The Medical Publishing Insights and Practices (MPIP) Initiative

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MPIP MEDICAL PUBLISHING INSIGHTS AND PRACTICES INITIATIVE

www.mpip-initiative.org

Disclosure

- Teresa Peña is an employee of AstraZeneca, 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

MPIP participants to date

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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 >26,000 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.*
****Chipperfield L, et al. Current Medical Research and Opinion 2010; 26: 8, 1967-82.*

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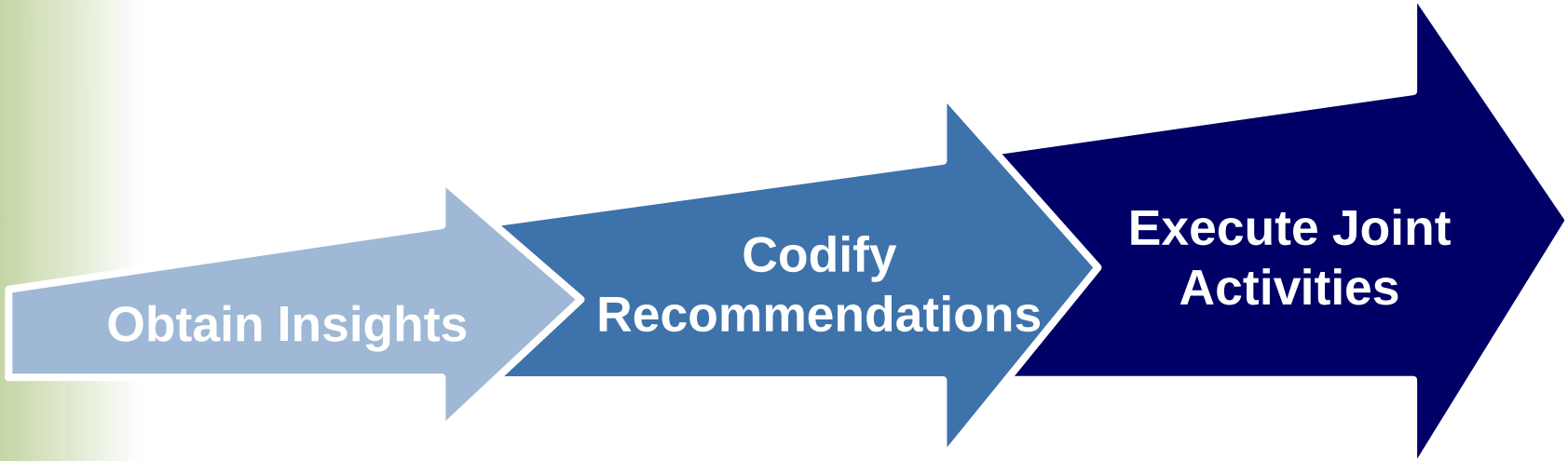
MPIP uses insights to drive joint activities with editors



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

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

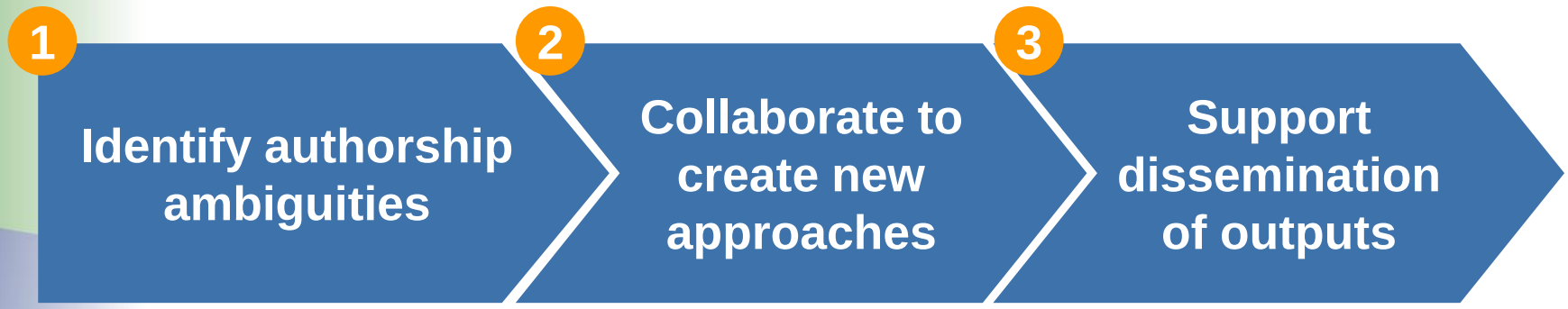
- Aligned on authorship as key area for focus of joint activities
- Worked with editors and other stakeholders to develop and implement activities

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

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 of harmonized definitions / criteria
- Continue to promote further transparency among stakeholders for industry-sponsored clinical trial publications



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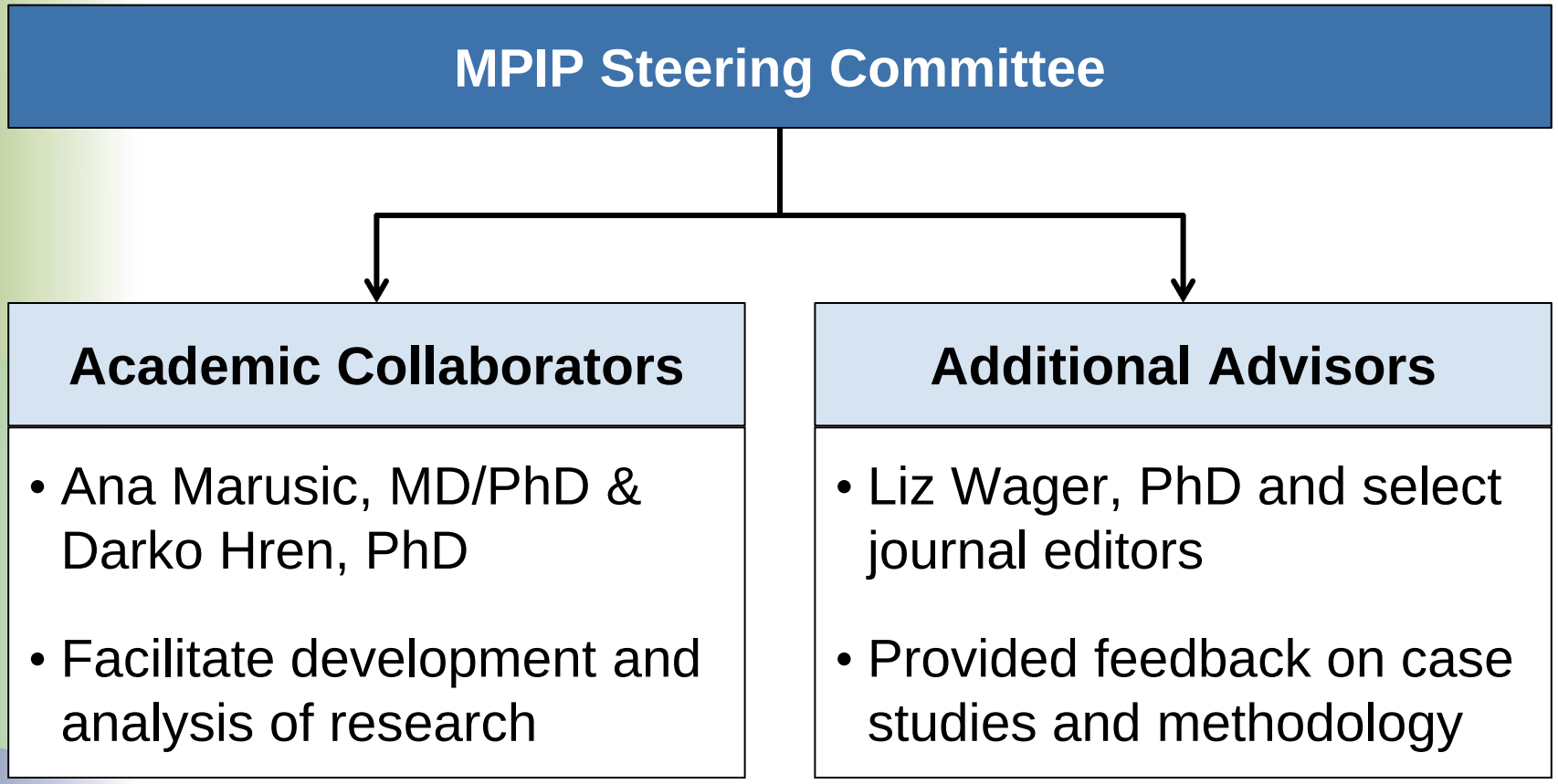
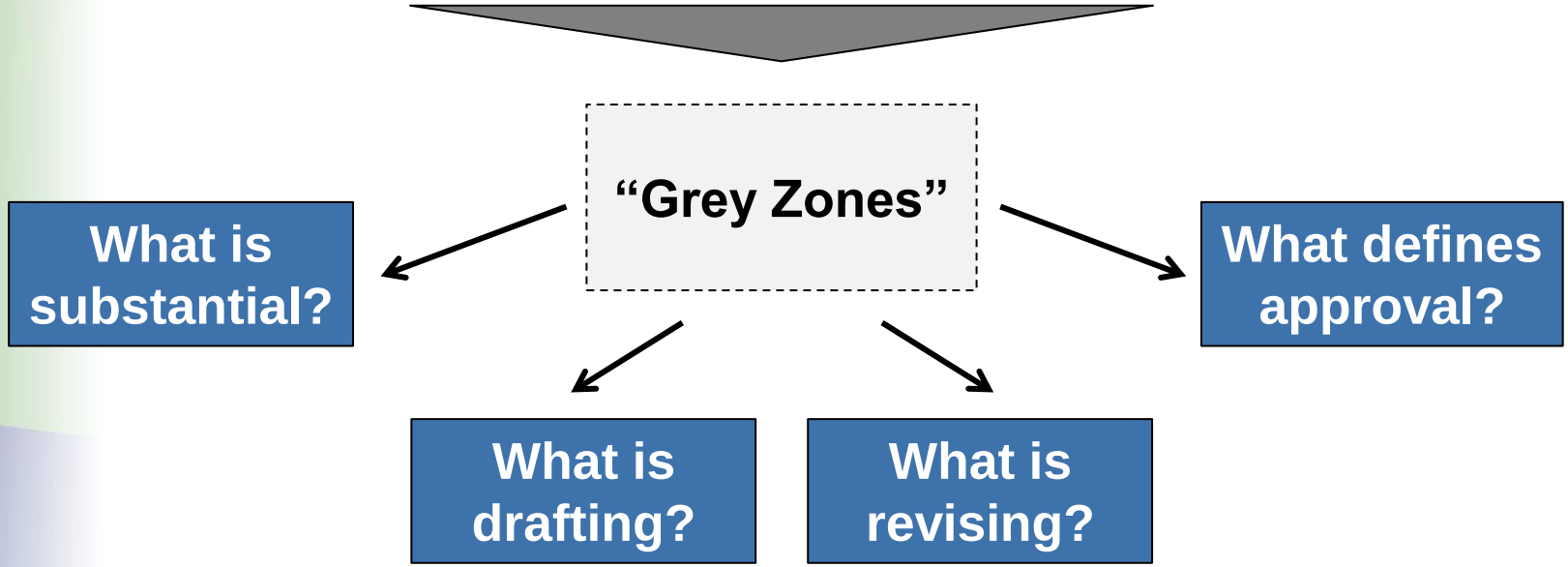
MPIP formed an external research team to execute this plan



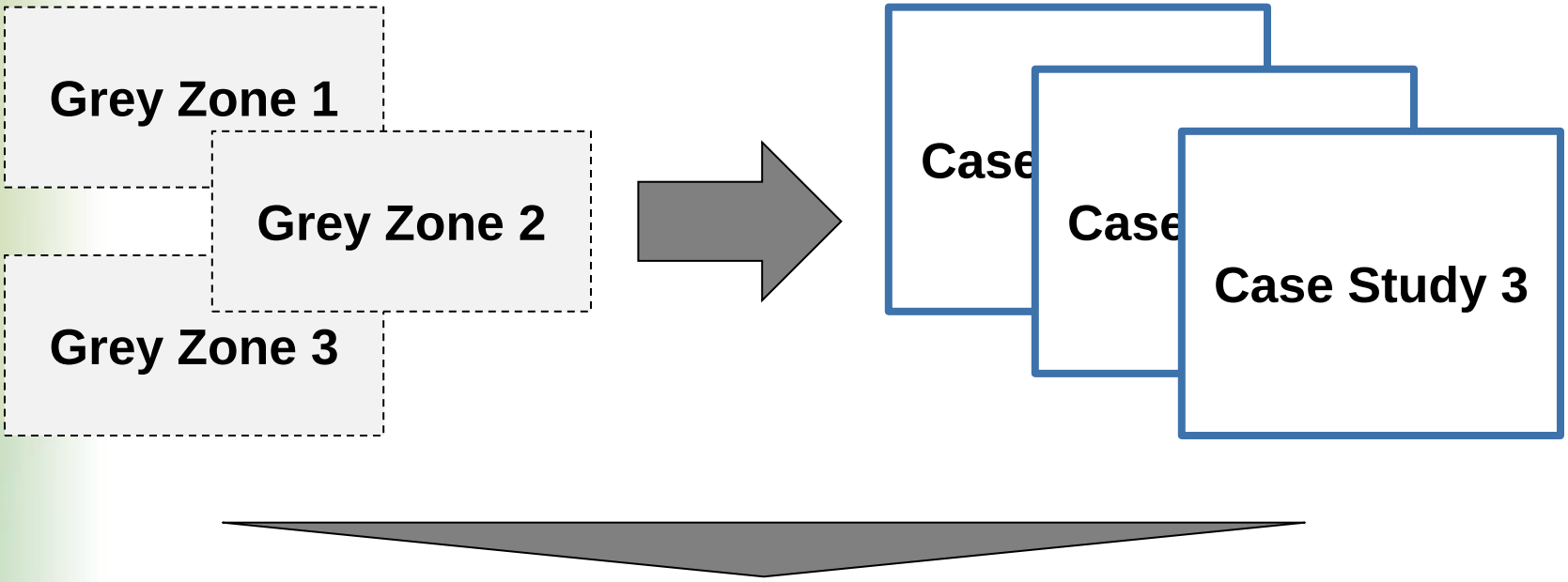
Initial qualitative research uncovered multiple "Grey Zones" with current authorship guidelines

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*



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?
- What rules / guidelines do key stakeholders use to adjudicate authorship?

Audience Question #1

A clinical investigator for a multi-center trial enrolled the most patients from dozens of investigators but did not contribute to trial design or data analysis/interpretation.

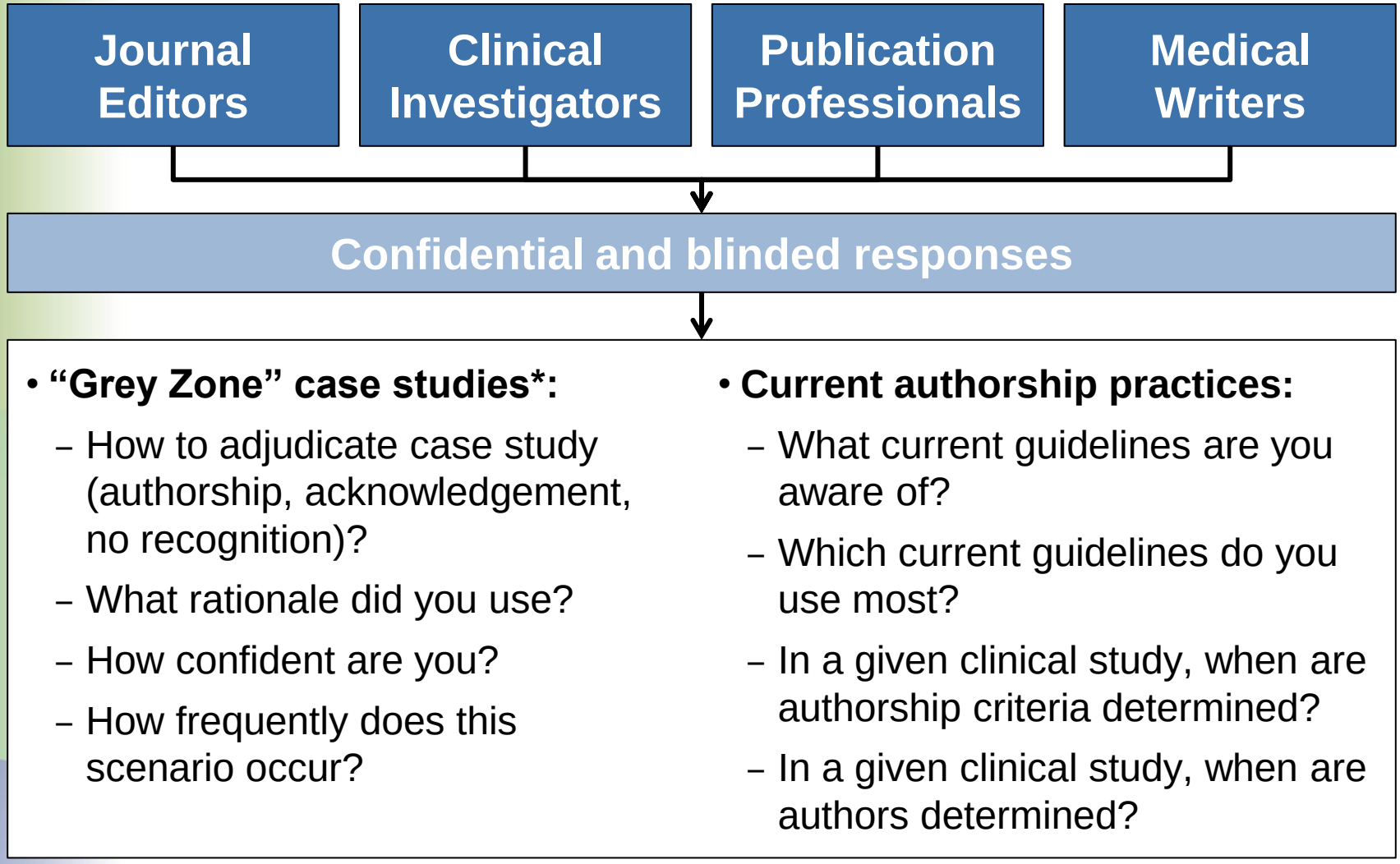
What is the most appropriate way to recognize the contribution of this clinical investigator?

a. I would invite the investigator to help draft the manuscript as an author listed on the byline

b. I would list the investigator's contribution in the acknowledgement section

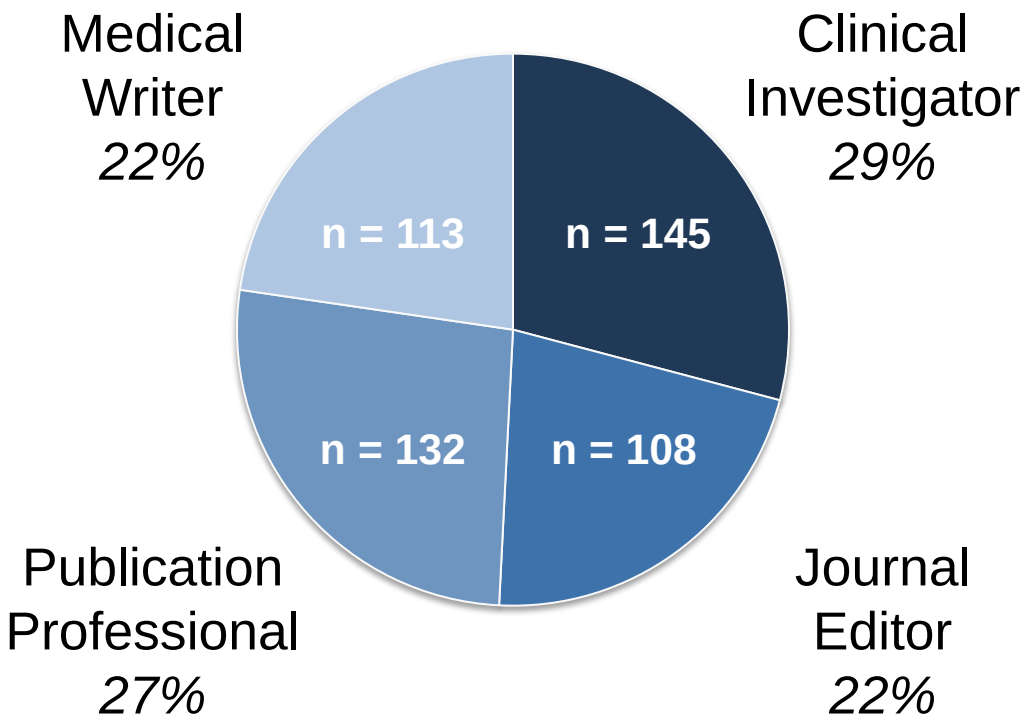
c. I would not invite the investigator to be an author nor recognize the investigator in the manuscript

Authorship survey overview



Survey demographics (1)

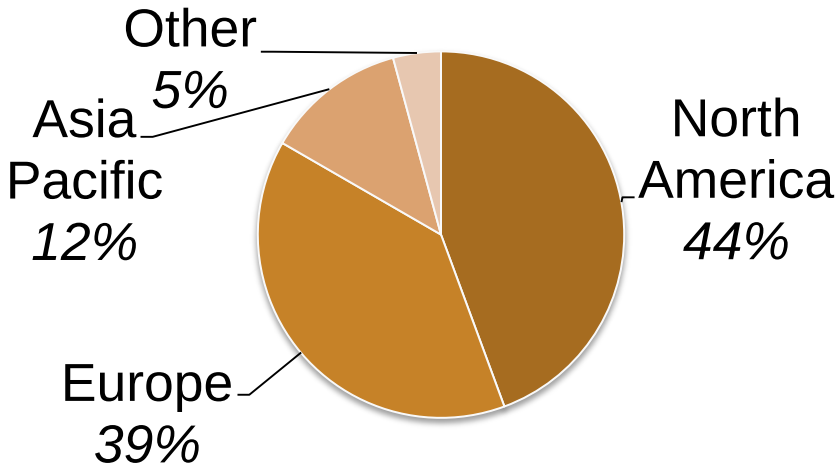
Professional Affiliation



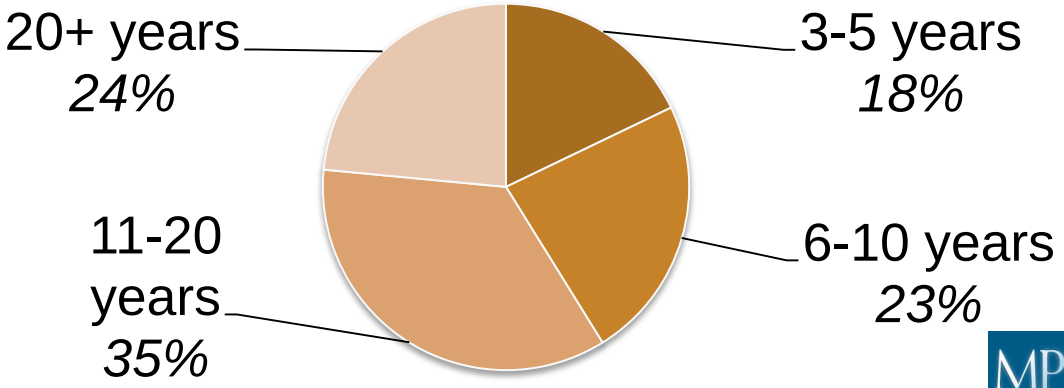
Total Respondents = 498

Survey demographics (2)

Geographic Distribution



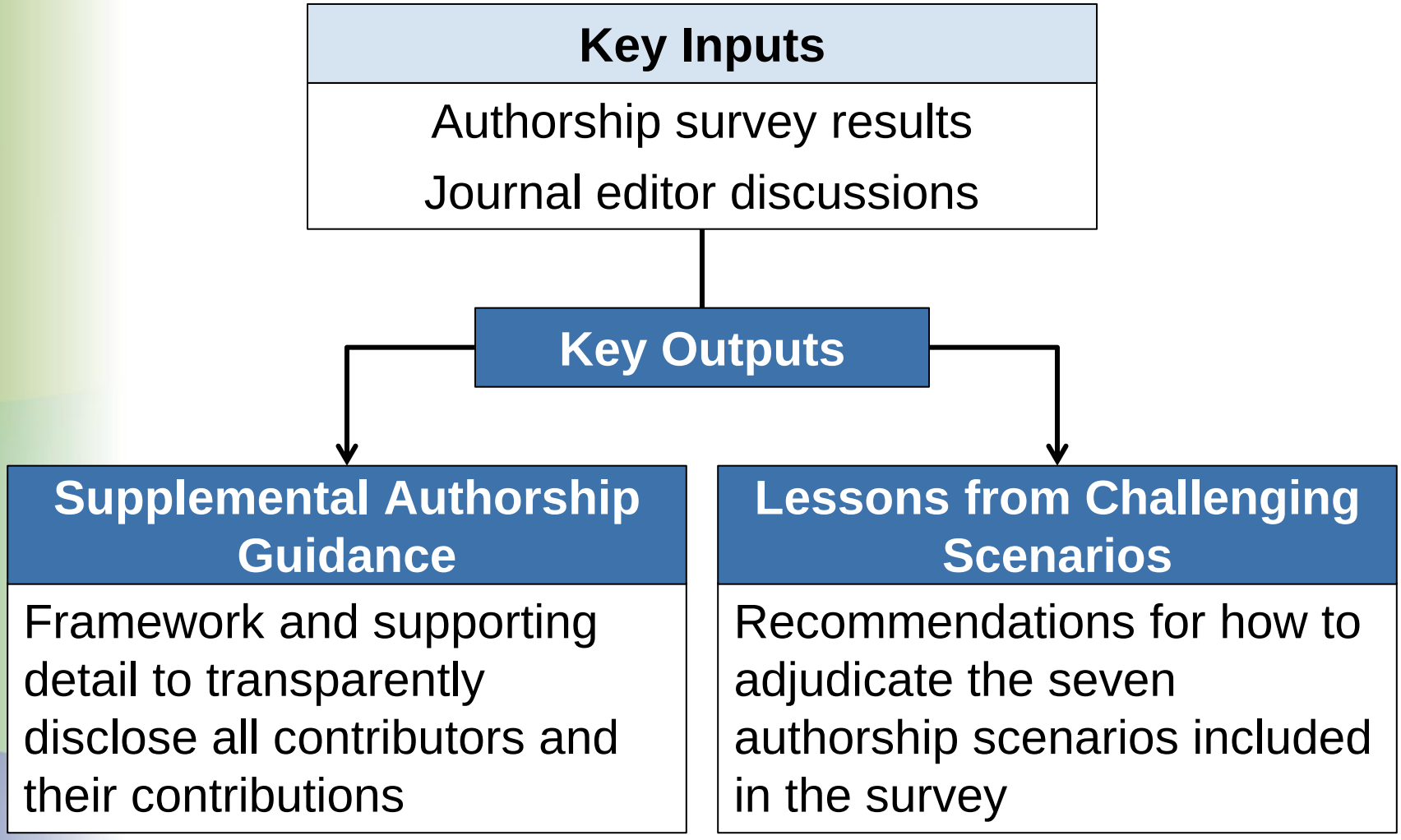
Industry-Sponsored Clinical Trial Experience



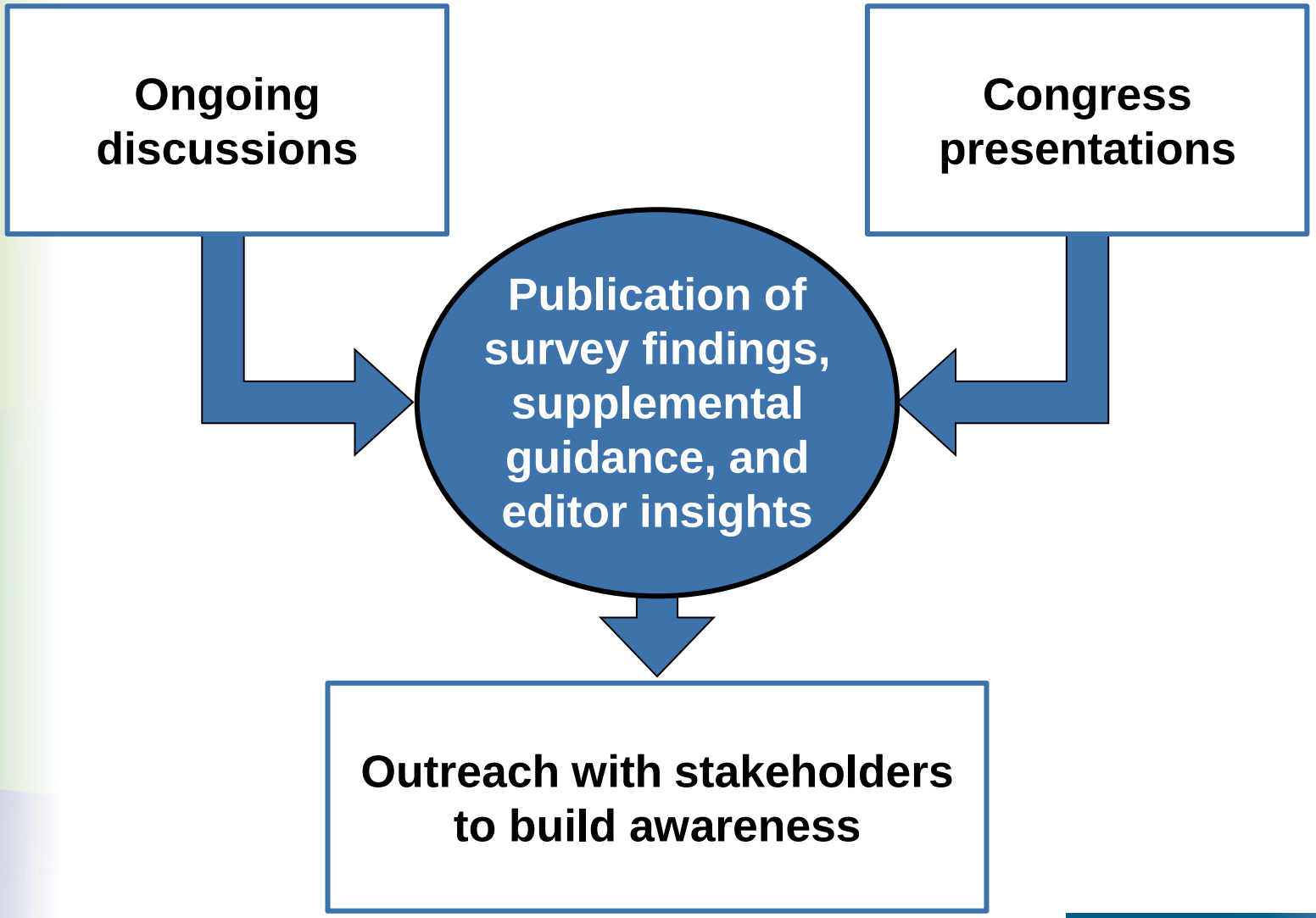
Roundtable discussions about the survey results with journal editors provided valuable feedback

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

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



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



Audience Question #2

What activity from the "Ten Recommendations" list would you like to see MPIP focus on next?

a. Further work in authorship in other regions (e.g., Asia)

b. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy

c. Educate authors on how to develop quality manuscripts and meet journal expectations

d. Report adverse event data more transparently and in a more clinically meaningful manner

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 or a top 30 journal by ISI or Page Rank • Serves in an editorial capacity
Clinical Investigators	• Participation in industry-sponsored clinical trials, phase I or above (from Adis database collaboration)
Publication Professionals	• Membership in ISMPP
Medical Writers	• Membership in AMWA/EMWA