



Building Trust in Industry-Sponsored Research

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- Maureen Garrity is an employee of Astellas, a sponsor-company of MPIP
- The views and opinions presented here during discussion are her own and may not represent those of her employer

MPIP Vision

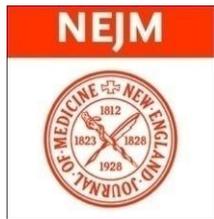
To develop a culture of **mutual respect, understanding, and trust** between journals and pharma that will support more **transparent and effective** dissemination of results from industry-sponsored trials



MPIP activities supported by Leerink Swann LLC

Introduction

MPIP participants to date



THE LANCET



Annals of Internal Medicine



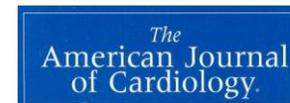
Clinical Therapeutics



JOURNAL OF CLINICAL ONCOLOGY



THE JOURNAL OF CLINICAL PSYCHIATRY



CMAJ



PHARMACOTHERAPY

The Journal of Infectious Diseases

Journal of Opioid Management

Clinical Cancer Research



Introduction

Highlights of MPIP accomplishments since 2008

Raising Standards

- Journal-pharma roundtable reached consensus on “Ten Recommendations” to close the credibility gap in industry-sponsored research, published in *Mayo Clinic Proceedings**
- Collaborated with journals on publication to raise standards and streamline publication process**



Driving Best Practices

- Developed *Authors' Submission Toolkit* collaboratively with editors and publishers
- Published in *Current Medical Research and Opinion****, and downloaded >30,000 times



Engaging Key Stakeholders

- Executed research project to understand challenges to determining authorship for industry-sponsored clinical trials
- Awarded 2010 Communiqué Trust and Reputation Award
- Presented at CSE, ISMPP, and other forums



* Mansi B, et al. *Mayo Clinic Proceedings* 2012; 87(5):424-429

** Clark J, et al. *International Journal of Clinical Practice* 2010; 64(8): 1028-33. Page 5

***Chipperfield L, et al. *Current Medical Research and Opinion* 2010; 26: 8, 1967-82.

MPIP is using insights to drive joint activities with editors



- Surveyed editors
- Convened workshop with editors and industry co-sponsors
- Brainstormed and prioritized ways to close the “credibility gap” for industry-sponsored trials

- Assembled editors and industry co-sponsors to draft whitepaper
- Peer-reviewed article published by *Mayo Clinic Proceedings* in May 2012*

- Aligned on authorship as key area for focus of joint activities
- Worked with editors and other stakeholders to develop and implement activities

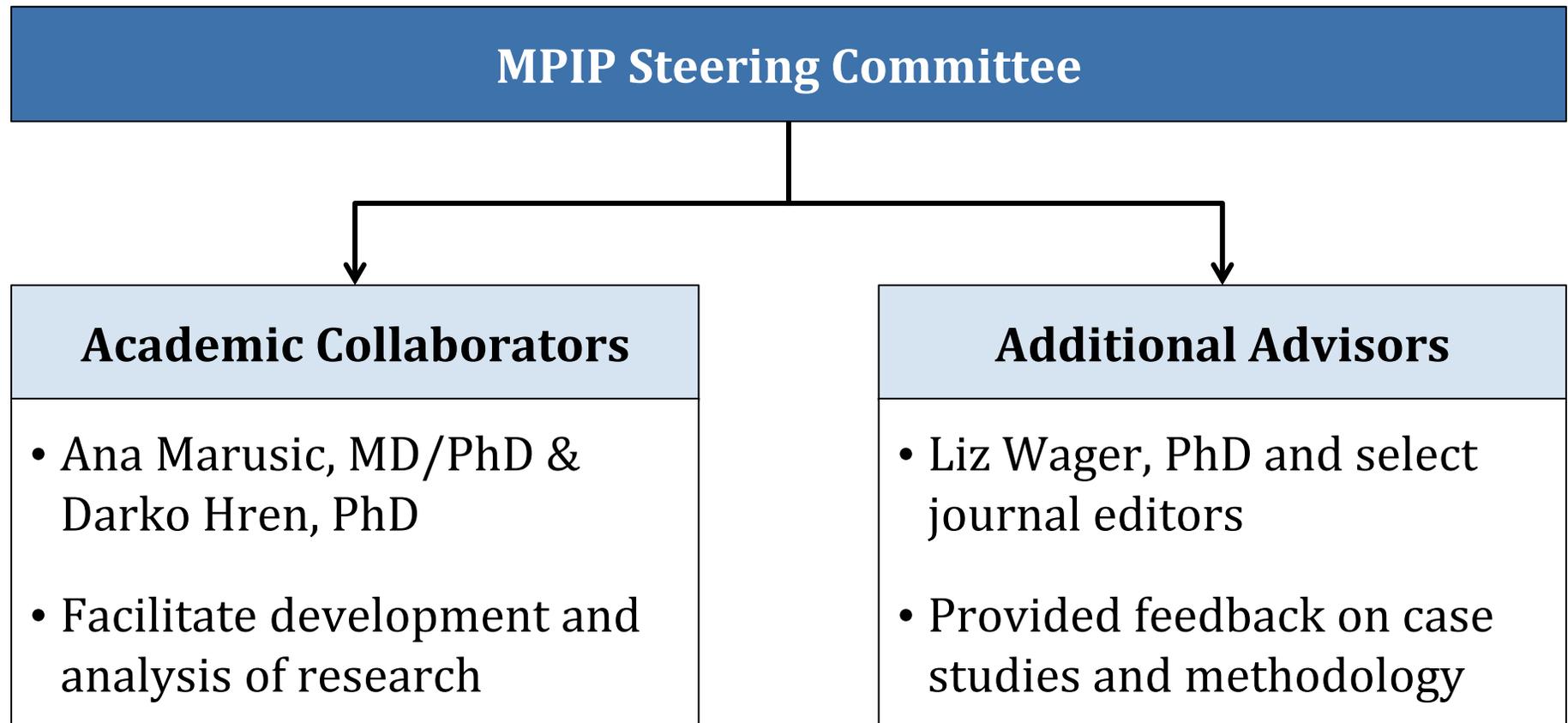
MPIP developed a 3-part approach for its authorship activities

Goals for MPIP's Authorship Activities

- Clarify definitions of authorship that resolve challenging ambiguities for industry-sponsored trial publications
- Inform development and distribution of harmonized definitions / criteria
- Continue to promote further transparency among stakeholders for industry-sponsored clinical trial publications



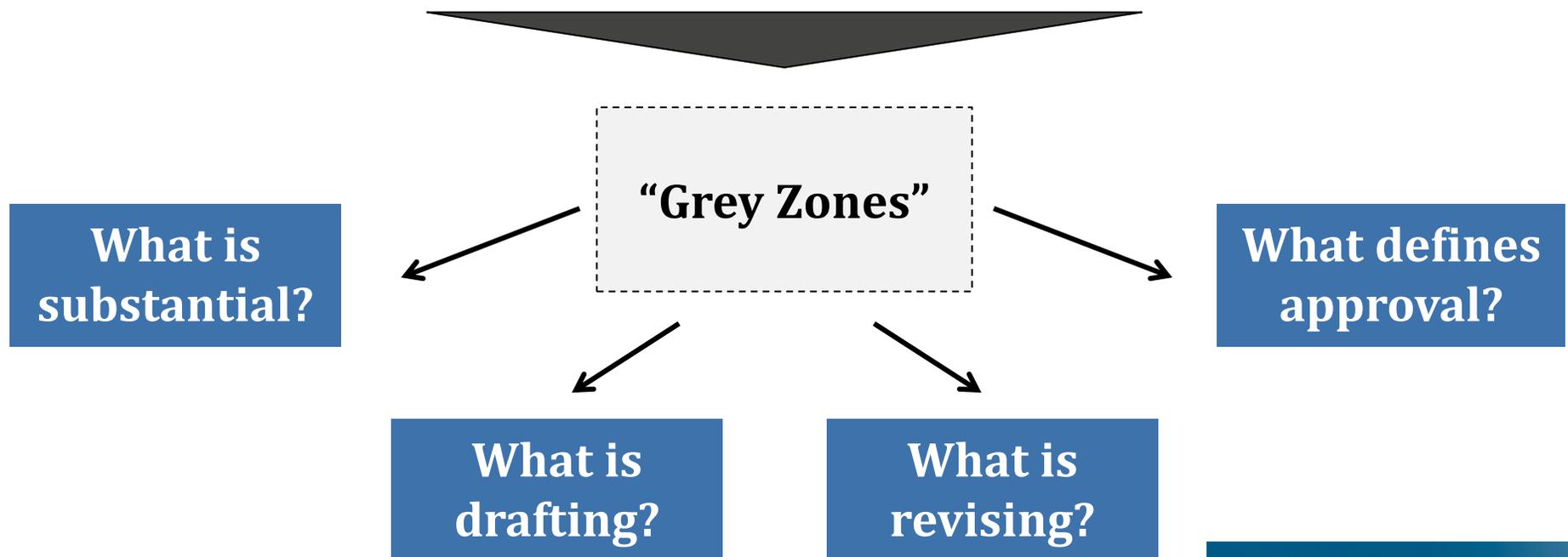
MPIP formed an external research team to execute this plan



Initial qualitative research uncovered multiple “Grey Zones” with current authorship guidelines

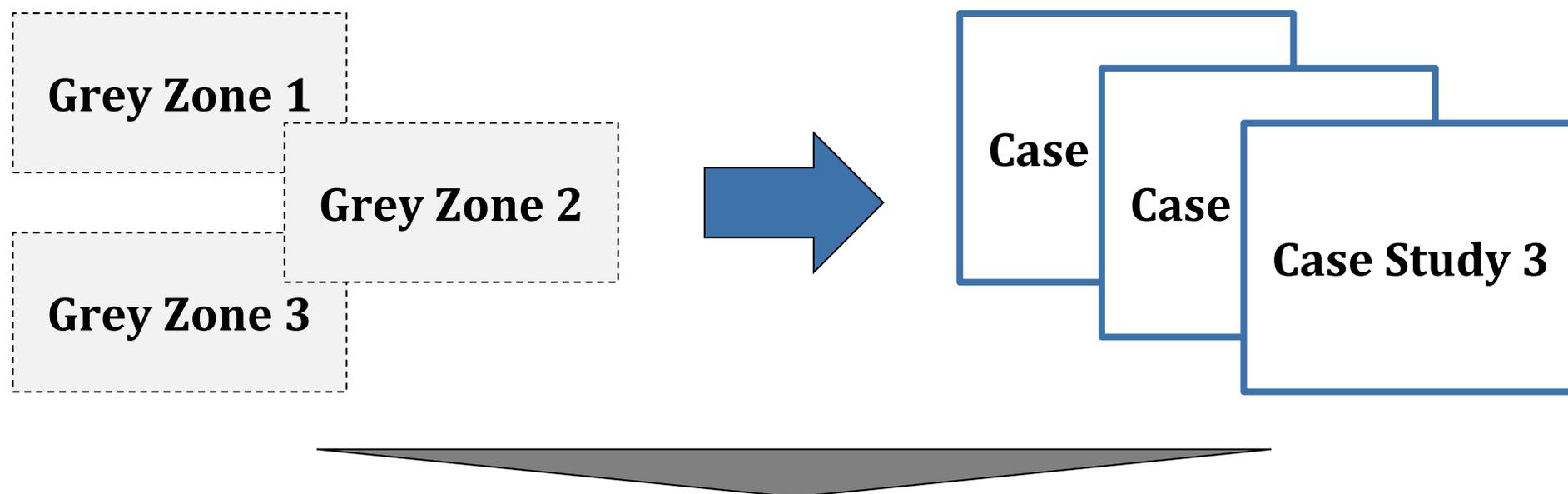
ICMJE guidelines state authorship credit should be based on:

1. *Substantial contributions to 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*



Authorship

MPIP and its collaborators created a case-based survey to further test these “Grey Zones”



- Is there agreement on who should be an author for these scenarios within and across stakeholders?
- How often are these scenarios likely to occur?
- What rules / guidelines do key stakeholders use to adjudicate authorship?

Authorship survey overview

Journal
Editors

Clinical
Investigators

Publication
Planners

Medical
Writers

Confidential and blinded responses

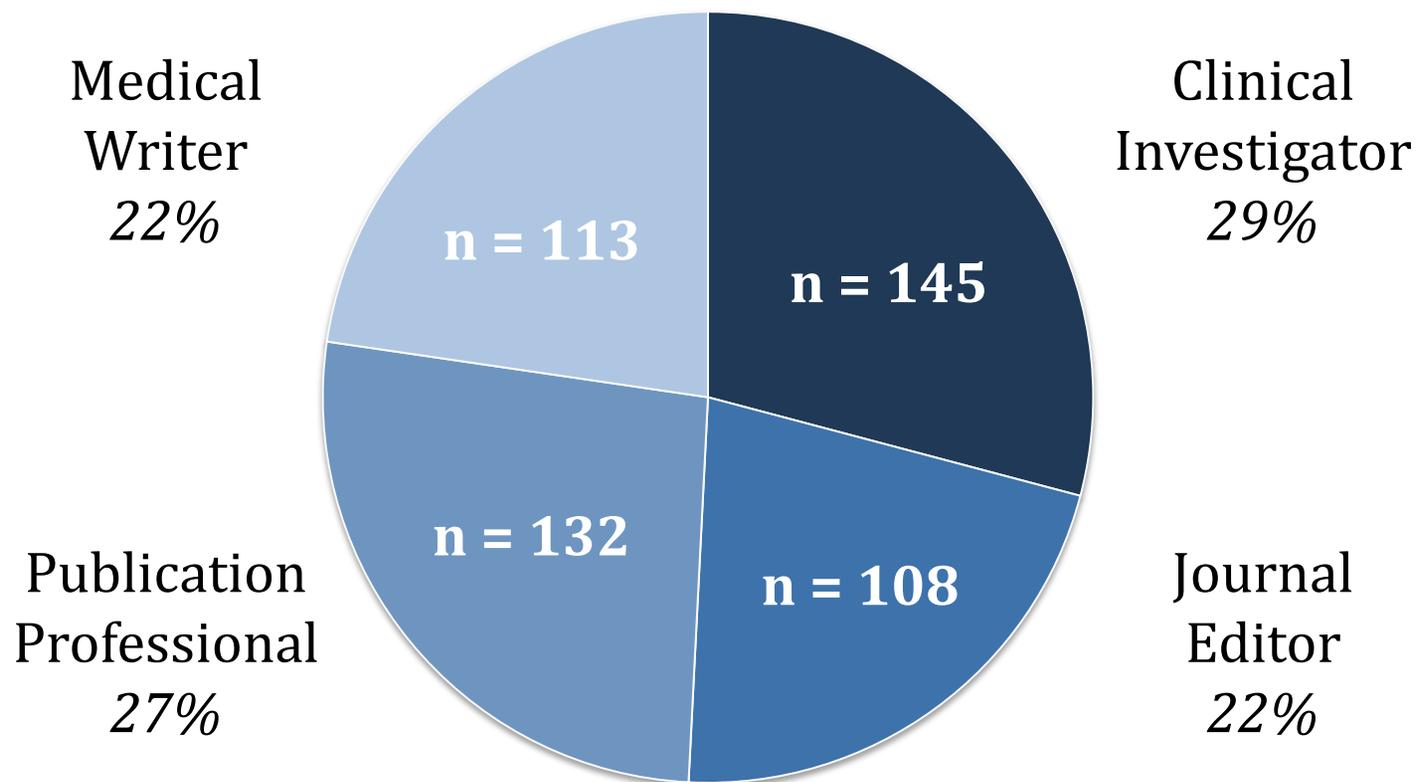
Survey design

- **“Grey Zone” 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?
- **Current 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 demographics (1)

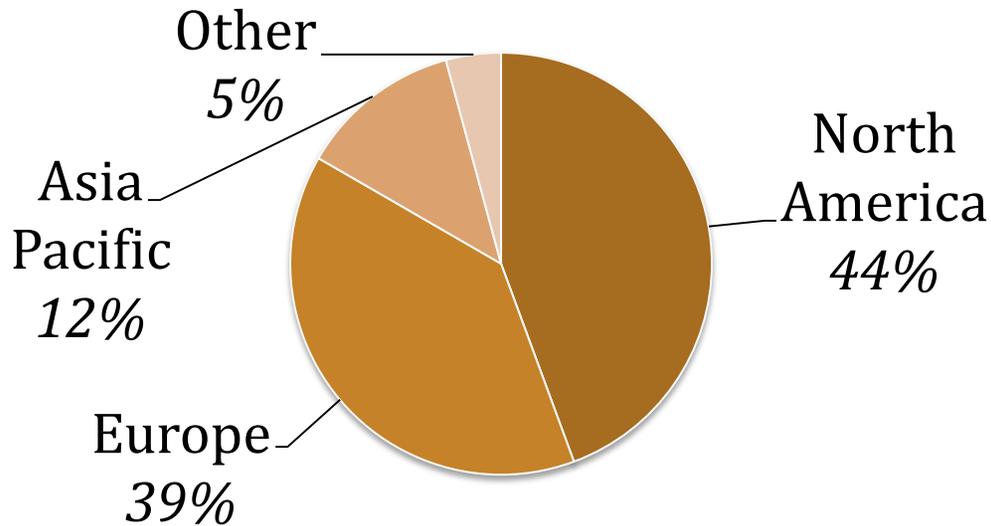
Professional Affiliation



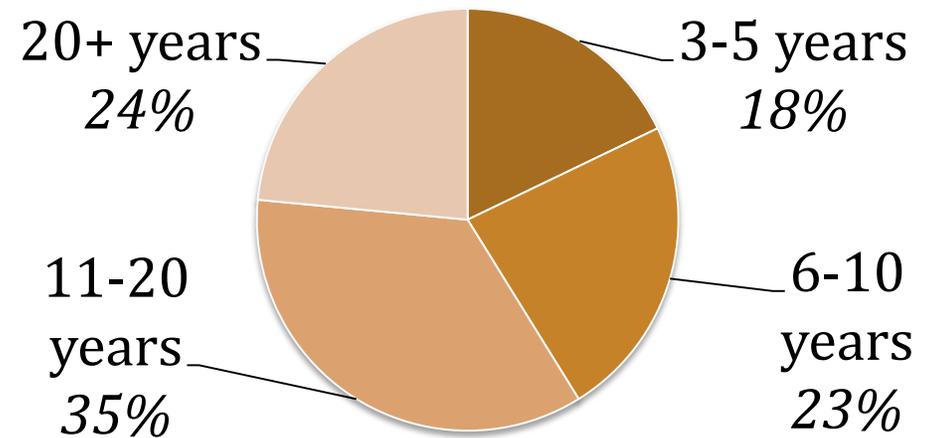
Total Respondents = 498

Survey demographics (2)

Geographic Distribution



Industry-Sponsored Clinical Trial Experience



Authorship

Roundtable discussions about the survey results with journal editors provided valuable feedback

1

Prospectively set authorship criteria

- Set authorship criteria early in the trial, ensure all understand the responsibilities of authorship, and document agreement

2

Systematically document contributions

- Document relevant contributions from trial participants in a consistent and transparent way

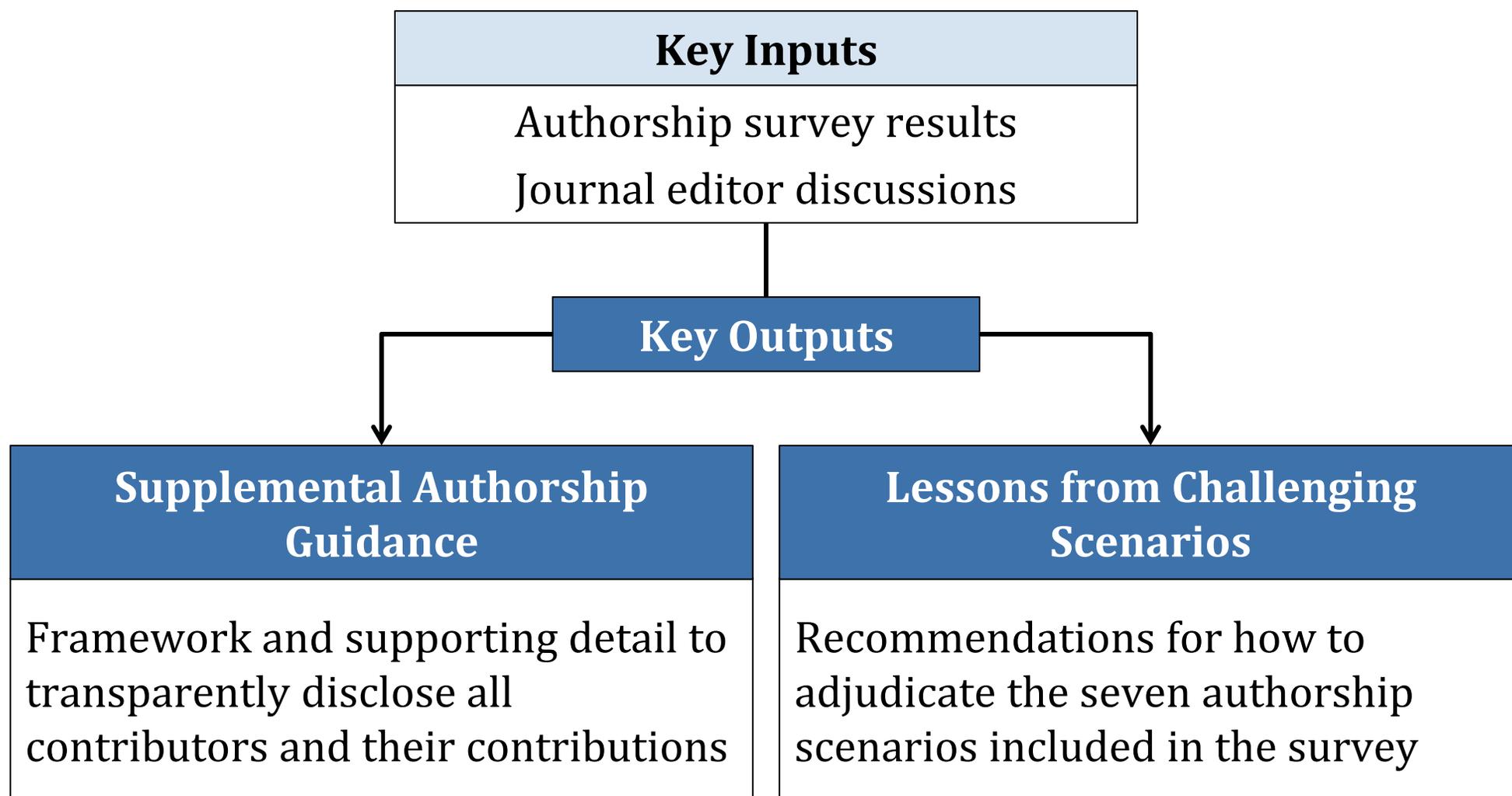
3

Authorship changes approved by entire group

- Any changes to byline must be discussed and agreed to by entire author list on publication

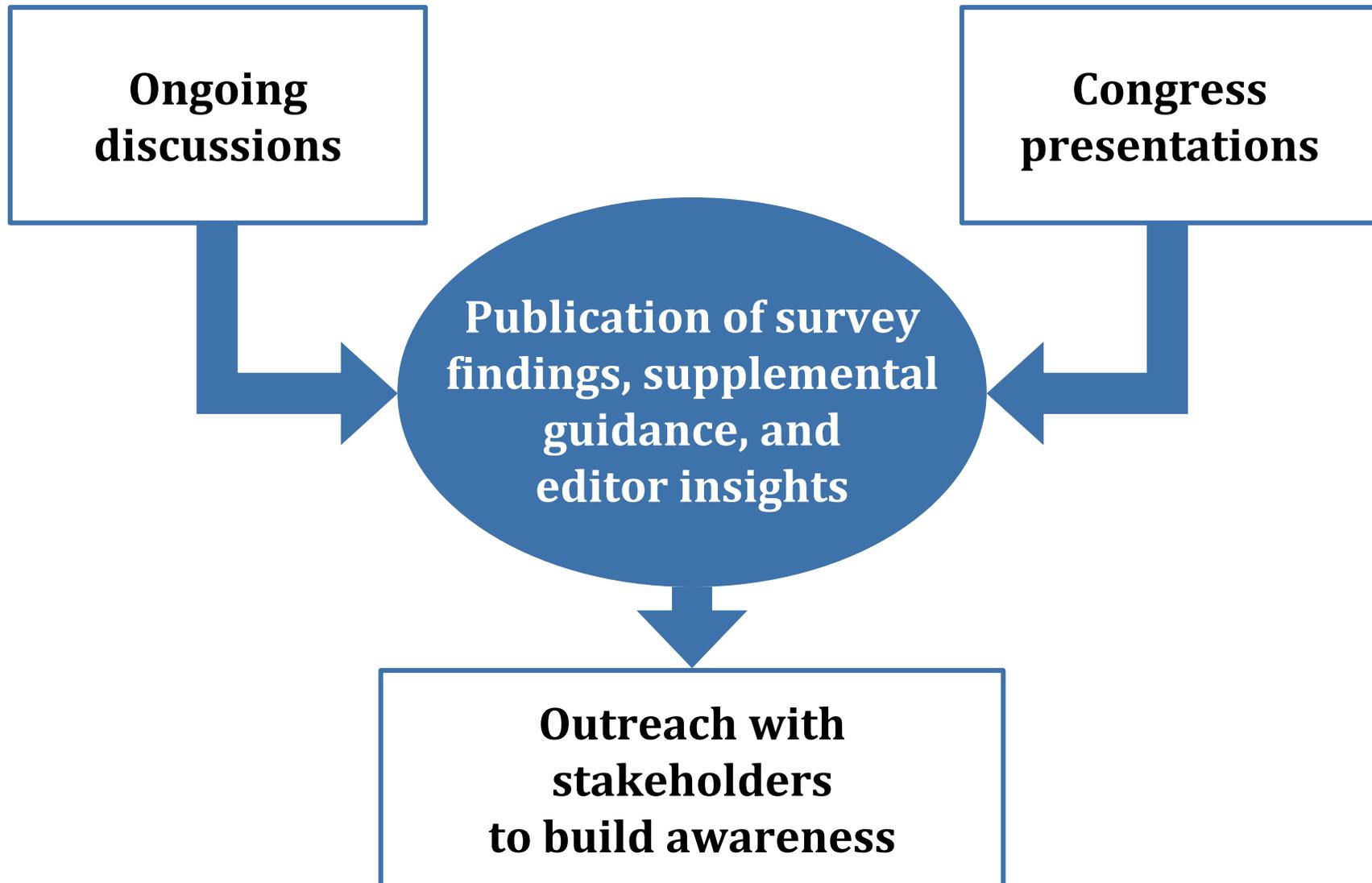
Authorship

MPIP worked with journal editors to develop outputs to supplement current authorship guidance



Authorship

For the rest of 2013, MPIP will broaden its outreach to refine and disseminate outputs from the Authorship project



Thank You

Appendix

“Ten Recommendations for Closing the Credibility Gap”

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 definitively end ghost writing 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

Criteria to define survey respondents

Journal Editors

- Indexed on NIH's Abridged Index Medicus list of clinical journals or a top 30 journal by ISI or Page Rank
- Listed on masthead of respective journal as editor-in-chief, associate editor, deputy editor, scientific editor, or positions of similar influence

Clinical Investigators

- Participation in industry-sponsored clinical trials, phase I or above (from Adis database collaboration)

Publication Planners

- Membership in ISMPP

Medical Writers

- Membership in AMWA/EMWA