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Authorship Challenges & Solutions: It's Not WHO You are, it's WHAT You Do

ISMPP Authorship Algorithm Taskforce

July 22, 2020

International Society for Medical Publication Professionals™

Webinar will begin promptly at:
11 AM ET / 4 PM GMT

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- We will make every effort to respond to all questions live (out loud)

Speakers

- **Maggie Hodgson, RN, BSN, MBA,** Director Publication Management, Oncology Lead, Merck & Co., Inc.
- **Rob Matheis, PhD, MA,** President and CEO, ISMPP
- **Avishek Pal, MSc, ISMPP CMPP,™** Scientific Communications Director, Cell & Gene, Novartis Oncology
- **Sonia A. Schweers, PharmD, ISMPP CMPP™,** Medical Capabilities / Global Publication Practices Lead, Bristol-Myers Squibb
- **Moderator: Carolyn Hustad, PhD,** Chair, Annual Program Committee; Associate Vice President, Global Medical and Scientific Publications, MRL Scientific Affairs, Merck & Co., Inc.

Disclaimer

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

Background & Objectives

- The International Committee of Medical Journal Editors (ICMJE) criterion #1 is the basis for author selection as it refers to contributors to the research – prior to the initiation of the publication.
- Interpretation of ICMJE criterion #1 varies within and between companies, resulting in inconsistent author decisions, disagreements, and disputes.
- This presentation will discuss industry-wide challenges in author selection. Representatives of the ISMPP Authorship Algorithm Taskforce will unveil recommendations to standardize the interpretation of ICMJE criterion #1 and discuss next steps for adoption.
- Learning objectives:
  - Discuss challenges impacting author selection for industry-sponsored research
  - Discuss the interpretation of ICMJE criterion #1 to inform development of algorithm for author selection
  - Identify next steps in the implementation of the recommendations

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Case Study

- Publication Lead has been working with authors on the first draft of the primary manuscript for a Phase 3 study.
- A study steering committee (SC) member sends an email asking when the primary publication will kick-off as he expects to be an author. He indicates that he proposed the idea for this study and helped revise the inclusion criteria to speed enrollment. He was not a study investigator and did not recruit any patients.
- Clinical research lead is new to the company and has not worked with the SC member.
- SC member escalates the authorship question to his former colleague, our Chief Medical Officer…

Considerations

- Do these contributions amount to authorship or acknowledgement?
- Can the contributions be corroborated by company personnel (ICMJE criterion #1)?
- What contributions were considered for the existing authors?

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Audience Participation

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- Clinical research lead is new to the company and has not worked with the SC member.
- SC member escalates the authorship question to his former colleague, our Chief Medical Officer…

What would you do?

A. Include SC member as author

B. Acknowledge SC member but not include as author

C. Promise authorship in a future publication

D. Consult co-authors, extended clinical & medical team, legal, and/or compliance

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Evolution of ISMPP Authorship Taskforce

ISMPP Annual Meeting 2018

- Informal discussion among BMS, GSK, Merck & Sanofi

ISMPP US Executive Forum 2018

- 17 companies
- Unanimous agreement
- Proposed as ISMPP initiative

ISMPP Informational Session Q1 2019

Invitation
Feedback

ISMPP Annual Meeting 2019

- Senior Session

Working Groups Kick-off Q2 2019

Develop and implement plan
35+ volunteers

Steering Committee Kick-off

- Charter
- Deliverables
- Governance

Joint Face to Face Meeting Q4 2019

- Review progress
- Focus plan

ISMPP Members Update

MAPS article

ISMPP EU

CBI / TIPPA Authorship Panels

ISMPP U July 2020

ISMPP Authorship Algorithm

Authorship decisions are based on ICMJE criterion #1. Detailed guidance is needed for consistent and transparent use of ICMJE criterion #1 to ensure a fair and consistent author selection process

GOALS

- Define substantial contributions for authorship (ICMJE #1) for external and internal authors
- Optimize documentation of contributions for contribution-based author selection
- Increase transparency about authorship decisions

WG#1 Substantial Contributions

- Interpret substantial contributions for authorship
- Provide guidance on use of contributions for author selection

WG#2 Documentation

- Develop tool to facilitate documentation and scoring of contributions
- Provide guidance on handling authorship disputes, author order and number

WG#3 Transparency

- Develop communication & education plan for external stakeholders

WG#4 Communication

- Develop and execute communication strategy

ICMJE: International Committee of Medical Journal Editors
WG: Working Group

Defining Substantial Contribution

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ICMJE Criteria for Authorship

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work, AND
2. Drafting the work or revising it critically for important intellectual content, AND
3. Final approval of the version to be published, AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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Approach

Objective: Define substantial contributions for authorship (ICMJE criterion #1)

Working Group 1 led literature search and review of existing tools. Steering Committee led the survey.

Literature Search

Literature Search in PubMed, Biosis and Scopus, 2014 – 2019 for author contribution definitions, author order, author versus contributor, unethical vs ethical practices

108 articles identified, 69 were relevant to authorship

69 articles were reviewed and categorized as Very Relevant (40), Authorship Order (19), and/or Background (n=20)

40 articles were summarized by the team and divided into concept/design, data acquisition, analysis, interpretation, 2 additional manuscripts were included as identified by team

Thank you to Tine Sorgenfrei and Beth Whann for leading the literature search and evaluation

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Preliminary Definition of ICMJE #1

DRAFT

Study Concept or Design	Acquisition of Data	Data Analysis and Interpretation
Conceptualizing/creating/refining a research idea/study design	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection	Defining the analysis plan
Protocol development, concept, design and methodology (review of/input to protocol document, including amendments)	For Clinical Trials: Dependent on number of patients enrolled/completed and level of protocol compliance and quality of data	Performing statistical analyses and computations
Leads/contributes to development of inclusion/exclusion criteria	Data Collection: efficacy, safety and tolerability (including determination of relationship to study drug and severity of AEs)	Interpretation of statistical analyses
Input to statistical tests/analyses (Statistical Analysis Plan); including ad-hoc analyses	Subjects enrolled (ie acquisition of data per study protocol) - Quantity	Study outcome interpretation
Selecting an Instrument/ measure	Subjects enrolled (ie acquisition of data per study protocol) - Quality	Evaluation of data/results for interpretation, advice, insights and conclusions (ie Overall interpretation of the study results/data)
Providing insights before and during the conduct of the study	Data cleaning and interpretation (“evaluable data”)	Contextualized the results (with current literature/advances in field)
Oversight and leadership responsibility for the research activity planning	Data Handling/Data Storage	Ensured conclusions consistent with the data
Scientifically substantive development and/or modification (review not sufficient) of the detailed synopsis of study concept and/or study protocol – for secondary analyses		

Additional Factors/Considerations:

- Contributions made as part of steering committees or advisory boards, lead PI
- Geographical considerations
- Other publication types such as systematic literature reviews and meta-analyses

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Interpre

Study Concept or Design

Conceptualizing and/or refining a research idea and/or a study design

Development or modification of protocol and/or methodology (e.g. inclusion/exclusion criteria)

Development or modification of statistical analysis plan

Detailed Descriptions

Study Concept or Design	
High-level	Descriptor
Conceptualizing a research idea/creating a study design	Conceptualizing/Creating includes but is not limited to contributions related to identifying unmet need or scientific knowledge gap, framing the research question/hypothesis/aims, identifying the procedure or techniques to be used in the research, developing the concept (creating synopsis document); Footnote: Research includes all clinical/non-clinical/translational study types, primary/secondary/exploratory analyses, and experimental designs
Refining a research ide design	
Leading development c methodology, defining inclusion/exclusion crit	
Refining/contributing t development of protoc methodology, defining inclusion/exclusion crit	
Leading statistical tests including exploratory a analyses if relevant for development	
Refining/contributing t tests/analyses includin and ad-hoc analyses if publication development	

DRAFT

Preliminary Definition of ICMJE #1

Study Concept or Design	Acquisition of Data	Data Analysis and Interpretation
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Providing insights before and during the conduct of the study	Data cleaning and interpretation ("evaluable data")	Contextualized the results (with current literature/advances in field)
Oversight and leadership responsibility for the research activity planning	Data Handling/Data Storage	Ensured conclusions consistent with the data
Scientifically substantive development and/or modification (review not sufficient) of the detailed synopsis of study concept and/or study protocol – for secondary analyses	Additional Factors/Considerations: • Contributions made as part of steering committees or advisory boards, lead PI • Geographical considerations • Other publication types such as systematic literature reviews and meta-analyses	

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Interpretation of ICMJE Criterion #1

Study Concept or Design	Acquisition of Data	Analysis	Interpretation
Conceptualizing and/or refining a research idea and/or a study design Development or modification of protocol and/or methodology (e.g. inclusion/exclusion criteria) Development or modification of statistical analysis plan	Relative Quantity Numbers of participants (enrolled, randomized or retained) relative to the total number of participants Collecting/managing and maintaining metadata for secondary/subset or exploratory analyses as applicable Quality Collecting/managing and maintaining quality data that meets the requirements of protocol-defined analyses	Performing data/statistical analyses	Interpreting the overall study/research, data/results, supporting/critiquing key observations and deriving conclusions Providing insights to contextualize the results based on published literature/advances in the field Identifying knowledge gaps for further exploration

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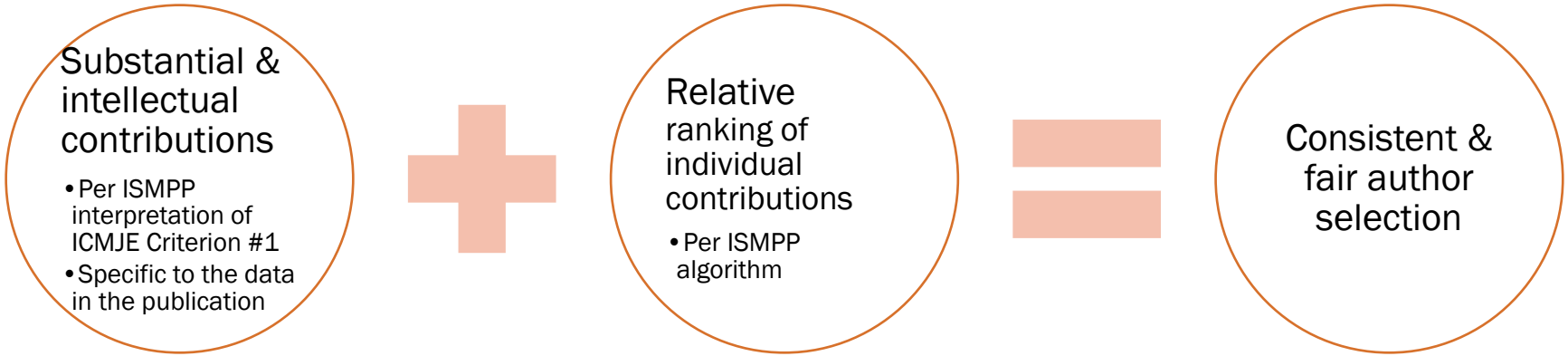
Authorship Framework



Authorship Algorithm

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Approach

Objective: Develop tool to facilitate documentation and scoring of contributions

Review & Validation of ICMJE criterion #1

- Steering Committee & Working Groups
- Refine concepts
- Consensus

Algorithm

- Requirements
- Challenges
- Weighting

Ideation

- Prototype
- Pilot
- Feedback

Working Group 2 led the efforts with input from Working Group 1.

Authorship Algorithm: Aspirations and scope

Develop a universal eligibility framework to:

- Quantify/rank relative substantial contributions
- Allow flexibility for implementation
- Establish a feedback mechanism to refine and evolve

Primary scope:

Define and rank relative substantial contributions in a study/project with a large number of contributors

Secondary scope:

Decide author sequence in the byline

Identify first and senior author positions

Define a universal cut-off or benchmark score for eligibility to be an author

Authorship Algorithm: Quantifying relative substantial contribution

DRAFT

Author candidate 1

ICMJE criterion 1

Study Concept or Design		
High-level	**Descriptor**	**Score**
Conceptualizing a research idea/creating a study design	Conceptualizing/Creating includes but is not limited to contributions related to identifying unmet need or scientific knowledge gap, framing the research question/hypothesis/aims, identifying the procedure or techniques to be used in the research, developing the concept (creating synopsis document); Footnote: Research includes all clinical/non-clinical/translational study types, primary/secondary/exploratory analyses, and experimental designs	5
Refining a research idea/study design	Refining includes but not limited to input leading to scientifically substantive development and/or modification of research concept/design	3
Leading development of protocol, methodology, defining inclusion/exclusion criteria	Leading includes but is not limited to development of protocol, concept, design and methodology, selection of an outcome, instrument, measure; Footnote: Methodology includes but is not limited to procedures or techniques used to identify, select, process, and analyze data; Contribution includes but is not limited to provision of substantial intellectual input to protocol	3
Refining/contributing to development of protocol, methodology, defining inclusion/exclusion criteria	Refining/Contributing includes but is not limited to input leading to scientifically substantive development and/or modification of protocol (i.e., amendment), concept, design and methodology	3
Leading statistical tests/analyses including exploratory and ad-hoc analyses if relevant for publication development	Leading includes but not limited to identifying the most appropriate statistical techniques and computational tools in the context of the research question under investigation and developing the Statistical Analysis Plan	0
Refining/contributing to statistical tests/analyses including exploratory and ad-hoc analyses if relevant for publication development	Refining/contributing includes but not limited to input leading to scientifically substantive development and/or modification of the Statistical Analysis Plan (i.e., amendments)	0

Sub-score I = 14

Contribution scoring levels*:

- Significant participation: 5
- Moderate: 3
- Minimal participation: 1
- None/not applicable: 0

*Flexible to be reset per requirements of any organization and implemented consistently at a brand / study level

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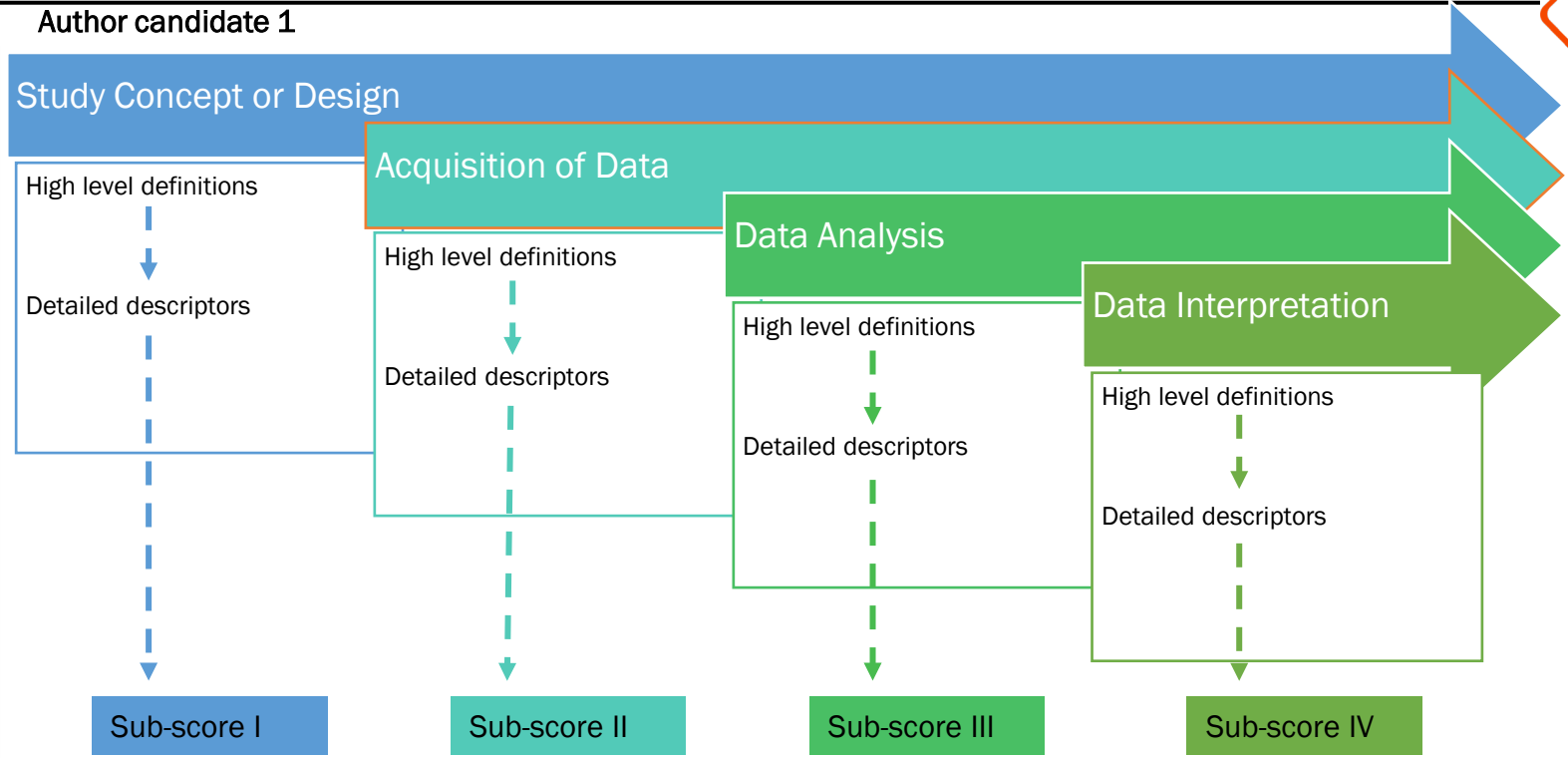
Authorship Algorithm: Quantifying relative substantial contribution

DRAFT

ICMJE criterion 1

Author candidate 1



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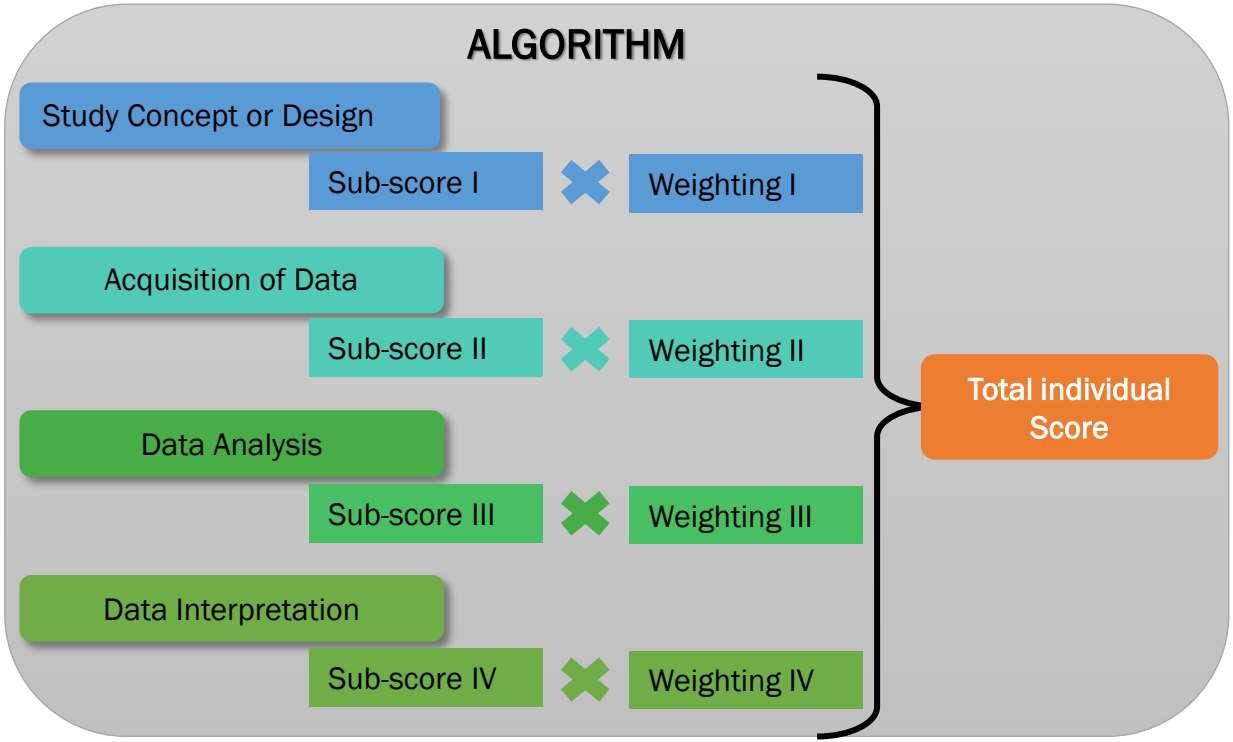
Authorship Algorithm: Quantifying relative substantial contribution

DRAFT

Author candidate 1

ICMJE criterion 1



Universal weighting scheme*:

	Min	Max
Study Concept or Design	2	4
Acquisition of Data	2	3
Data Analysis	2	3
Data Interpretation	2	4

*Flexible to be reset per requirements of any organization and implemented consistently at a brand / study level

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Authorship Algorithm: Putting it to use

Descriptors	• Use independently to assess substantial contribution
Algorithm	• Use to independently quantify substantial contribution

Projected rollout*: Q4 2020

*Subject to outcomes of pressure tests!

Acknowledgement: Yaming Wang for his extensive support in developing the concept for quantifying substantial contribution

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Future State

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Next Steps

- Dissemination and adoption of recommendations for consistent application to author selection
- Algorithm to document and rank contributions to the work

"It's Not WHO You are, It's WHAT You Do"

"Change the world, ONE author at a time"

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Authorship Algorithm Taskforce Volunteers
Thank You!

WG#1 Substantial Contributions
Michelle Carfagno, GSK

Members:
Yaswant Dayaram, Bayer
Susan Hannah, BMS
*Maggie Hodgson, Merck**
*Teri Michelini, Sanofi**
Abbie Pound, Ipsen
Tine Sorgenfrei, Novo Nordisk
Fran Young, Takeda
Tajana Zanki, Pfizer

WG#2 Documentation
Avishek Pal, Novartis /
Rob Matheis (formerly)

Members:
Yaming Wang, AlphabetHealth
Rekha Rao, Amgen
*Sonia Schweers, BMS**
Aruna Seth, Envision
Simon Page, Ipsen
Santosh Mysore/
Julie Vandekerckhove, GSK
Carolyn Watson, Grifols
Merry Saba, Novartis
Beth Whann, Pfizer

WG#3 Transparency
Stephanie Brown, Eli Lilly

Members:
Susan Siska, AbbVie
Anja Schmidt, Bayer
Heather Abourjaily, Biogen
*Rosanna Tedesco, GSK**
Rikke Egelund Olsen, Hoffmann-La Roche
Radhika Adiga, Novo Nordisk

WG#4 Communication
Meera Kodukulla, AstraZeneca

Members:
Radha Narayan, Alexion
Susan Nastasee, BMS
Namit Ghildyal, J&J
Karen Mittleman, Independent*
Norbert Brunhuber, Vertex

ISMPP Sponsor: Carolyn Hustad, Merck

* Steering Committee (SC) Members

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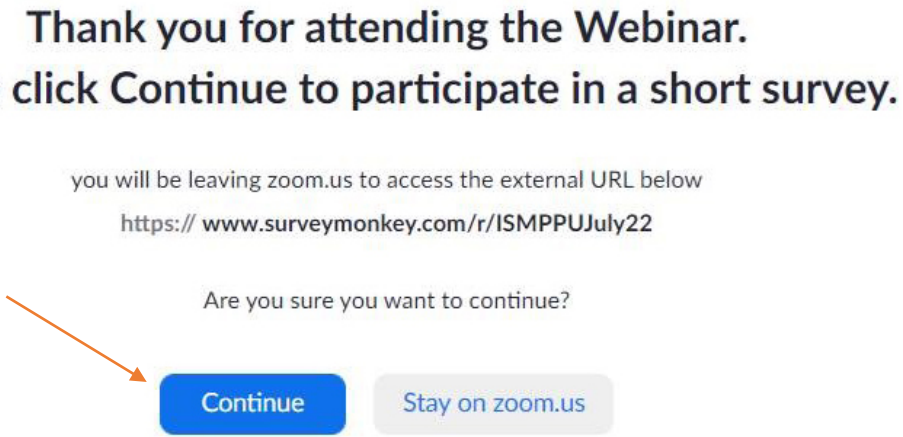
Thank You for Attending!

- We hope you enjoyed today's presentation.
- After closing out of Zoom, please click the CONTINUE button on your screen to take our short survey. Thank you!



Faculty Bios

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Maggie Hodgson

Maggie is a Director of Publications Management and serves as the Oncology Lead in the Department of Global Scientific and Medical Publications at Merck & Co., Inc. in North Wales, PA. Maggie has twenty years' overall experience in medical communications within the pharmaceutical industry, the majority being in global publications management. For 14 of these years, she has driven the development and implementation of global oncology publication plans. Prior to her pharmaceutical tenure, Maggie practiced as a registered nurse in both the hospital and office settings. She received her BSN from West Chester University and her MBA in Health Care Administration from Penn State University. She is a member of ASCO and ISMPP and is CMPP certified.

Rob Matheis

Rob has a long tenure within scientific and medical communications and has been an integral part of ISMPP for more than a decade. He joined ISMPP in July of 2019 from his role as the Executive Director and Head of Global Scientific Communications at Celgene Corporation. Previously, he was Senior Director of Evidence Based Medical Communications at Sanofi. Rob began his ISMPP journey as inaugural Chair of the ISMPP Credentialing Board of Trustees, with oversight of examination development and establishment of credentialing criteria. He also served as the 7th President of the ISMPP Board of Trustees. During his tenure, Rob was an influential champion for transitioning ISMPP governance to a permanent board-appointed President and CEO. Most recently, Rob has been Chair of the ISMPP Global Transparency and Trends Committee and a Workstream Lead for the ISMPP Authorship Selection Best Practices Task Force.

His professional interests include establishing the value proposition for medical affairs and enriching the role of medical publication professionals to include medical communication capabilities.Dr. Matheis is a licensed clinical psychologist with specializations in behavioral statistics, neuropsychology, and organizational psychology. He is well-published with an extensive bibliography covering brain and spinal cord injury, multiple sclerosis, and alternative medicine.

Avishek Pal

Avishek is a Microbiologist by training and a Certified Medical Publication Professional™ (CMPP™), with more 13 years of experience in the field of scientific communications spanning publication management and strategy, medical education and scientific events for global brands across Oncology, Pharma and Vaccines. He has led enterprise-wide initiatives in defining and overseeing publication standards and best practices, optimizing publication management platforms and integrating innovative digital and plain language trends into publication strategy to enhance the reach and engagement of publications. He takes active interest in data transparency initiatives, patient engagement in publications, publication ethics, and has led various workshops and training sessions on publication writing and publication ethics. In his current role as Scientific Communications Director, Cell & Gene Therapy, Novartis Oncology, Avishek leads scientific communications and engagement strategy for Novartis' CAR-T program.

Sonia Schweers

Sonia is a publication professional with 20+ years of expertise in Medical Affairs and Publishing. She is responsible for incorporating compliance into publication standards and process improvement efforts while monitoring adherence to good publication practices (GPP) at Bristol-Myers Squibb,. Previously, Sonia's responsibilities at Sanofi included development and implementation of publication standards, training and monitoring adherence to GPP in addition to publication planning & execution in allergy. During her tenure with Elsevier, Sonia served as accepting editor for several clinical journals. Sonia holds Bachelor and Doctorate degrees in Pharmacy from Ernest Mario School of Pharmacy and Bachelor in Biology from Saint Peter's University in NJ. Sonia is an ISMPP member and Certified Medical Publication Professional who serves in the Global Transparency and Author Algorithm Taskforces. Sonia is married to Greg, an actor and former prosecuting attorney, and they enjoy traveling with their daughter Sofia

Moderator: Carolyn Hustad

Carolyn has been with Merck & Co., Inc. since 2001, starting as a medical writer, then progressing through roles of increasing responsibility until assuming leadership of the Global Scientific & Medical Publications department in 2016. She has a BS in Chemistry/Marine Science from the University of Miami and a PhD in Biochemistry and Molecular Biology from the University of Southern California, where she studied epigenetic regulation of gene expression. She has been a member of ISMPP since it began [Merck was a founding member company] and is also a member of the steering committee of Medical Publishing Insights and Practices (MPIP).

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