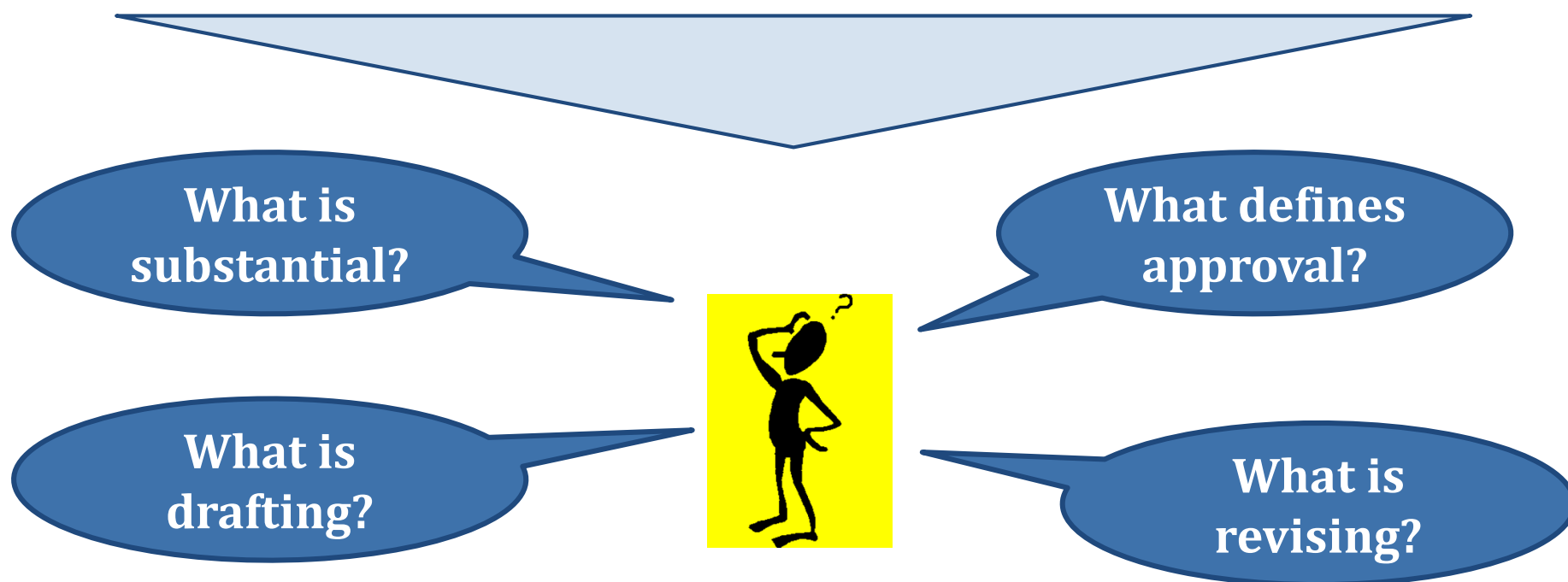
Council of Science Editors (CSE) White Paper

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*

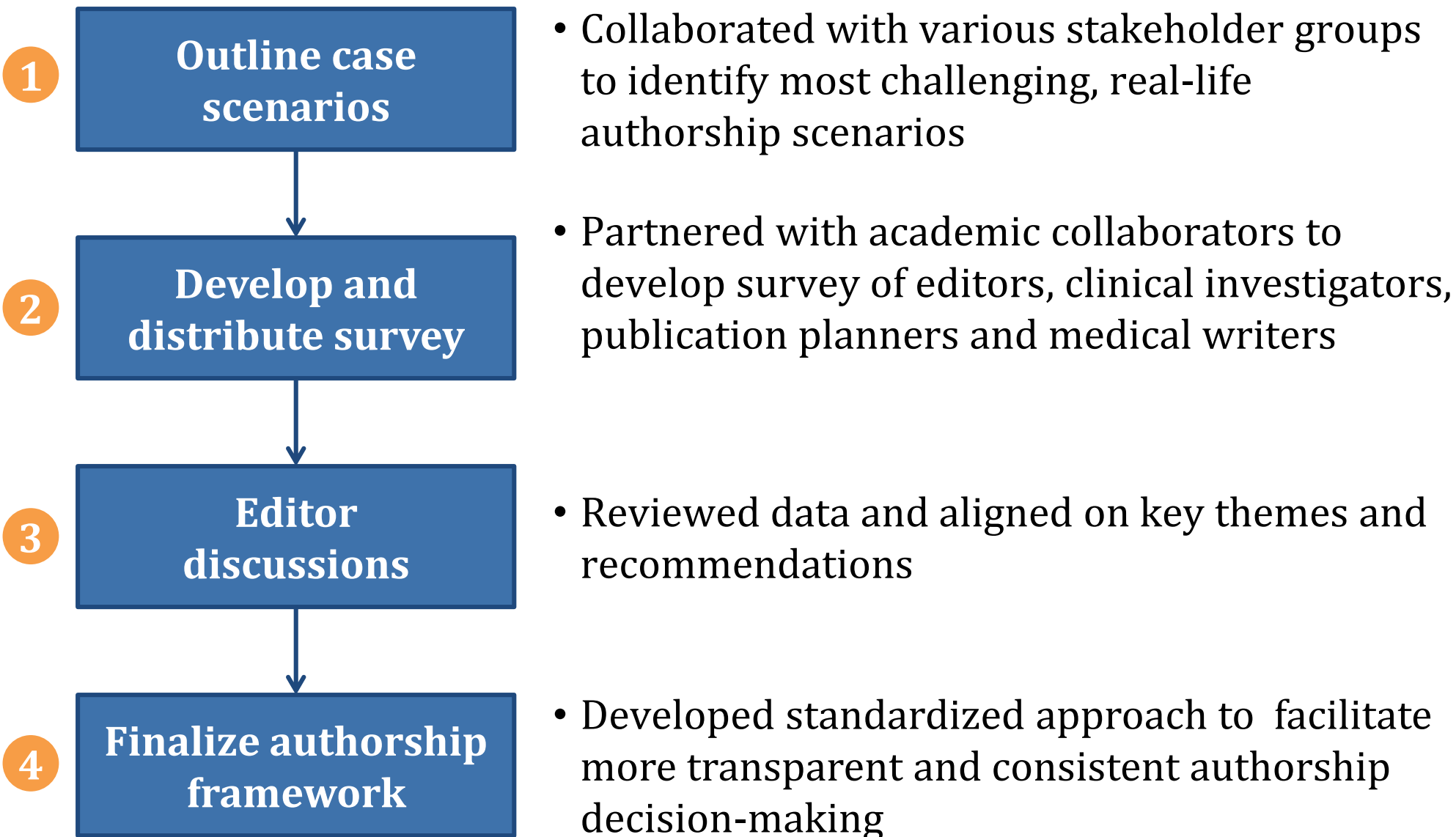


What is the Unmet Need

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



Sample design

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



Survey design

Quantitative

- How to adjudicate case study (authorship, acknowledgement, no recognition)?
- What rationale did you use?
- How confident are you?
- How frequently does this occur?

Qualitative

- What guidelines are you aware of?
- Which guidelines do you use most?
- In a given clinical study, when are authorship criteria determined?
- In a given clinical study, when are authors determined?

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



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



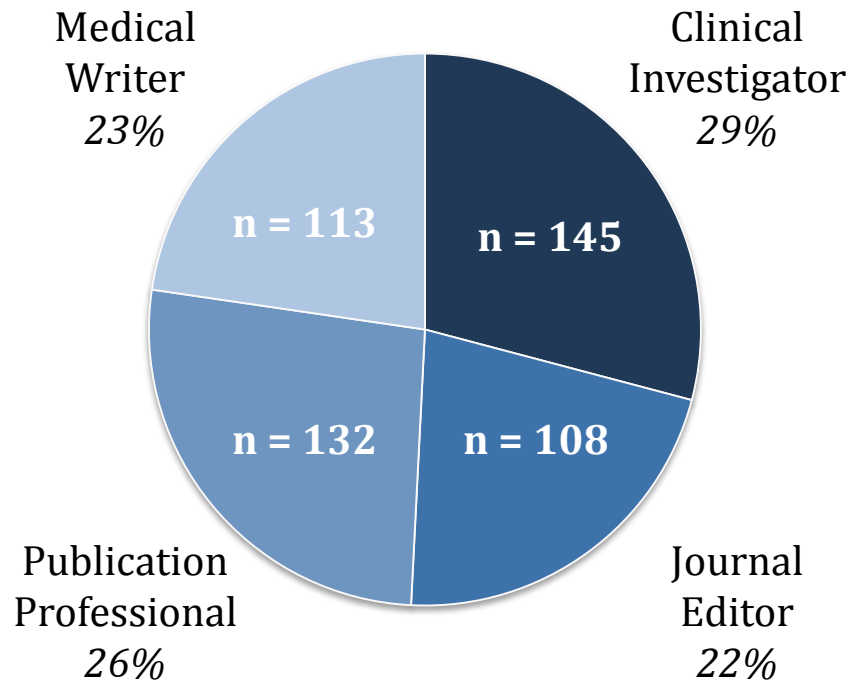
Final Sample	N
Clinical investigator	145
Journal editor	108
Publication professional	132
Medical writer	113



Total of 498 respondents with at least 96 respondents per group enabled estimates with a 10% margin of error

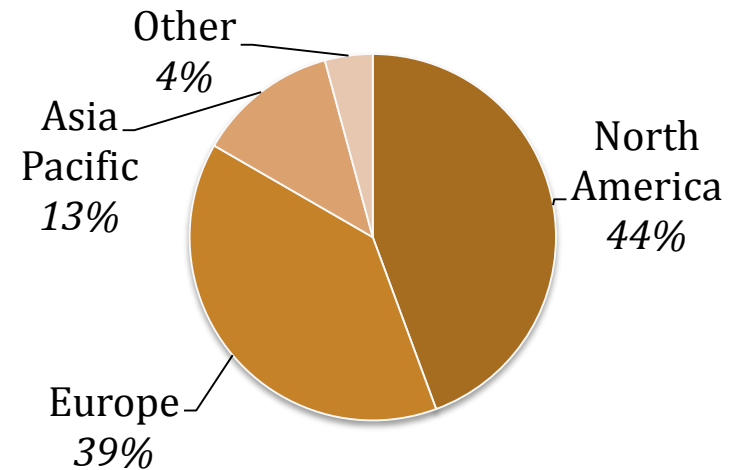
Results: Respondents were Diverse and Experienced

Professional Affiliation

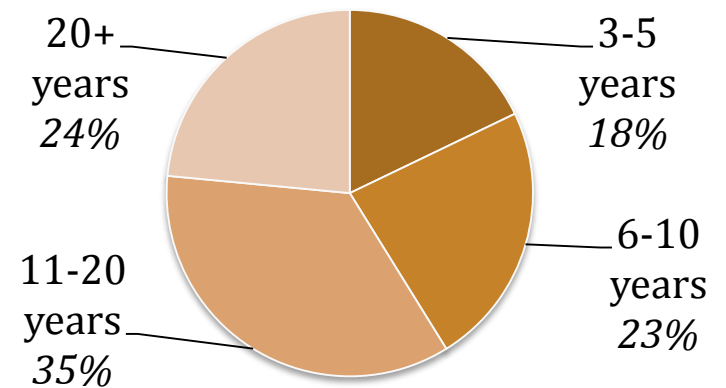


Total Respondents = 498

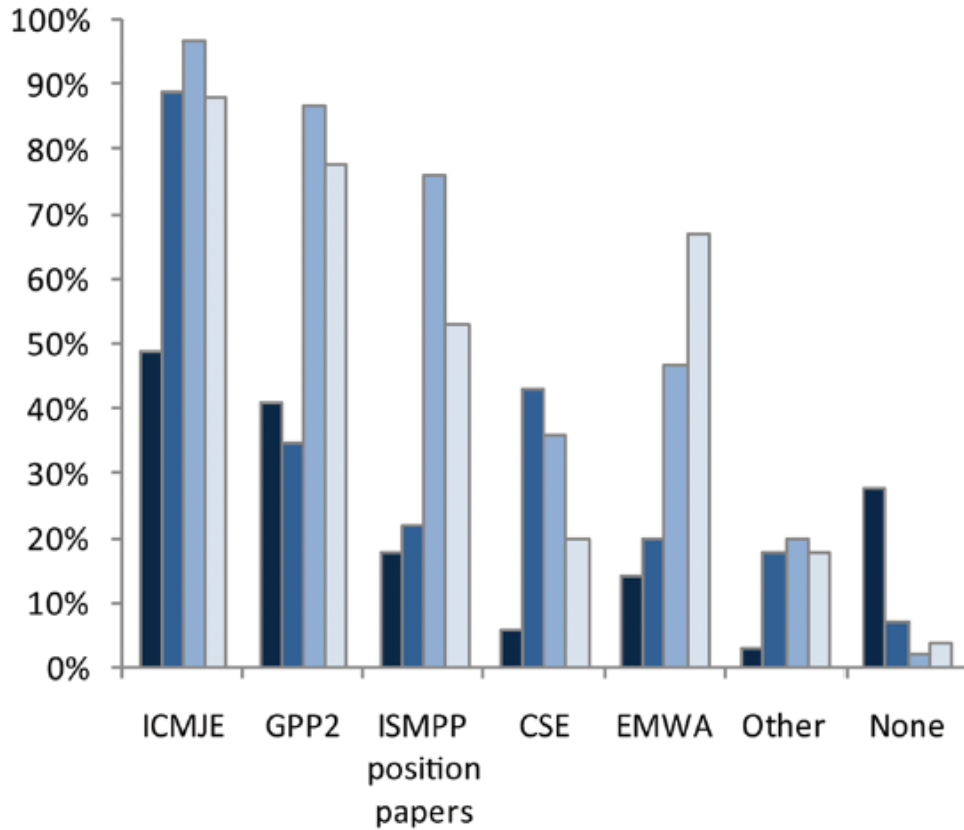
Geographic Distribution



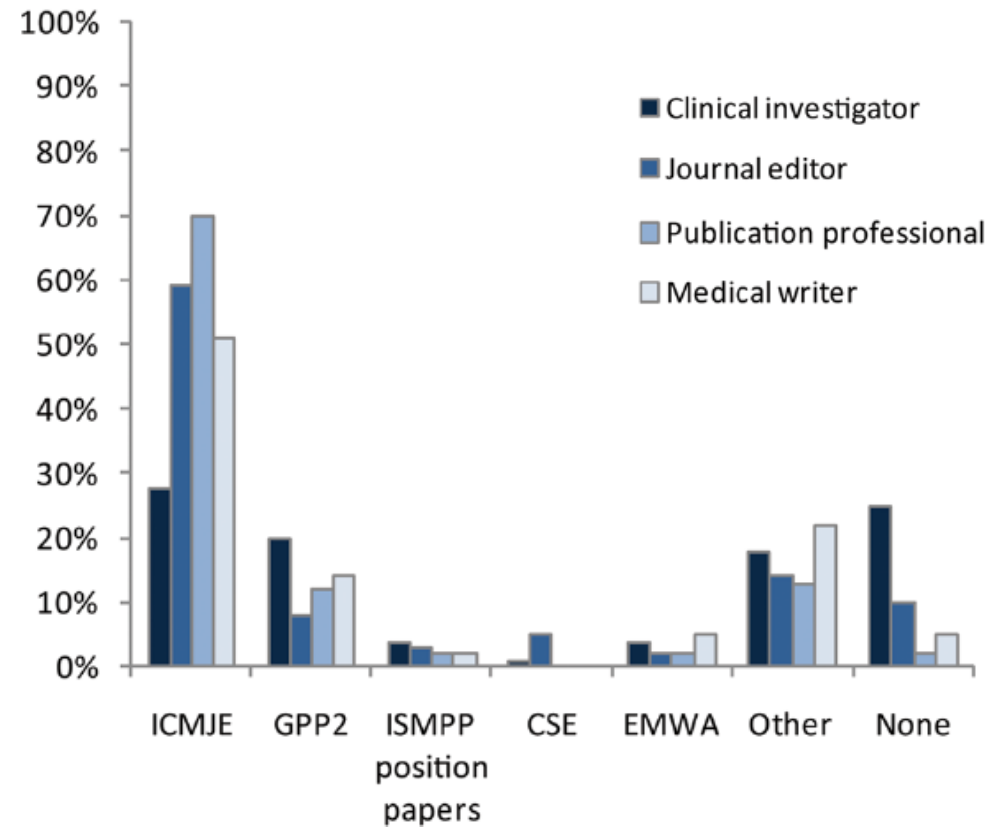
Industry-Sponsored Clinical Trial Experience



Familiarity with Guidelines



Reliance on Guidelines



Clinical investigators had the lowest awareness of and reliance on authorship guidelines

Case	Description
1	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

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

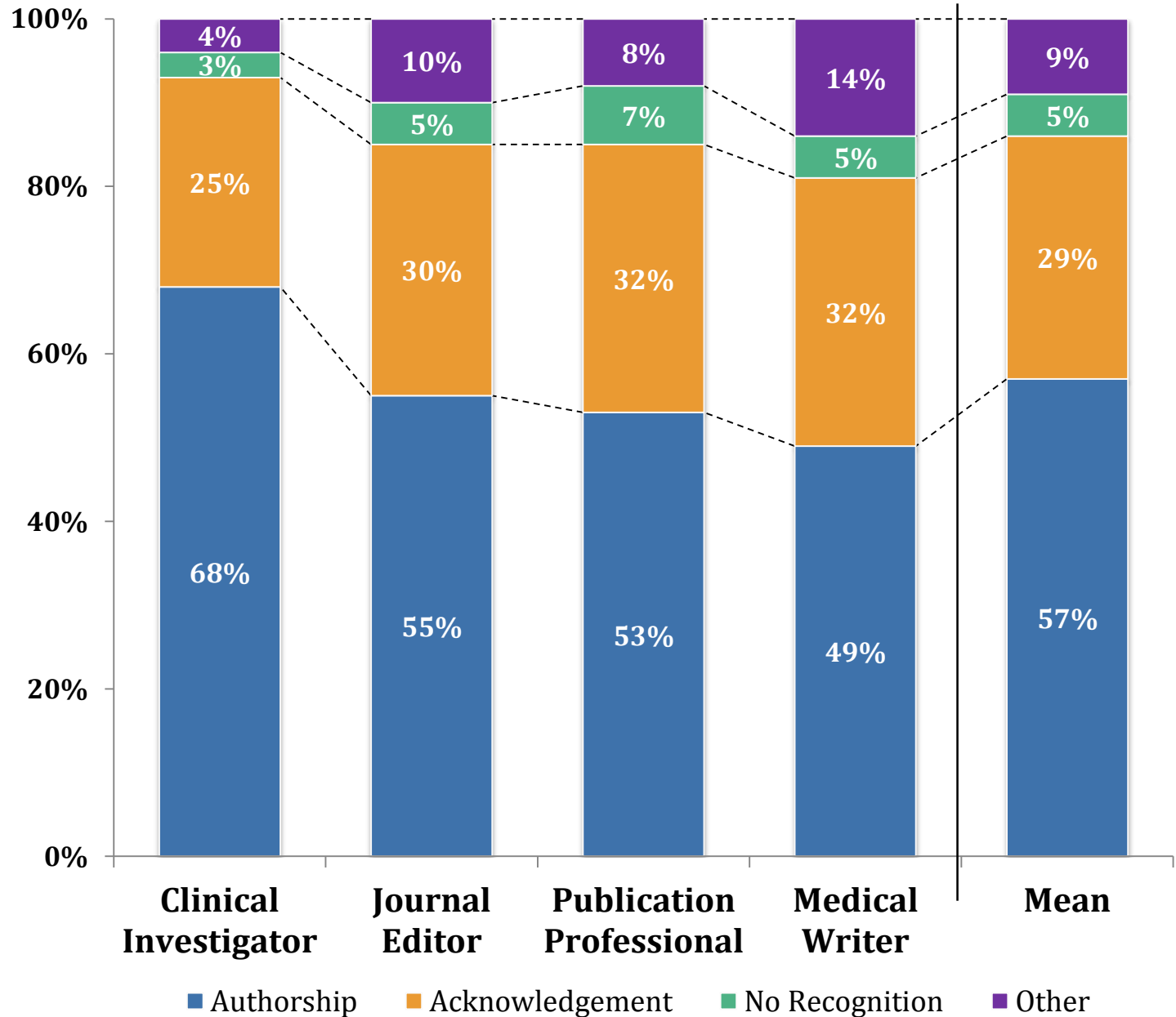
1. Authorship
2. Acknowledgement
3. No Recognition
4. Other

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



Case	Description
3	A medical writer drafts and helps with revisions for a manuscript from an initial trial report through acceptance

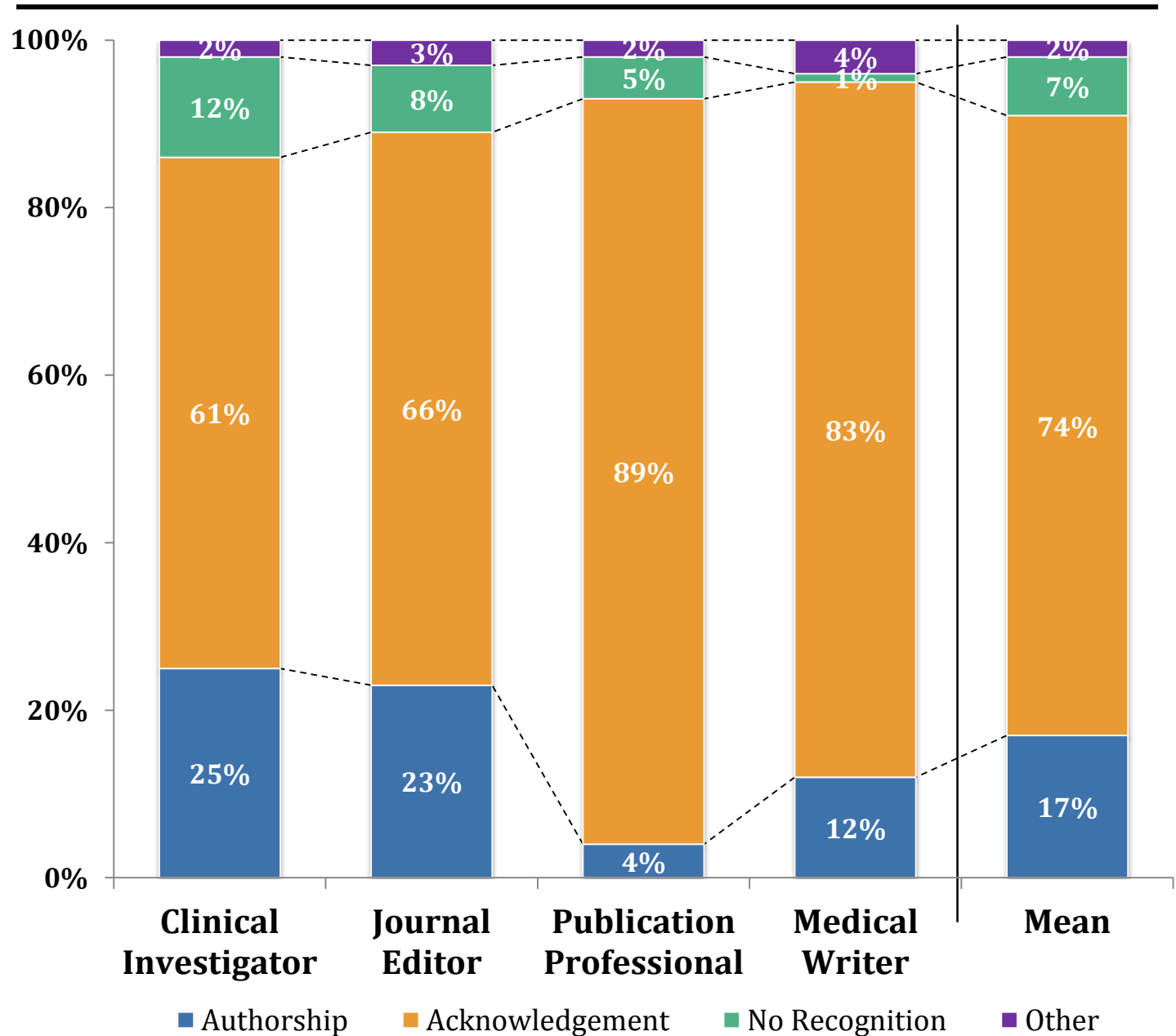
In your opinion, what would be the most appropriate way to recognize the contribution of the medical writer?

1. Authorship
2. Acknowledgement
3. No Recognition
4. Other

Case #3 - Description

A medical writer drafts and helps with revisions for a manuscript from an initial trial report through acceptance.

Survey Results



Case	Description
6	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.

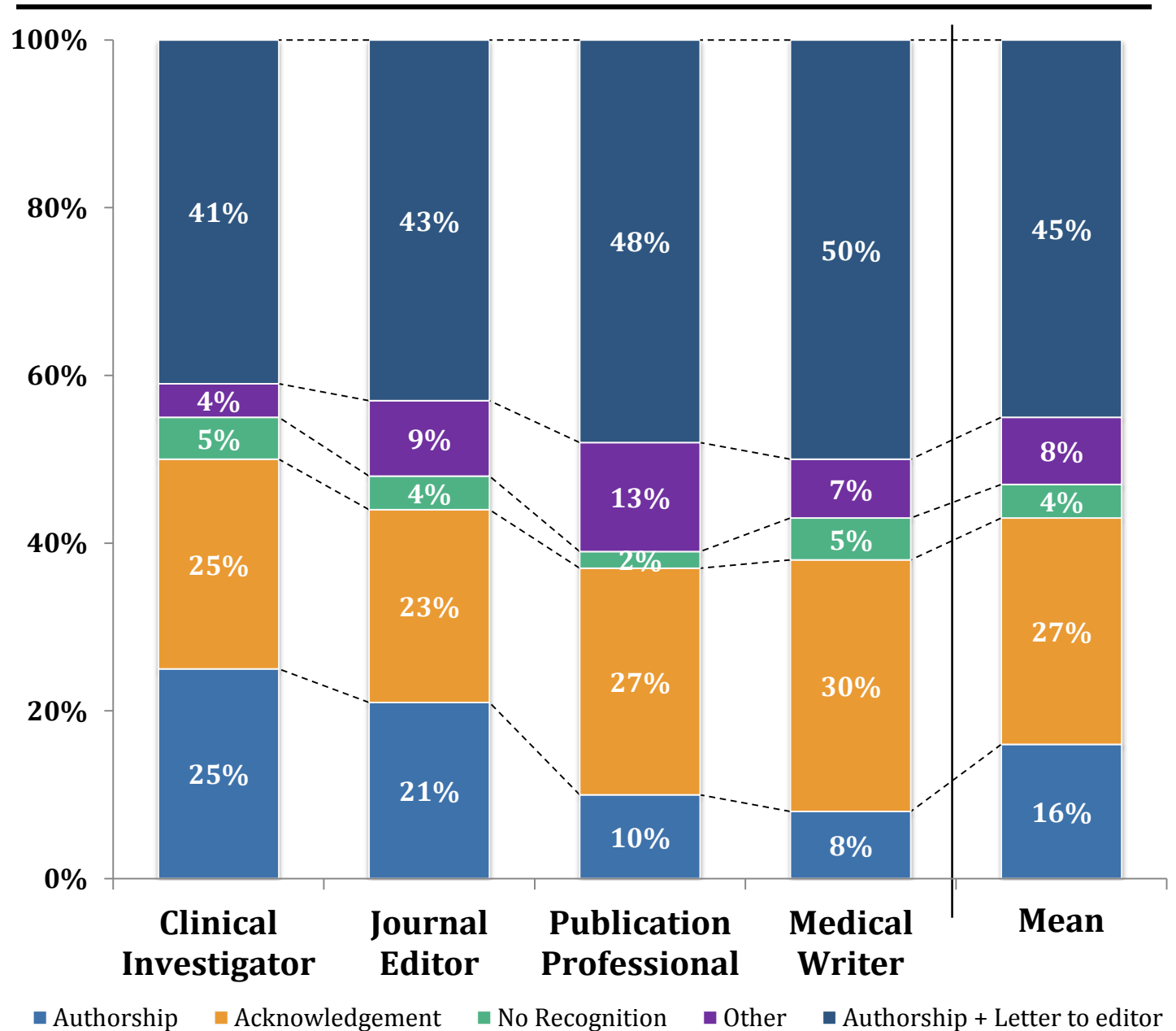
In your opinion, what would be the most appropriate way to recognize the contribution of the unresponsive clinical investigator?

1. Authorship
2. Acknowledgement
3. No Recognition
4. Authorship + Letter to editor
5. Other

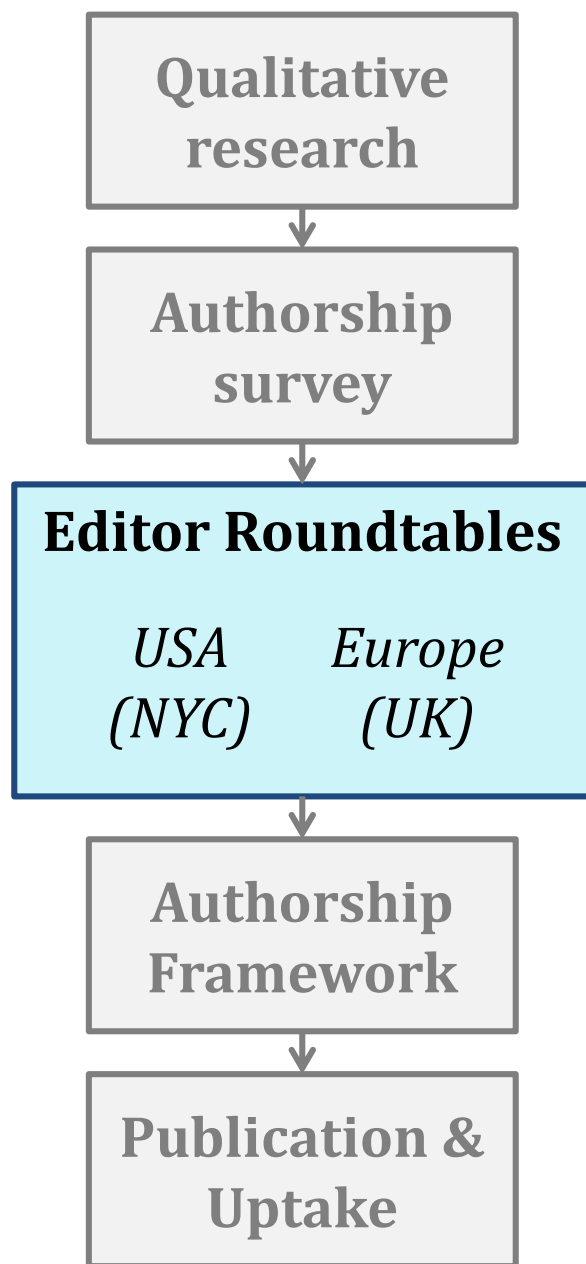
Case #6 - Description

Multiple attempts to secure final manuscript approval with author prior to submission – with no response

Survey Results



- ✓ **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**



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

Marušić et al. BMC Medicine 2014, 12:197
http://www.biomedcentral.com/1741-7015/12/197

BMC Medicine

CORRESPONDENCE Open Access

Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications

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Abstract
Authorship guidelines have established criteria to guide author selection based on significance of contribution and helped to define associated responsibilities and accountabilities for the published findings. However, low awareness, variable interpretation, and inconsistent application of these guidelines can lead to confusion and a lack of transparency when recognizing those who merit authorship. This article describes a research project led by the Medical Publishing Insights and Practices (MPIP) Initiative to identify current challenges when determining authorship for industry-sponsored clinical trials and develop an improved approach to facilitate decision-making when recognizing authors from related publications. A total of 496 clinical investigators, journal editors, publication professionals and medical writers were surveyed to understand better how they would adjudicate challenging, real-world authorship case scenarios, determine the perceived frequency of each scenario and rate their confidence in the responses provided. Multiple rounds of discussions about these results with journal editors, clinical investigators and industry representatives led to the development of key recommendations intended to enhance transparency when determining authorship. These included: forming a representative group to establish authorship criteria early in a trial, having all trial contributors agree to these criteria and documenting trial contributions to objectively determine who warrants an invitation to participate in the manuscript development process. The resulting Five-step Authorship Framework is designed to create a more standardized approach when determining authorship for clinical trial publications. Overall, these recommendations aim to facilitate more transparent authorship decisions and help readers better assess the credibility of results and perspectives of the authors for medical research more broadly. Please see related article: <http://www.biomedcentral.com/1741-7015/12/214>.

Keywords: Authorship, Transparency, Clinical trial, MPIP Initiative, Journal editors, Medical writers, Clinical investigators, Publication professionals

Introduction
The designation of authorship is essential for published research to be represented by those who provide significant intellectual contribution to its development and execution. More recently, authorship selection has evolved to confer not only the credit for the research but also accountability and responsibility for accuracy and integrity of the work. Yet, making this determination can be especially challenging due to the ambiguous nature of available authorship guidelines and the increasing complexity of clinical trial research [1]. The most common and frequently referenced authorship guidelines in biomedicine are issued by the International Committee of Medical Journal Editors (ICMJE). The goal of the ICMJE criteria is to enhance transparency in authorship disclosure and ultimately to build trust and credibility with the medical literature readership [2,3]. Another authorship model, referred to as contributorship, lists each person's contributions to the research and manuscript, even for those who are not authors. One or more of these contributors will fulfill the role as guarantors of the paper [4]. Despite implementation of these and other approaches by journals

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Following qualitative research, the authorship survey, and the editor feedback, a **Five-Step Authorship framework** was developed and published



Five-step Authorship Framework

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

Five-step Authorship Framework - Step 1

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

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



<p><u>Step 1</u> Form authorship working group</p>
<p><u>Step 2</u> Define substantial contributions</p>
<p><u>Step 3</u> Track & document contributions</p>
<p><u>Step 4</u> Invite authors</p>
<p><u>Step 5</u> Meet remaining ICMJE criteria</p>

“See where I’m coming from?”



Removing the ambiguity from the
definition of ‘substantial contributions’
for authorship

Five-step Authorship Framework - Step 2

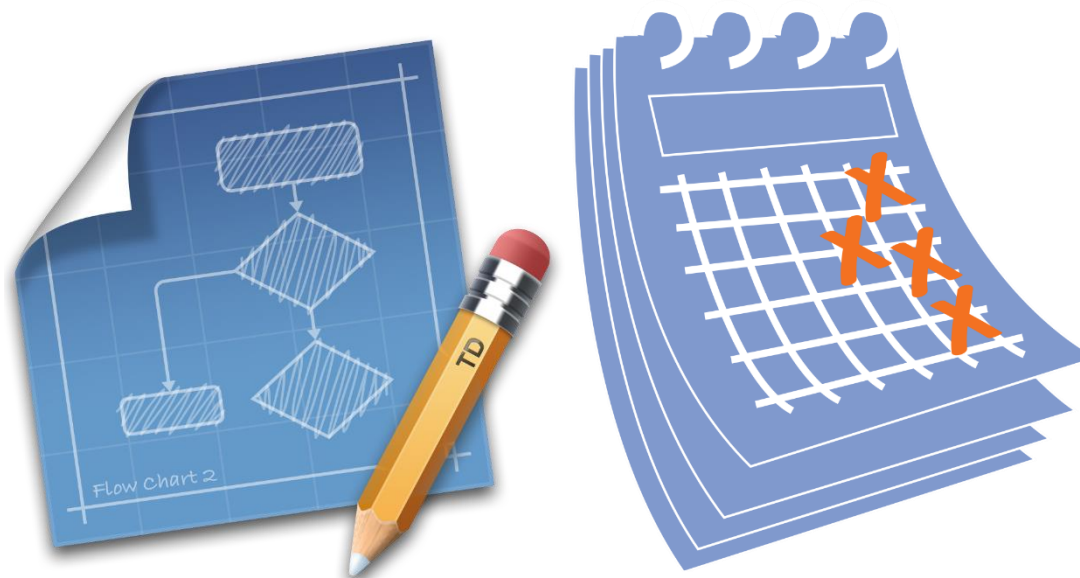
<p><u>Step 1</u> Form authorship working group</p>
<p><u>Step 2</u> Define substantial contributions</p>
<p><u>Step 3</u> Track & document contributions</p>
<p><u>Step 4</u> Invite authors</p>
<p><u>Step 5</u> Meet remaining ICMJE criteria</p>

- 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

<p><u>Step 1</u> Form authorship working group</p>
<p><u>Step 2</u> Define substantial contributions</p>
<p><u>Step 3</u> Track & document contributions</p>
<p><u>Step 4</u> Invite authors</p>
<p><u>Step 5</u> Meet remaining ICMJE criteria</p>

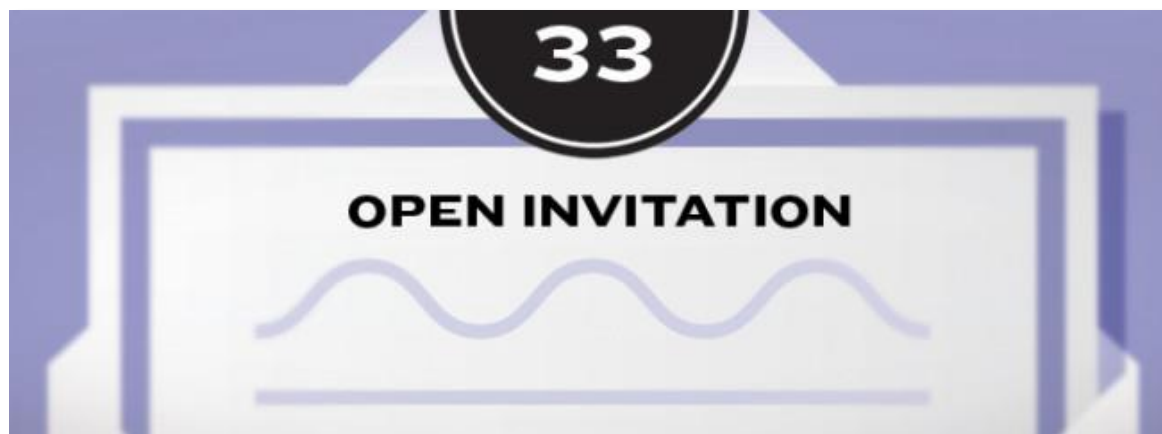
- Working group creates and implements a plan to catalogue all relevant trial contributions



- 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

<p><u>Step 1</u> Form authorship working group</p>
<p><u>Step 2</u> Define substantial contributions</p>
<p><u>Step 3</u> Track & document contributions</p>
<p><u>Step 4</u> Invite authors</p>
<p><u>Step 5</u> Meet remaining ICMJE criteria</p>



- 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

<p><u>Step 1</u> Form authorship working group</p>
<p><u>Step 2</u> Define substantial contributions</p>
<p><u>Step 3</u> Track & document contributions</p>
<p><u>Step 4</u> Invite authors</p>
<p><u>Step 5</u> Meet remaining ICMJE criteria</p>

- 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

Editor Feedback to Authorship Scenarios

Scenario	Suggested Guidance by Editors
1. Does patient recruitment count as substantial contribution?	<ul style="list-style-type: none"> Recruiting alone should not qualify as a substantial contribution unless clear intellectual insight is involved
2. Can an author be added after drafting has begun?	<ul style="list-style-type: none"> Timing of substantial contribution should not play a role Must be agreed upon by entire author list prior to submission
3. Can an author remove his/her name from recognition?	<ul style="list-style-type: none"> Authorship cannot be compelled, but acknowledgement is encouraged All contributions should be included in documentation Agreed upon by entire author list prior to submission
4. How should contributions from a medical writer be recognized?	<ul style="list-style-type: none"> Medical writers should be treated as trial contributors All relevant contributions documented and those making substantial contribution warrant invitation for authorship
5. How should external contracted work be evaluated for authorship?	<ul style="list-style-type: none"> External contracted work should be cataloged and evaluated for potential substantial contribution equally with other work
6. What can be done when an author does not provide final approval?	<ul style="list-style-type: none"> Lead investigator should be empowered to ensure approval Any change to the byline or acknowledgements must be agreed upon by entire author list prior to submission Unresponsive authors should be removed and acknowledged
7. What happens when a contributor leaves prior to trial completion?	<ul style="list-style-type: none"> Data confidentiality does not trump transparency of recognition Departing contributors should not be cut off from study Contributions must be evaluated through authorship criteria Authorship decision needs to be made prior to submission

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 policies when conducting any clinical trial.

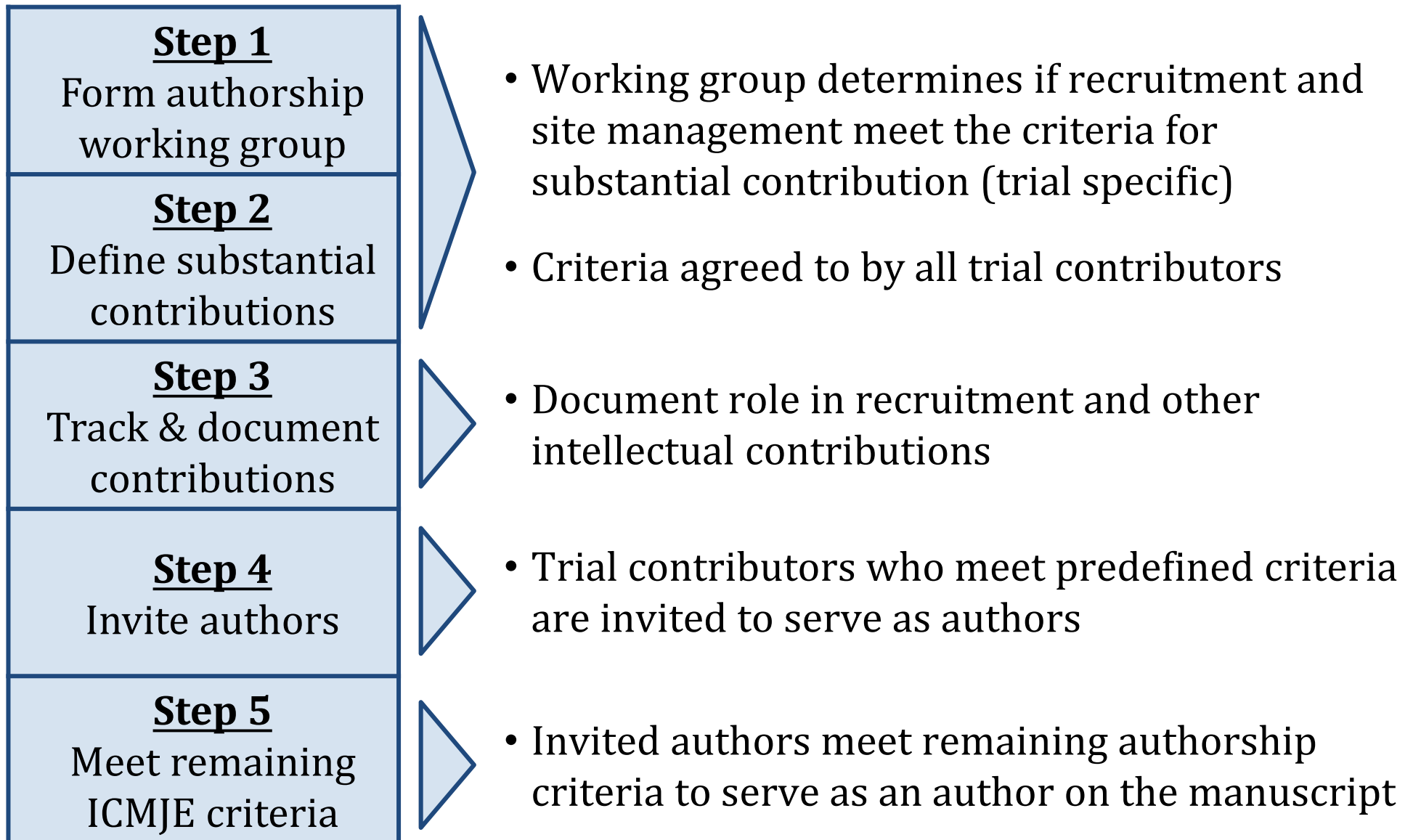
- Dr. David Moher, member of CONSORT and EQUATOR

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



MPIP

- Implementation of process in MPIP Steering Committee member companies' best practice
- Collaborations with additional organizations to drive outreach and education



Beyond

- Continue to build awareness of industry tools for authorship
- Gather additional feedback on the framework

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

