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

February 25, 2015

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Introductions

- **<u>Faculty:</u> Bernadette Mansi** is Head of Publications & Disclosure Practices at GlaxoSmithKline Pharmaceuticals. For over 25 years, she has successfully led global scientific communications programs and teams and spearheaded efforts to raise industry standards and elevate transparency. In 2008, she founded the Medical Publishing Insights and Practices Initiative (MPIP) and has collaborated with journal editors and industry representatives to develop and co-author various publications, including the *Ten Recommendations for Closing the Credibility Gap in Reporting Industry-sponsored Clinical Research* (*Mayo Clinic Proceedings*, 2012) and the "Five-step Authorship Framework" (*BMC Medicine*, 2014).

Introductions

- **<u>Faculty:</u>** **Ananya Bhattacharya** is the Director of Publication Policy & Education in the Global Medical Publications department in Bristol Myers Squibb. In this role, Ananya leads a team of publication professionals who work across all therapeutic areas and geographies to ensure that high quality publications, communicating the value of Bristol-Myers Squibb's innovative medicines to the medical and scientific community, are developed with the highest degree of ethics and transparency. Ananya is a member of the MPIP Steering Committee and in collaboration with journal editors has co-authored the "Five-step Authorship Framework" (BMC Medicine 2014).

Introductions

- **Moderator:** **Charles Rosenblum** is Associate Director, Global Scientific and Medical Publications, supporting Diabetes and Cardiovascular Disease programs at Merck & Co., Inc. He has worked in the medical communications area since 2008. Prior to this, he was a drug discovery researcher working in pharma. Charles has been a member of the ISMPP U committee since 2011.

Disclaimer

- Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or ISMPP.

Today's Objectives

- At the conclusion of this educational session, attendees should be able to:
  - Understand rationale behind the MPIP Authorship Research Initiative
  - Discuss key findings of the survey and qualitative editor discussions
  - Understand the principles behind the Five-step Authorship Framework
  - Know how to apply the Framework to help improve transparency in disclosing contributors to industry-sponsored trial publications

Agenda

- **MPIP Background**
- **Authorship Research Initiative – Rationale/Approach**
- **Authorship Results**

Bernadette Mansi, GSK

- **Five-step Authorship Framework**
- **Implementation Considerations**

Audience Poll #1

What is your familiarity with the MPIP?

A. Unfamiliar

B. I've heard of the group

C. I've seen a few presentations/published papers

D. I'm familiar with MPIP initiatives or publications

MPIP Vision and Objectives

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

MPIP Collaborative Model

- ***Conduct research*** to understand key barriers impacting trust, transparency and credibility in publishing industry-sponsored research
- ***Hold Annual Journal-Industry Roundtables*** to align on unmet needs, brainstorm actionable solutions and agree recommendations
- ***Collaborate with journal editors and societies*** to disseminate outputs, conduct outreach and educate stakeholders

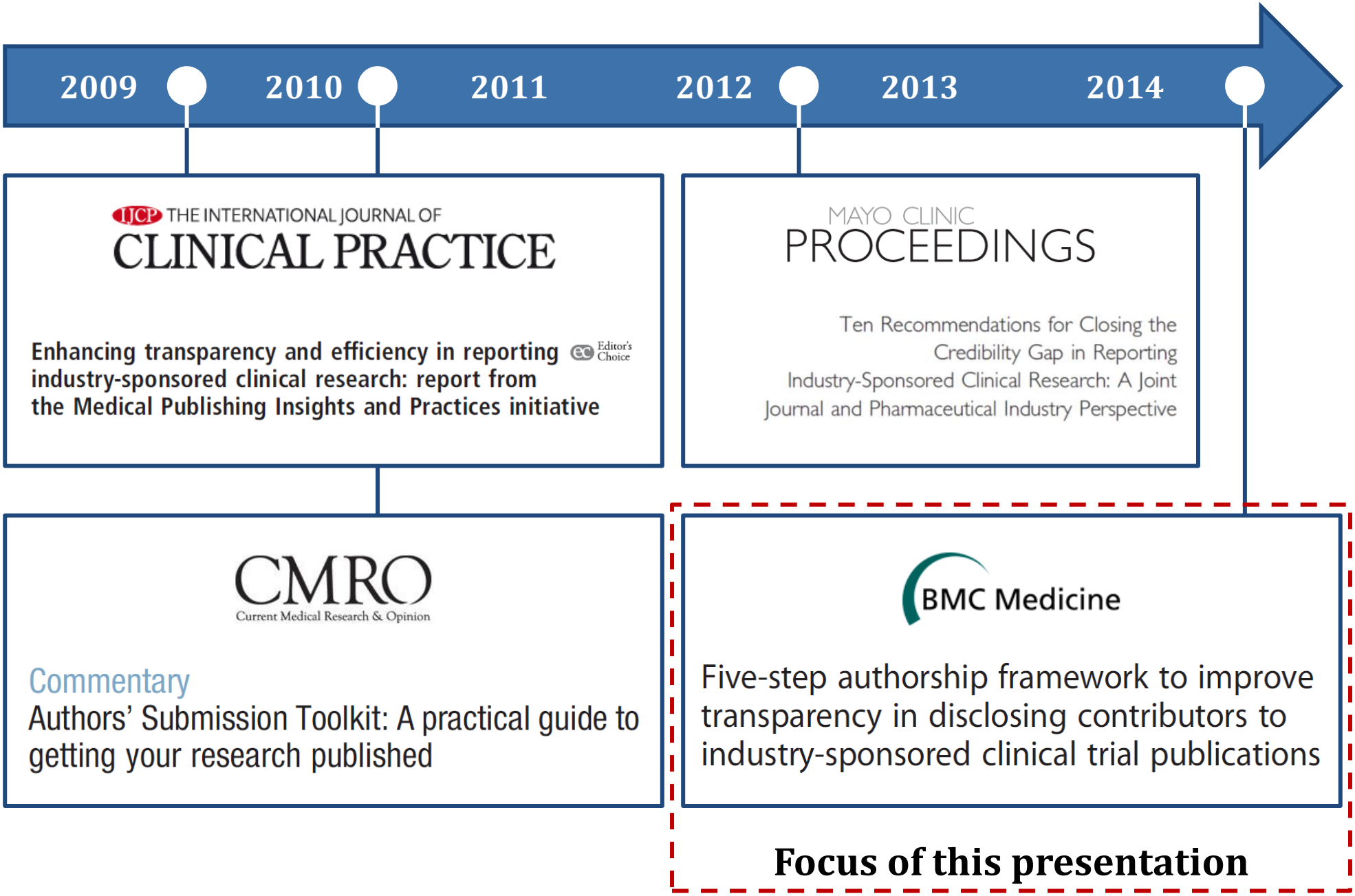
Ten Recommendations

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
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 –
10 Recommendations serve as MPIP's "strategic roadmap"

MPIP Outputs



Audience Poll #2

What is your familiarity with the MPIP publication on the Five-step Authorship Framework?

A. Unfamiliar

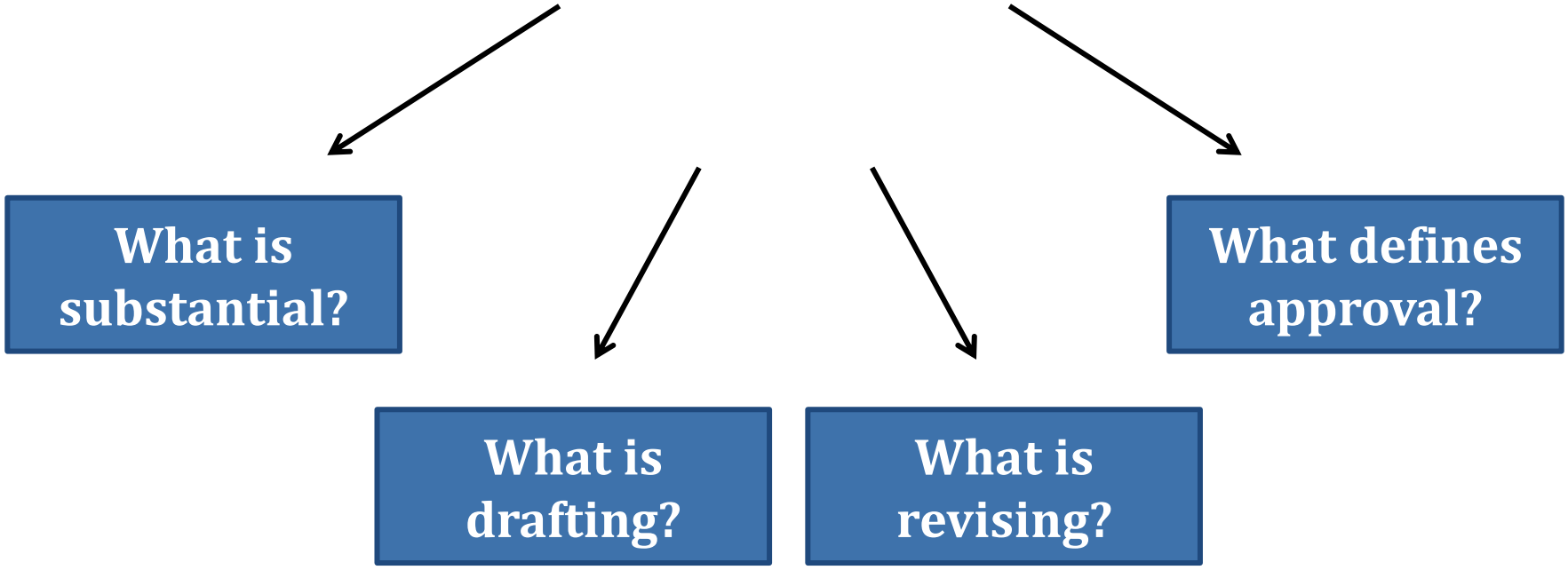
B. I've heard of MPIP's Five-step Authorship Framework, but I do not know much about it

C. I've seen an MPIP presentation or publication on the Five-step Authorship Framework

D. I've read the *BMC Medicine* publication in detail and know it well

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*



MPIP's Authorship Initiative

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

Authorship Initiative - Approach

- Collaborated with various stakeholder groups to identify most challenging, real-life authorship scenarios
- Partnered with academic collaborators to develop survey of : editors, clinical investigators, publication planners and medical writers
- Reviewed data and aligned on key themes and recommendations
- Developed standardized approach to facilitate more transparent and consistent authorship decision-making

Authorship Initiative - Case Scenarios

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

Authorship Initiative - Survey

Journal editors | **Clinical investigators** | **Publication professionals** | **Medical writers**

Confidential and blinded responses

Survey design

Quantitative - Authorship case studies*:

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

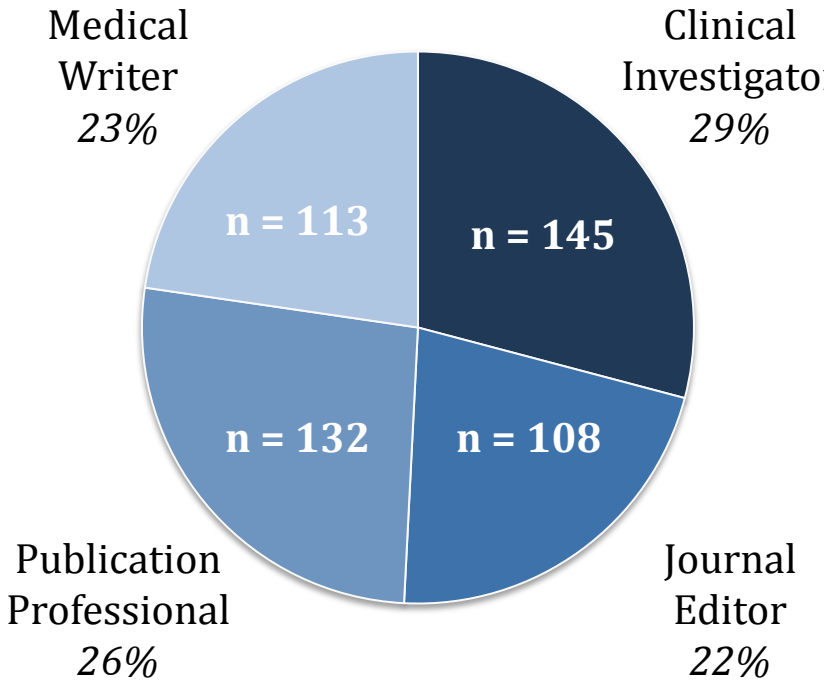
Qualitative - Authorship practices:

- 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?

**Note: Cases were presented in a random order to avoid fatigue bias*

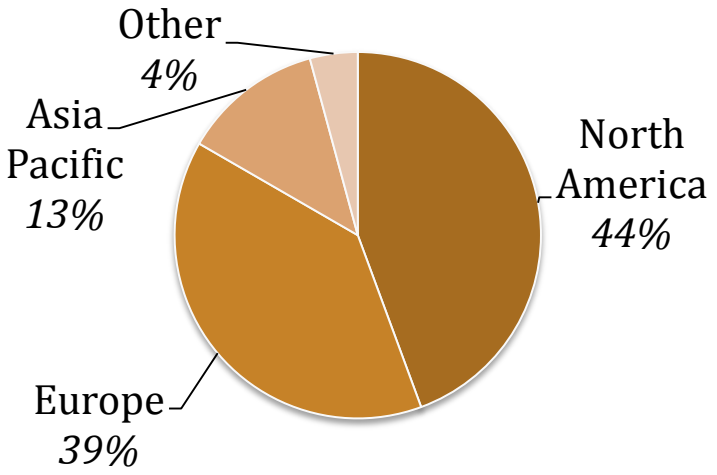
Survey Respondents were Diverse and Experienced

Professional Affiliation

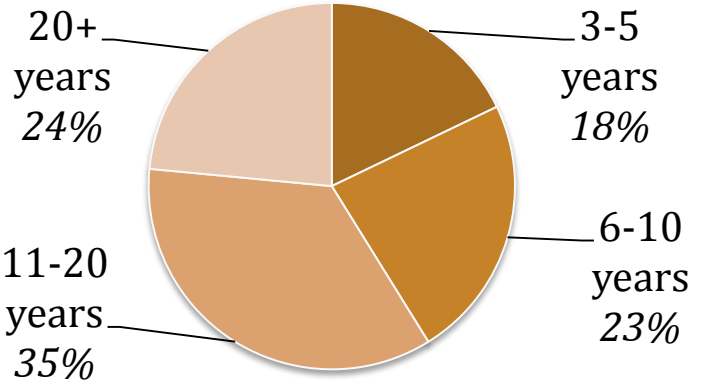


Total Respondents = 498

Geographic Distribution



Industry-Sponsored Clinical Trial Experience

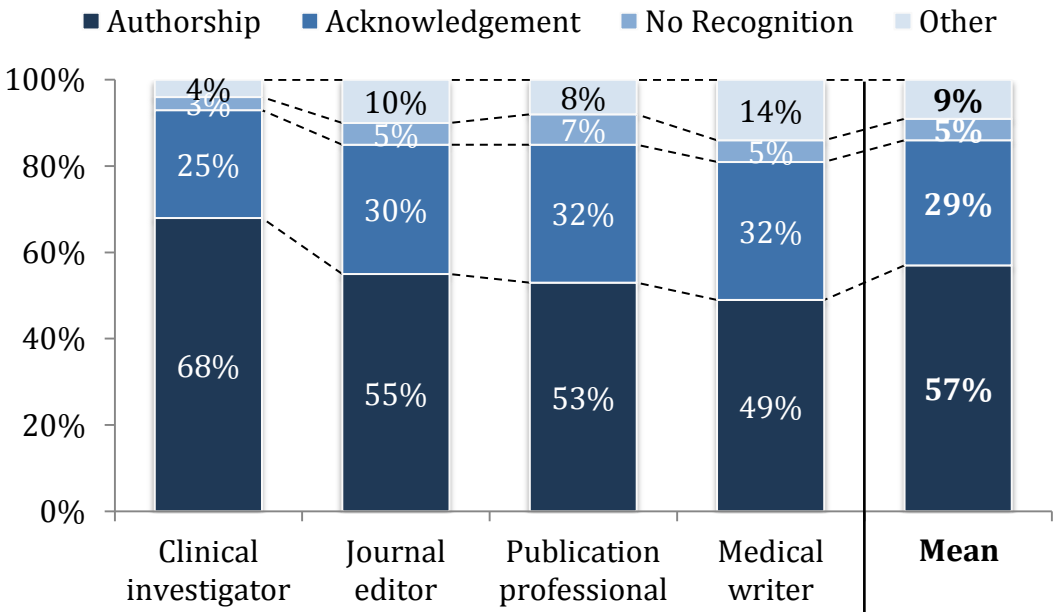


Authorship Case Scenario 1

Case #1 - Description

A clinical investigator enrolled the most patients from dozens of investigators and was involved in the day-to-day management of the trial at her institution. She feels these contributions were substantial and merit an invitation for authorship on the manuscript.

Survey Results



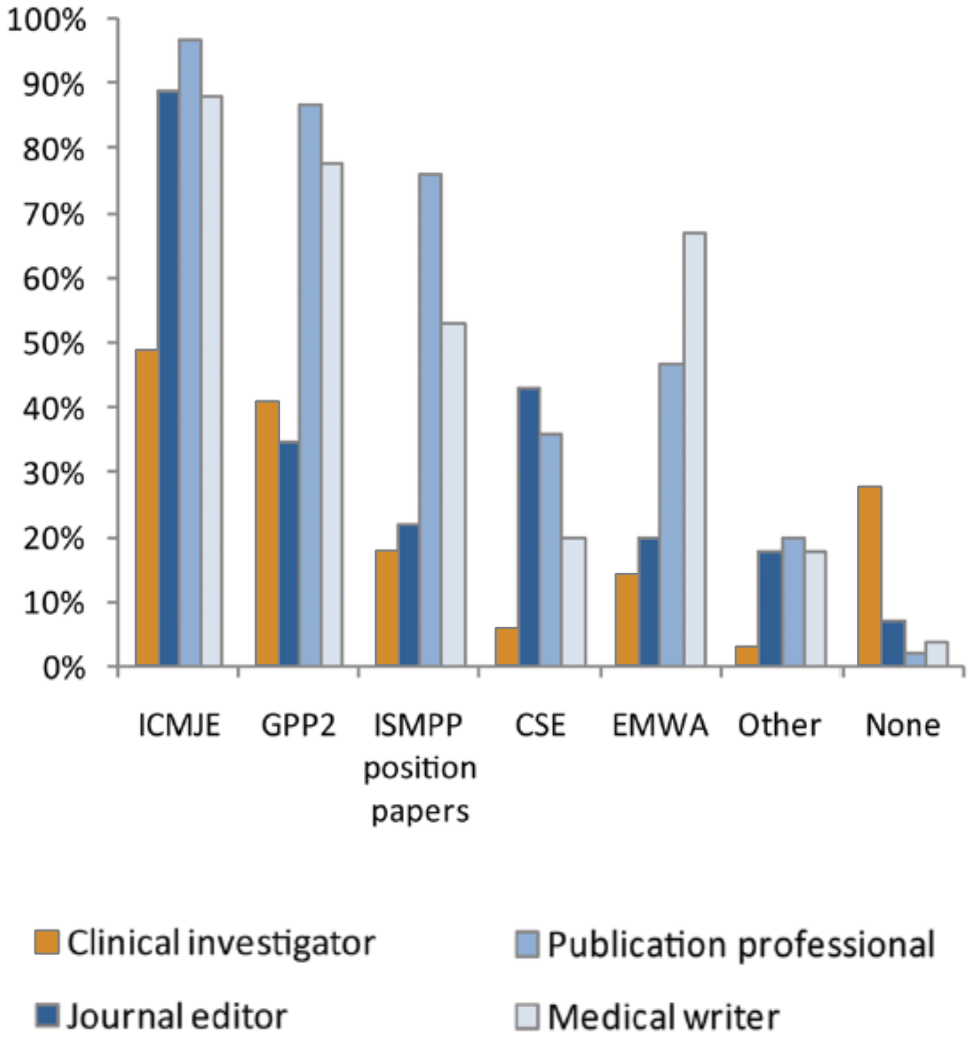
	Clinical investigator	Journal editor	Publication professional	Medical writer	**Mean**
Confidence*	1.9	2.0	1.8	2.1	**2.0**
Frequency*	2.8	2.7	2.4	3.0	**2.7**

Key Takeaways

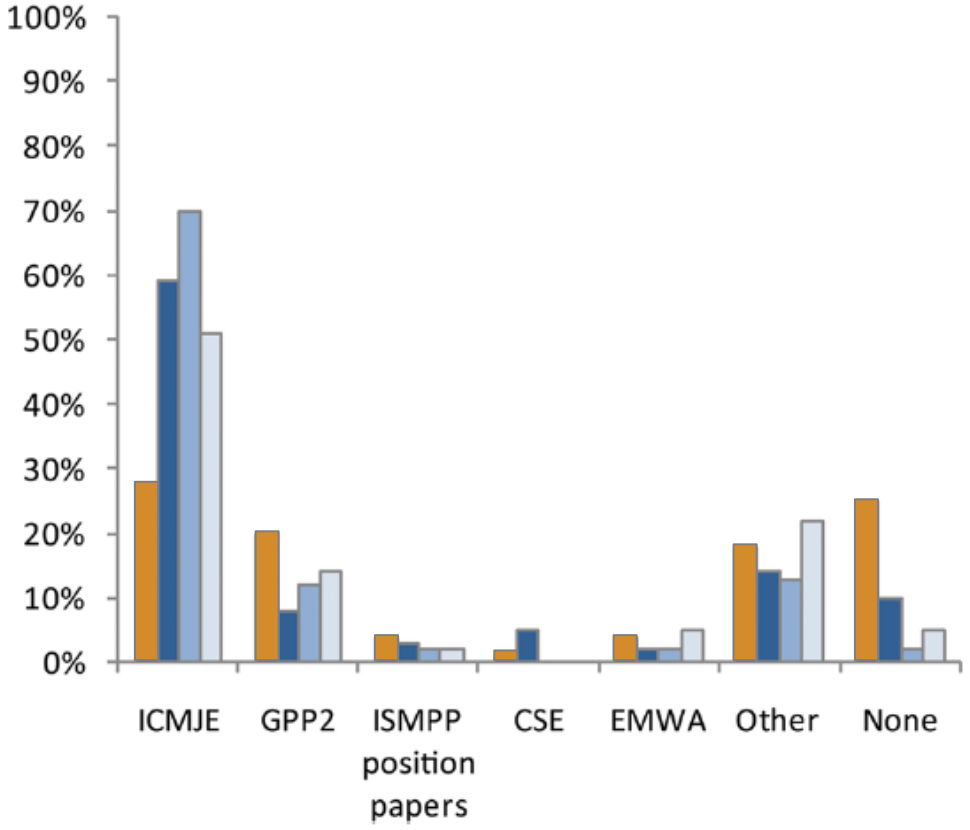
- All groups were split between opportunity for authorship or acknowledgement
- >~50% from all groups would like to offer the opportunity for authorship
- Clinical investigators tended to favor authorship more than other respondent groups

Familiarity with / Reliance on Authorship Guidelines

Familiarity with Authorship Guidelines

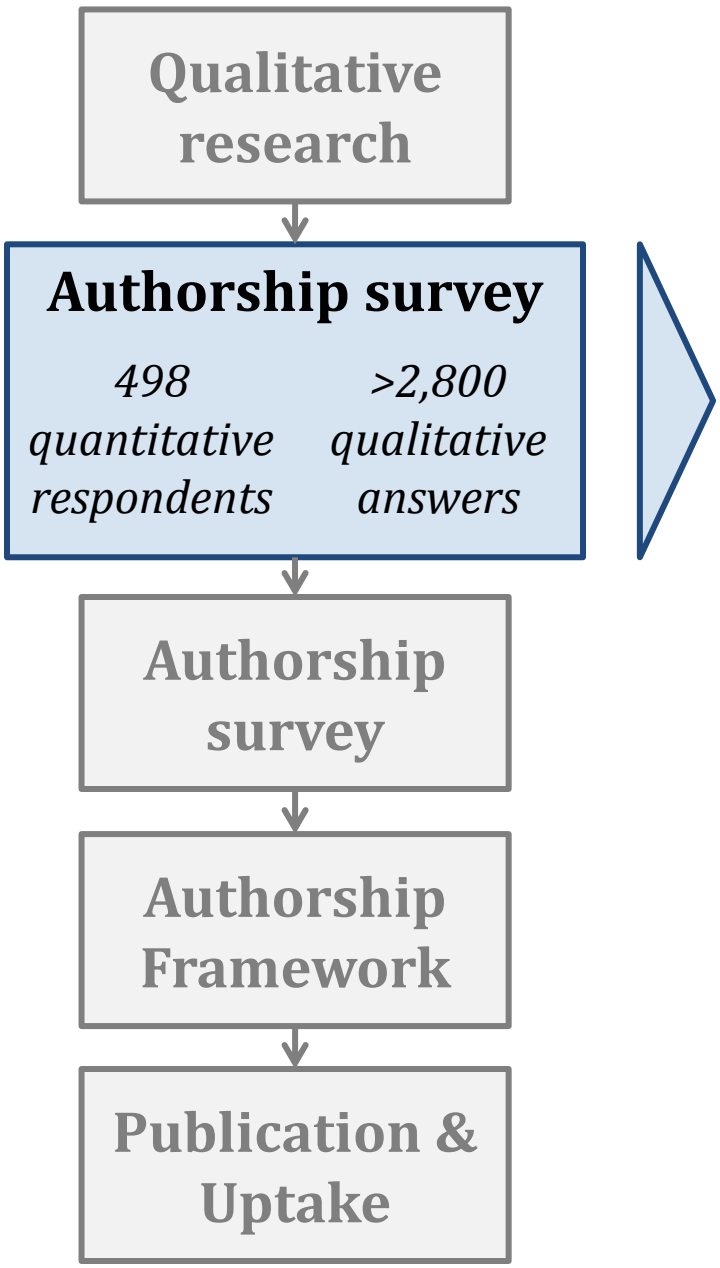


Reliance on Authorship Guidelines



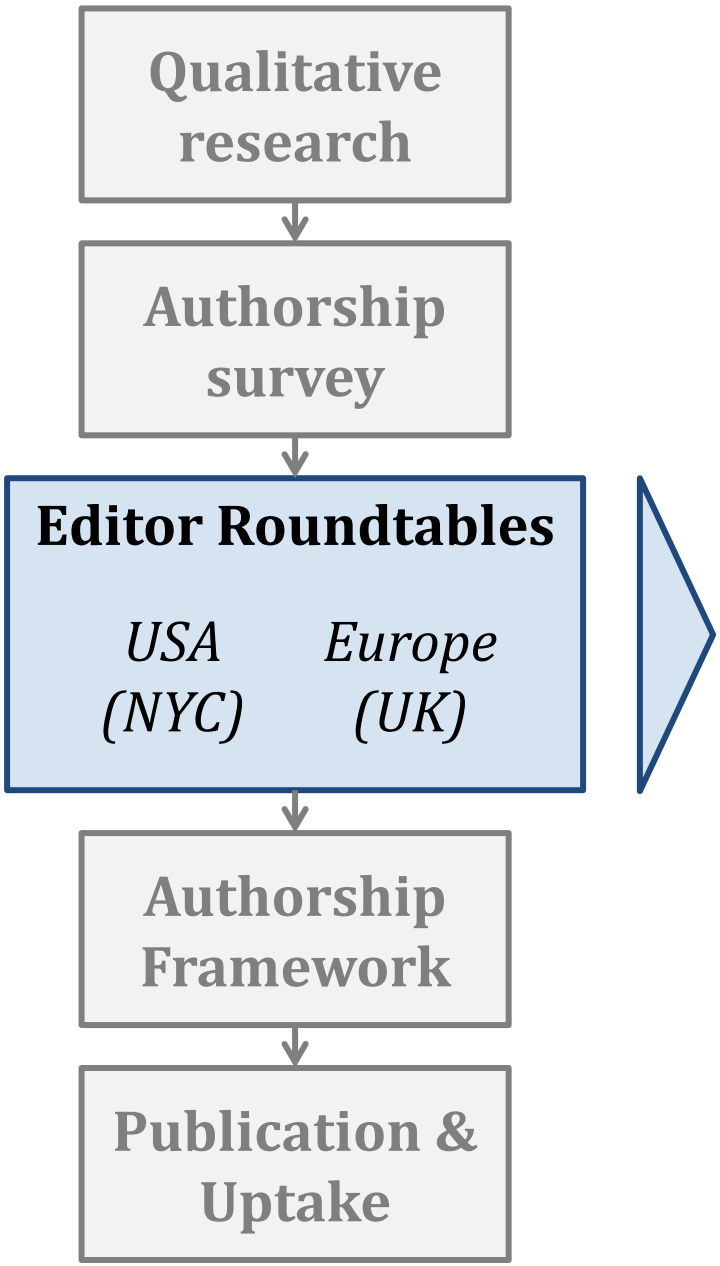
Clinical investigators had the lowest awareness of and reliance on authorship guidelines

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 Discussions about Survey Results



Summary of Editor Feedback

- **Authorship is best defined by a "unique intellectual contribution"**
- **Prospectively set authorship criteria and document all contributions**
- **Authorship changes should be approved by entire working group**
- **Educate investigators and other potential authors**

Agenda

- MPIP Background
- Authorship Research Initiative – Rationale/Approach
- Authorship Results
- **Five-step Authorship Framework**
- **Implementation Considerations**

Ananya Bhattacharya, BMS

Five-step Authorship Framework

Step	Task
1	Establish an authorship working group of core trial contributors as close as possible to trial commencement
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
5	Ensure invited authors meet remaining ICMJE authorship criteria

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

Five-step Authorship Framework - Step 2

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 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

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

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

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

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

Detailed information about the Five-step Framework can be found at: www.mpip-initiative.org

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?	• 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?	• 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?	• 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?	• 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?	• 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?	• 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?	• 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

Detailed information about the Authorship Research Project can be found at: www.mpip-initiative.org

Case Study – Patient Recruitment

Editor Feedback to Case 1
Recruiting alone should not qualify as a substantial contribution unless clear intellectual insight is involved

Step 1 Form authorship working group	• Working group determines for this particular trial if patient recruitment and site management meet the criteria for substantial contribution • Criteria agreed to by all trial contributors
Step 2 Define substantial contributions	
Step 3 Track & document contributions	• Document role in recruitment and other intellectual contributions
Step 4 Invite authors	• Trial contributors who meet predefined criteria are invited to serve as authors
Step 5 Meet remaining ICMJE criteria	• Invited authors meet remaining authorship criteria to serve as an author on the manuscript

Next Steps

MPIP	• Continue to build awareness with key stakeholders in authorship process • Collaborations with additional organizations to drive outreach and education • Implementation of key process in MPIP Steering Committee member companies' best practice
Industry	• Share and discuss findings from the Five-step Authorship Framework publication within your organization • Consider implementation of framework to improve transparency in disclosing contributors • Consult MPIP or our website for further guidance

Call to Action

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

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

Questions

To ask a question, please type your query into the ‘Q&A’ chat box at the bottom left of your screen.

Every attempt will be made to answer all questions.

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
- Bryce McMurray, Dave Dustin, and Adrian Beasley - Springer Healthcare

QUESTIONS.....

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UPCOMING ISMPP U

- Wednesday, March 25, 2015
  - Topic: Patient registries in publication planning: opportunities and planning
  - Faculty: Nick Combates, Celgene, and Scott Newcomer, Shire
  - Moderator: Gary Burd

THANK YOU FOR ATTENDING!

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