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# The Medical Publishing Insights and Practices Initiative (MPIP) Publishes "Five-step Authorship Framework" to Improve Transparency in Disclosing Contributors to Industry-Sponsored Trial Publications

New tool creates more standardized approach when determining authorship -

BOSTON, October 24, 2014 -- The Medical Publishing Insights and Practices Initiative (MPIP), in collaboration with academic researchers, conducted a novel qualitative attitude study to identify approaches for determining authorship for clinical trial publications. Results from the study, which included clinical investigators, journal editors, publication professionals and medical writers, led to the development of a novel tool designed to create a more standardized and transparent approach when determining authorship. The *Five-step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-sponsored Clinical Trial Publications* was published today in *BMC Medicine*.

Improving disclosure of authorship contributions and writing assistance was identified as one of ten recommendations to close the credibility gap in reporting industry-sponsored research in an industry-journal roundtable sponsored by MPIP<sup>1</sup>. MPIP is a collaboration among pharmaceutical companies and the International Society for Medical Publication Professionals (ISMPP) to elevate trust, transparency, and integrity in publishing industry-sponsored studies.

Following a survey of four respondent groups involved in the publication of clinical trial results and further exploration of the issue, it was found that low awareness, variable interpretation, and inconsistent application of authorship guidelines can lead to confusion and lack of transparency when recognizing those who merit authorship. The *Five-step Authorship Framework* provides a structured approach to facilitate decision making and improve transparency when recognizing authors from clinical trial publications, including: identifying a representative group to establish authorship criteria early in the trial, having all trial contributors agree to these criteria, documenting trial contributions, objectively determining who warrants an invitation to participate in the manuscript development process, and ensuring authors meet remaining authorship criteria.

"As clinical trials continue to evolve in complexity, it is increasingly important for the designation of authorship for published research to be represented by those who provide significant intellectual contribution to its development and execution. This is critical to ensure credit for the research, and more so, accountability and responsibility for accuracy and integrity of the work," said Prof. Ana Marušić, MD, PhD, Department of Research in Biomedicine and Health, University of Split School of Medicine, Split, Croatia, and lead author of the research.

Best practices and recommendations are currently available from groups such as the International Committee of Medical Journal Editors (ICMJE), the Good Publication Practice guidelines, the Committee on Publication Ethics, and the EQUATOR (Enhancing the QUAlity and Transparency Of health Resources) Network. However, it can be challenging to bridge the gap between guidelines and practical application when determining authorship. The *Five-step Authorship Framework* helps close this gap while aligning with the latest ICMJE guidance.

"There is a growing demand for increased transparency in publications for clinical trials. The MPIP Initiative sought to identify authorship ambiguities encountered in industry-sponsored trials not well addressed by current guidelines and develop a framework that can be used prospectively to facilitate more transparent and consistent authorship decision-making," said Bernadette Mansi, Director of Publications & Disclosure Practices at GlaxoSmithKline and MPIP Steering Committee Member. "This framework aims to help readers better assess the credibility of results and perspective of the authors for medical research and can be applied more broadly to all clinical trial publications, not just those from industry-sponsored research."

### **About MPIP**

The Medical Publishing Insights and Practices Initiative (MPIP) was founded in 2008 by members of the pharmaceutical industry and the International Society for Medical Publication Professionals (ISMPP). MPIP seeks to promote more effective partnership between sponsors and journals to continue to raise standards in medical publishing and expand access to study results. To date, MPIP has identified issues perceived by journals to be barriers to transparency and trust and collaborated with journal editors and publishers on actionable solutions and resources. MPIP is a collaboration co-sponsored by Amgen, Astellas, AstraZeneca, Biogen Idec, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Research & Development LLC, Merck, Pfizer, Takeda and ISMPP. MPIP receives logistical support from Navigant Consulting LLC, a life sciences strategy consulting firm. For more information about MPIP, visit <a href="https://www.mpip-initiative.org">www.mpip-initiative.org</a>.

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### **NOTES TO EDITOR:**

1. Research article

Five-step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-sponsored Clinical Trial Publications

Ana Marušić, Darko Hren, Bernadette Mansi, Neil Lineberry, Ananya Bhattacharya, Maureen Garrity, Juli Clark, Thomas Gesell, Susan Glasser, John Gonzalez, Carolyn Hustad, Mary-Margaret Lannon, LaVerne A. Mooney, and Teresa Peña BMC Medicine 2014, **12**:168

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References

Mansi BA, Clark J, David FS, Gesell TM, Glasser S, Gonzalez J, et al: **Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective.** *Mayo Clin Proc* 2012, **87**:424-9.

<sup>&</sup>lt;sup>1</sup> MPIP's Ten Recommendations Publication