



# ISMPP University

## Authorship Algorithm Tool

July 27, 2022



Webinar will begin promptly at:  
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# ISMPP Announcements

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- This webinar has been approved for **1.5 ISMPP CMPP™ Recertification Credit**. *Please capture a screenshot to submit for credit*
- **Registration now open for ISMPP West, Sept 26-27, Irvine, CA**
- **Application deadline for the September CMPP exam is August 1st**
- **New InformED Podcast - Decentralized Trials & Impact on Medical Publications**
- **Check out the ISMPP Virtual Academy!** On-demand education for ISMPP members and non-members. Access for Annual Meeting content and ISMPP U webinars





# How To Ask Questions

Feel free to ask a question at any time, however all questions will be held until the end the of the presentation.

**To ask a question**, open the Q&A window, type your question into the Q&A box. **Click Send**

**Note:** Check **Send Anonymously** if you do not want your name attached to your question in the Q&A

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



# Disclaimer

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



# Objectives

- Be aware of the official launch of the Authorship Algorithm site
- Understand how to navigate through the Authorship Algorithm portal
- Understand the rationale and process behind the initiative, including incorporation of piloting feedback, technology behind the site and security features
- Identify the supporting resources and educational aids



# Faculty



**Moderator: Margaret Hodgson**

Executive Director, Publication Management, Oncology  
Lead, Global Scientific and Medical Publications  
Merck & Co



**Jeffrey Clemens**

Senior Director, Publications Strategy  
and Launch  
Eli Lilly & Company



**Meera Kodukulla**

Senior Director, Scientific Publications,  
AstraZeneca



**Robert Matheis**

President & CEO  
ISMPP



**Scott Thompson**

Co-CEO  
Acceleration Point





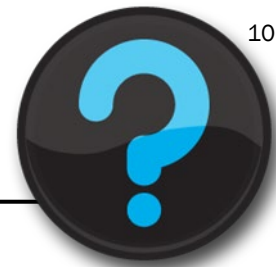
# Historical Perspective & Addressing the Need

Maggie Hodgson





# What is the top authorship priority for your organization?



10

- Applying a consistent definition of substantial contributions per ICMJE criterion 1
- Documentation of the ICMJE criterion 1 contributions to the research/work
- Maintaining a consistent approach to selection of authors
- All of the above



# Historical Perspective

**ICMJE: 1978 *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (URM) 1st Ed. published** – focused manuscript preparation

**ICMJE: 1988 URM 3rd edition** – “Each author should have participated sufficiently in the work to take public responsibility for the content” – first time the first 3 components of authorship appeared

**ICMJE: 1997 URM** – includes “Acknowledgments” section

**ICMJE: 2004 URM** – “Writing and Editing for Biomedical Publication” in title; mentions both authorship and contributions in one section

**GPP: 2003 First official publication** (updated 2009, 2015, 2022) – follows ICMJE criteria for authorship

**ICMJE: 2013 Update** – “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals”; Added 4th Authorship criteria and examples of “non-author contributors”

**ICMJE: 2021 Update** – Last update primary focus is on Preprints



# Why is Authorship Still an Issue for Publication Professionals Working in Pharma?

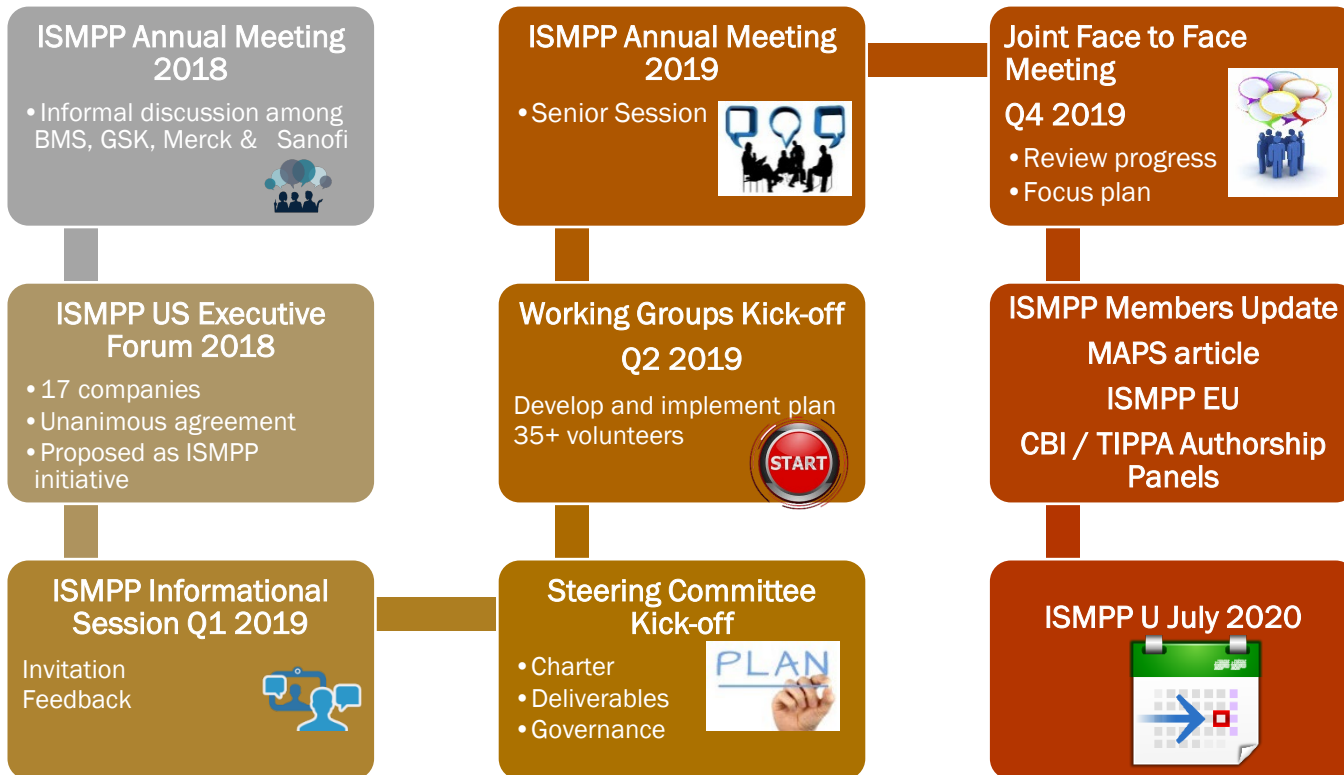
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- Old habits are difficult to break
- Pub Professionals – not always imbedded with clinical teams early on in research project
- Turnover

**At ISMPP Meetings, challenges were identified resulting in the Authorship Task Force**



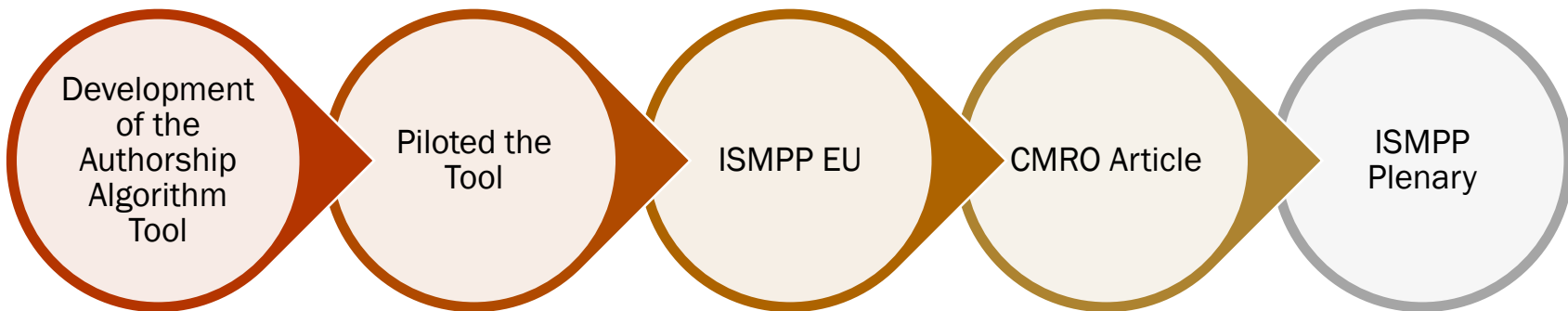
# Evolution of ISMPP Authorship Taskforce





# Evolution Continues

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# 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

G  
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A  
L  
S

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





# And Now A Word From Our Sponsor

**Carolyn Hustad, VP, Global Scientific & Medical Publications, Merck Sharp & Dohme**



**Thank You for Your  
Time and Hard Work!!**

Authorship  
Algorithm  
Steering  
Committee  
Members

Current and  
Former  
Working Group  
Members



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ISMPP and Rob  
Matheis for  
Support of the  
Authorship  
Algorithm Tool

ISMPP  
Membership for  
Your Continued  
Interest and  
Encouragement





# ISMPP Authorship Task Force Members and Contributors

- Heather Abourjaily (Biogen)<sup>†</sup>
- Radhika Adiga (Novo Nordisk)
- Norbert M. W. Brunhuber (Vertex)
- Michelle L. Carfagno (GlaxoSmithKline)
- Anny Chen (Novartis)
- Jeffrey W. Clemens (Eli Lilly)
- Yaswant Dayaram (Bayer)
- Lisa Doherty (Takeda)
- Rikke Egelund Olsen (Hoffmann-La Roche)
- Namit Ghildyal (Janssen)
- Susan Hannah (Bristol Myers Squibb)
- Margaret B. Hodgson\* (Merck Sharp and Dohme)
- Carolyn Hustad\* (Merck Sharp and Dohme)
- Brittany Jordan (Allergan)
- Meera I. Kodukulla (AstraZeneca)
- Teri Michelini\* (Sanofi)
- Karen D. Mittleman\* (Consultant)
- Santosh Mysore (GlaxoSmithKline)
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- Susan A. Nastasee (Bristol Myers Squibb)
- Simon Page (Ipsen)
- Avishek Pal (Novartis)
- Abbie Pound (Ipsen)
- Rekha Rao (Amgen)
- Merry Saba (Novartis)
- Anja Schmidt (Bayer)
- Sonia A. Schweers\* (Bristol Myers Squibb)
- Aruna Seth (Envision)
- Tine Sorgenfrei (Novo Nordisk)
- Rosanna Tedesco\* (GlaxoSmithKline)
- Sarah Thomas (Ipsen)
- Yaming Wang (Alphabet Health)
- Carolyn Watson (Grifols)
- Elizabeth A. Whann (Pfizer)
- Fran Young (Shire)<sup>††</sup>
- Tatjana Zanki (Pfizer)

\*Steering committee member; <sup>†</sup>Now at Vertex; <sup>††</sup>Now at Takeda.



# Task Force Recommendations

Meera Kodukulla





# Publication

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## **Building Consensus on Author Selection Practices for Industry-sponsored Research: Recommendations from an Expert Task Force of Medical Publication Professionals**

Michelle L. Carfagno, Sonia A. Schweers, Elizabeth A. Whann, Margaret B. Hodgson, Karen D. Mittleman, Susan A. Nastasee, Tine Sorgenfrei, Meera I. Kodukulla for  
The International Society for Medical Publication Professionals Authorship Task Force



# What are substantial intellectual contributions?

## Study concept or design

- Conceptualizing, refining, and/or modifying a research<sup>a</sup> idea and/or a design such as:
  - Identifying unmet need or scientific knowledge gap (i.e. rationale)
  - Framing the research question
  - Identifying the research procedures or techniques

### And/Or

- Significant intellectual input into development or modification of the protocol and/or methodology (e.g. inclusion/exclusion criteria, selection of outcome measures), and/or statistical analysis plan (e.g. selection of statistical tests/analyses)

## Or Data acquisition

- Contributing most data with high quality<sup>b</sup> to the final analyses such as:
  - Numbers of participants (enrolled, randomized, or retained) relative to the total number of participants, or
  - Generation of other types of data (e.g. database analyses)

## Or Data analysis

- Performing the analyses, interpreting the output in the context of the specific research objectives, and ensuring integrity and accuracy of the data

## Or Data interpretation

- Interpreting the overall study/research, results, deliberating on the strengths and limitations of the design or methodology, supporting/critiquing key observations and deriving conclusions

### And/Or

- Contextualizing the results based on published literature/advances in the field such as:
  - Deriving clinical implications
  - Providing insights on real-world experiences
  - Identifying knowledge gaps for further exploration

<sup>a</sup>Research includes clinical, pre-clinical, and translational studies, inclusive of primary, secondary, and exploratory analyses, as well as health outcomes and real-world evidence.

<sup>b</sup>Quality refers to meeting the protocol-defined requirements for primary and secondary analyses (e.g. complete data set with minimal missing data or errors).



# What are *not* substantial intellectual contributions?

## Study concept or design

- Review/approval of study synopsis / concept sheet, protocol, statistical analysis plan without provision of input that influences the research
- Oversight and/or managerial responsibility (e.g. lab head, site institution head)
- Writing the protocol or clinical study report
- Literature search
- Membership in Steering Committees or Advisory Boards
- Funding acquisition

## Or Data acquisition

- Study site activation, site monitoring, checking GCP compliance, data entry, query management
- Data collection without intellectual input following a standard process, data quality monitoring/assurance, data cleaning, data validation, programming
- Database management, data handling, data storage, sample handling, sample management
- Providing instrumentation, software, technology

## Or Data analysis

- Programming output tables, writing codes, data management
- Quality control, validation
- Oversight and/or managerial responsibility (e.g. team lead)

## Or Data interpretation

- Literature searches, reference compilation
- Editorial assistance
- Compiling submission package/submission



# Recommendations - Summary

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- Facilitate an author selection process grounded in the core principles of substantial intellectual contribution
  - to the work's conception or design, or to the acquisition, analysis, or interpretation of data
- Focus on author selection practices for industry-sponsored research *prior* to the start of a study/publication
  - they may be applied to publications in other areas of scientific and biomedical research
- Consistent adoption into company process and culture is key to ensure uniform approaches for authorship decisions
- Served as a basis for the ISMPP Authorship Algorithm Tool
  - to facilitate uniform application and documentation of contributions



# Authorship Algorithm Tool Sign Up, Demo & Support Materials

Jeff Clemens





# Go to the ISMPP Website first

- Visit [www.ismpp.org/ismpp-authorship-algorithm-tool](http://www.ismpp.org/ismpp-authorship-algorithm-tool) for all the details and to access the link for the tool!
- **Company Admin must be a member of ISMPP.**
- **Team Admins and Team Members do not have to be ISMPP members but should be assigned by the Company Admin.**
- **Company Admin will send request access link to Team Admin and Members.**



## Welcome to the latest resource from ISMPP, the Authorship Algorithm Tool!

ISMPP is delighted to provide our members and their companies with a useful tool, which will help you better [determine contributions to criterion 1](#) of the [ICMJF Recommendations for Authorship](#). The Authorship Algorithm Tool provides a web-based mechanism for scoring and weighting author contributions using the sub-criteria below of ICMJE criterion 1:

- Research idea
- Protocol/methodology
- Statistical analysis
- Acquisition of data
- Data analysis
- Data interpretation

**Please log in to the ISMPP Members' Only area for access to the tool.** A **Company Admin** needs to be assigned first. The **Company Admin** should be an active ISMPP member (**to become a member click here**) and will be responsible for assigning Team Admins and Team Members and disseminating the link for Team Admins and Team Members to request access to the Tool.

**Please note:** The Authorship Algorithm Tool has **three assigned roles:**

- **Company Admins\*** - in charge of overseeing and managing your company's contributions to the tool (including weighting), create/update teams, assigning Team Admins/Team Members, create projects. *Each company should have only one company admin. You must be an active ISMPP member to be a company admin. To become a member click here.*





# Requesting Access

- On the ISMPP Website, click on the link for the tool and request access



Home

Contact Us

Support Material

Request Access

Privacy Term and Conditions

1

Complete request for access by role

2

Acceleration Point sends instructions to complete registration process

3

Registered users can be added to Teams and Projects

First Name \*

Last Name \*

Email \*

\*\*\*Please only include your company email address\*\*\*

Company \*

ISMPP Authorship Algorithm Tool Role \*

**COMPANY ADMIN** - in charge of overseeing and managing your company's contributions to the tool (including weighting), create/update teams, assigning Team Admins/Team Members, create projects. Each company should have only one company admin.

**TEAM ADMIN** - in charge of managing specific team projects and Team Members; also able to add projects, contributors and team weighting.

**TEAM MEMBER** - able to add projects and assign contributors, adding scores to contributors.

[More Details](#) about the Tool

Submit





# Authorship Algorithm Tool (AAT) User Roles

## Company Administrator

Sponsor employee and ISMPP member

- **Owner of** each sponsor's AAT instance
- **Manages access** for individual Team Administrators at Sponsor
- **Creates** Teams
- **Manages** optional customized Weighting schemes for use on sponsor-wide basis

## Team Administrator

Sponsor employee that manages Teams

- **Manages** access for individual Team's Users as part of a specific Team
- **Weighting customization**

## Team Member

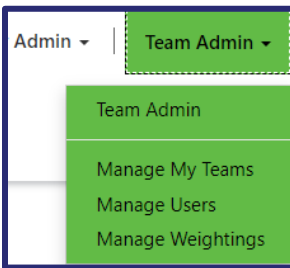
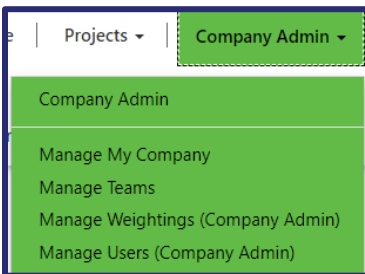
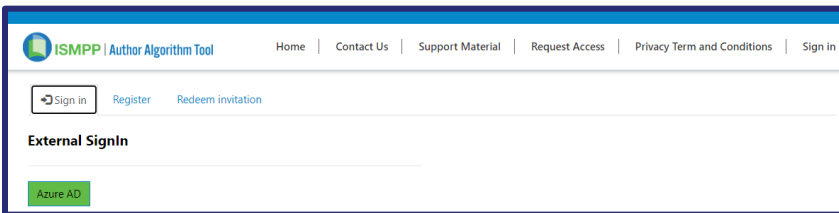
Sponsor employee that uses AAT to assess ICMJE Criterion 1 contributions

- **Creates projects** for each publication
- **Documents author's** contributions and level of effort for AAT's questions



# AAT Getting Started

- **Sign in securely to the tool**
- **Company Admin**
  - 1 (plus a backup) per Sponsor
- **Team Admin**
  - Suggested- By Therapeutic area or Compound/Product





# AAT Demonstration- Getting Started Video

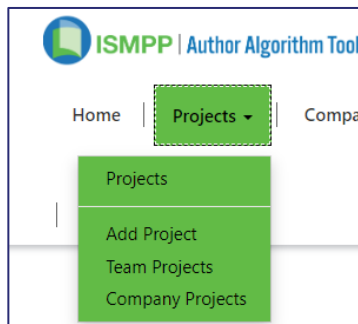




# AAT Adding Projects and Determining Relative Contributions

- **Project = single publication**

- Adding Projects
- Team Projects
- Company Projects



- **Scoring Relative Contributions for Potential Authors**

- Type and significance of ICMJE Criterion 1 contributions
- Generate project reports

**Project Title:** Demo project 1 Sunday 1512  
**Project Description:** Demo  
**Team Name:** Clinical  
**Project Owner:**  
**Weighting:** Default  
**Company Name:**  
**Date:** 7/24/2022 7:13:23 PM

**ISMPP Recommended Weightings**

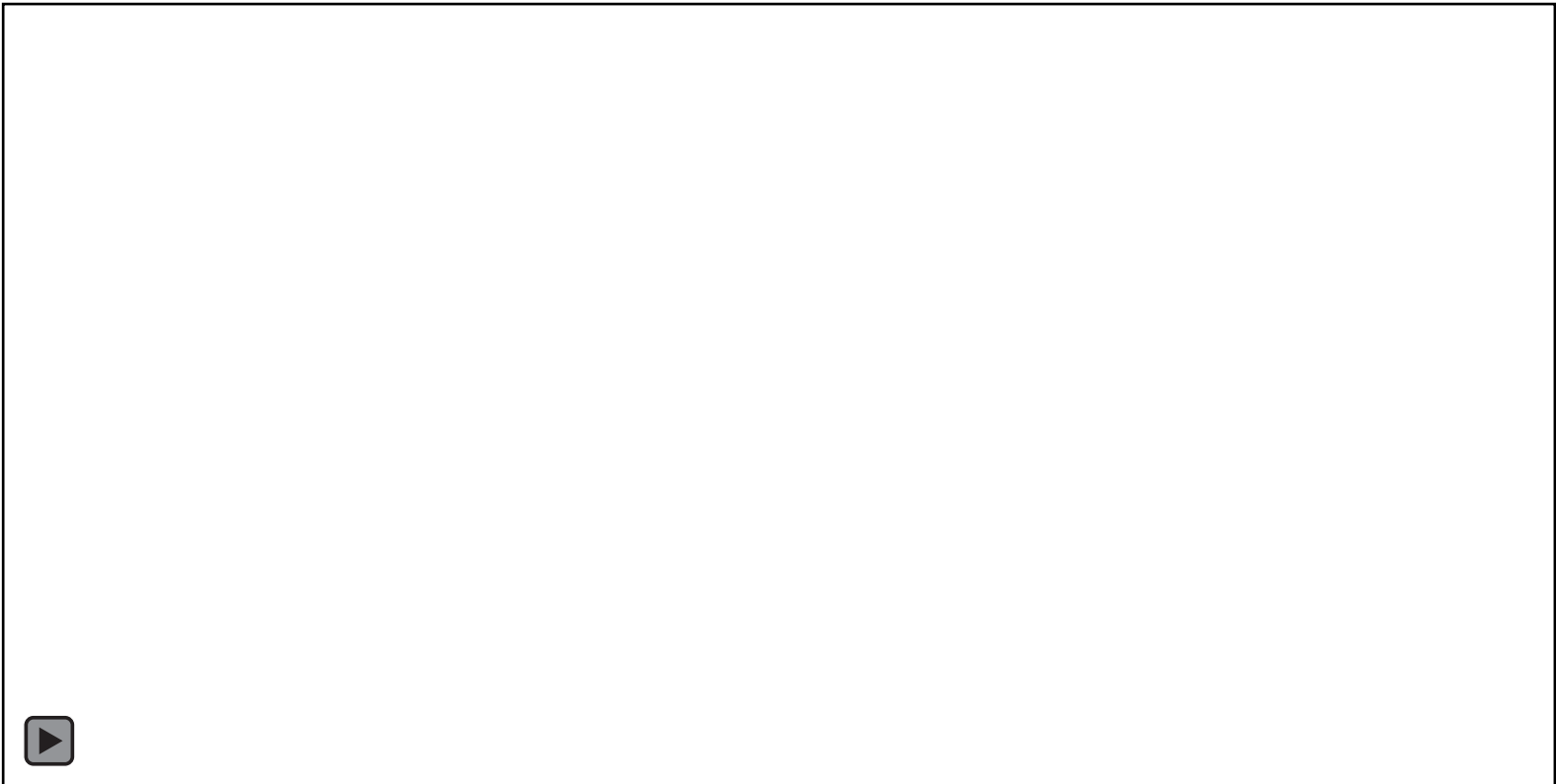
	Preclinical	Clinical	RWE/HEOR	Reviews
Study Concept/Design	3	5	2	3
Acquisition of Data	3	2	3	2
Data Analysis	2	2	3	3
Results Interpretation	4	4	3	2

[Click here for Weighting scheme guidance document](#)

Weighting	Study Concept or Design	Acquisition of Data	Data Analysis	Data Interpretation
Default	5	2	2	4



# AAT Demonstration- Projects and Contributions Video














# AAT Support Material

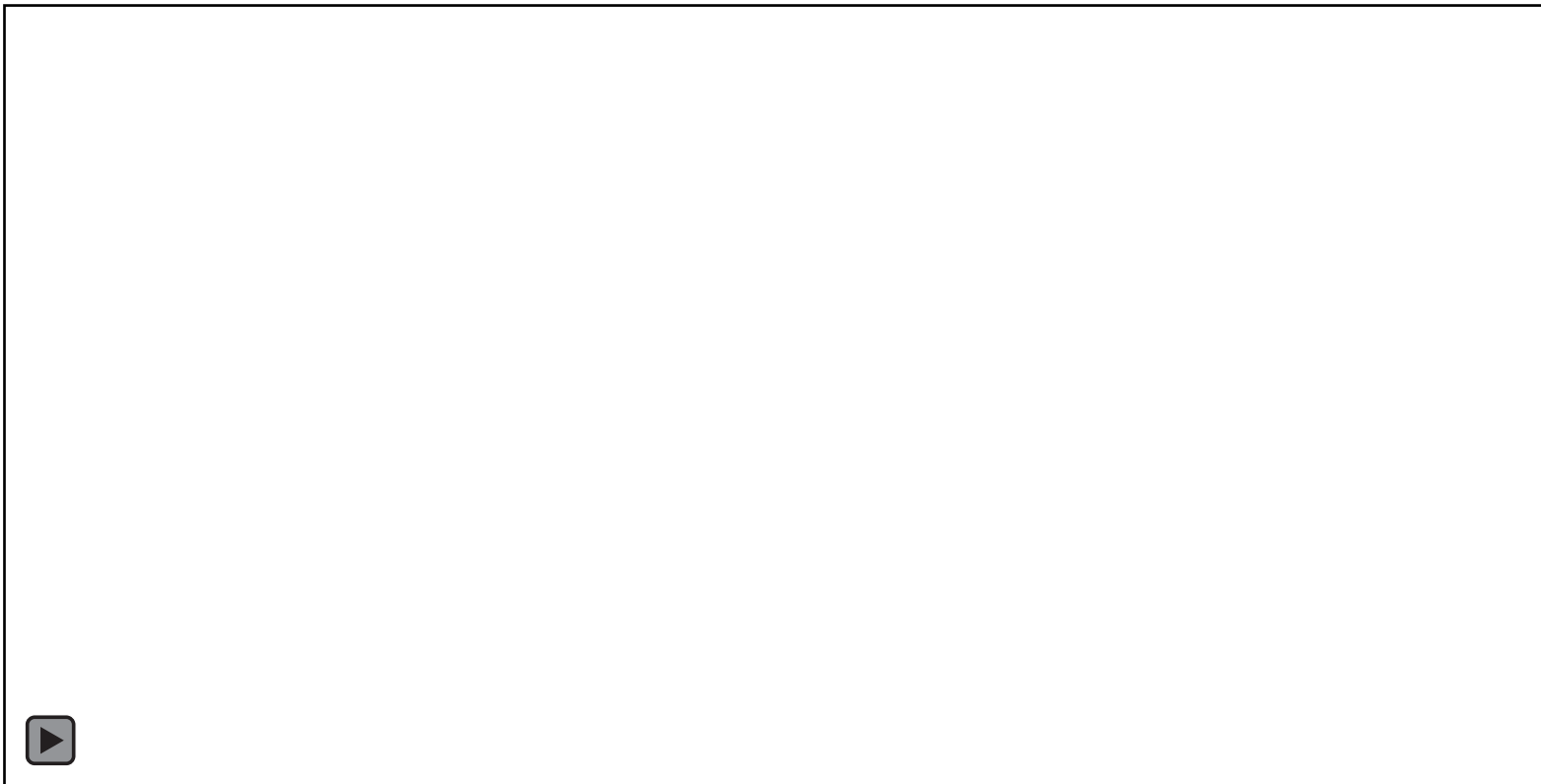
[Home](#)[Contact Us](#)[Support Material](#)[Request Access](#)[Privacy Term and Conditions](#)[Sign in](#)

## Support Material

1. Update on the Task Force initiatives introducing the Authorship Algorithm and planning the Pilot and Rollout. Please click the link to download. 
2. Building Consensus on Author Selection Practices for Industry Sponsor Research Recommendations from an Expert Task Force of Medical Publication Professionals. Please click the link to download. 
3. ICMJE Criterion checklist to confirm and document author contributions. Please click the link to download. 
4. ISMP document providing the background information of the weighting profile rationale, design and suggested usages. Please click the link to download. 
5. Guide for defining the contribution and eligibility for acknowledgement for study design, acquisition of data, data analysis and data interpretation. Please click the link to download. 
6. SSO Details. Please click the link to download. 
7. ISMP\_AuthorshipTaskForce\_AuthorBiomedPubPrinciples. Please click the link to download. 
8. Authorship Algorithm Tool Job Aids. Please click the link to download. 
9. AATool\_ImplementationGuideForSponsors\_2May2022. Please click the link to download. 



# AAT Demonstration - Support Material Video







# Technology and Security Considerations

Scott Thompson





# From Philosophy to Practice

Technology exists to help ensure easy and consistent executions of strategy.

Weighting

Companies

Authors

Calculations

Reports

## ISMPP Author Algorithm Tool

The screenshot displays the ISMPP Author Algorithm Tool interface. On the left, a dashboard shows project details for 'Acceleration Point' and a weighting scheme for 'Study Concept or Design', 'Acquisition of Data', and 'Data Analysis'. The 'Edit' window for candidate 'Andrew Clark' shows a 'Contribution Scoring Levels' table and five questions (Q1-Q5) with a 0-5 rating scale. Below the dashboard is a table of candidate scores.

Candidate Name	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total Score	
Andrew Clark	0	3	4	0	5	0	5	1	5	3	60
John Smith	1	0	5	0	0	3	5	5	5	5	40
Steve Jones	0	3	0	3	0	0	4	5	5	5	40
Tim Wilson	0	3	0	1	0	3	4	3	3	3	30
William Edwards	5	0	5	0	0	3	4	0	5	1	65

- 1 Microsoft Portal
- 2 Secure Single Sign-On
- 3 Support Materials
- 4 ISMPP Support



# Call to Action

Rob Matheis





# Since the Annual Mtg plenary session, have you introduced or implemented any Authorship Task Force recommendations?



36

- Currently implementing it
- Planning to implement in the next few weeks/months
- Considering implementing it
- Not considering it

# A Call to Action





# Recommendations – Next Steps

The focus is on author selection practices for industry-sponsored research *prior* to start of a study or publication

Reengage with stakeholders and help bring clarity and objectivity to the interpretation of ICMJE criterion 1 across teams and sponsors

Raise organization-wide awareness and educate stakeholders

Update company publication policies as applicable

Empower publication professionals: Build consensus internally with senior management\* to gain support and active partnership



## Audience Q&A

To ask a question, open the Q&A window, type your question into the Q&A box. [Click Send](#).



# Upcoming ISMPP U Webinars

September 21, 2022:

Data visualization techniques to communicate publications value

October 2022:

Current trends in Omnichannel/Multichannel platforms including Medical Affairs Website Content: What do publications professionals need to know?





# Thank you for attending!

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After closing out of Zoom, please click the CONTINUE button on your screen to take our short survey. Thank you!

Thank you for attending the Webinar.  
Please click Continue to participate in a short survey.

you will be leaving zoom.us to access the external URL below

[https:// www.surveymonkey.com/r/ISMPPU](https://www.surveymonkey.com/r/ISMPPU)

Are you sure you want to continue?

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# ISMPP University

## Authorship Algorithm Tool

July 27, 2022



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



# Faculty Bios

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# Jeffrey Clemens

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- Publications professional with 19 years of experience as writer, publication planner in multiple therapeutic areas, and policy and process subject matter expert
- Authorship Task Force Workgroup 3 Lead
- Led Lilly's 2019 Publication Strategy Transformation



# Margaret Hodgson

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- Publications professional with over twenty years overall experience in medical communications within the pharmaceutical industry, the majority in global publications management
- 15 years' experience driving the development and implementation of global oncology publication plans
- Lead an internal focus group within Merck to establish an authorship criteria selection tool
- Current member of the ISMPP Authorship Algorithm Steering Committee and Task Force
- A coauthor on a recent publication entitled "Building Consensus on Author Selection Practices for Industry-sponsored Research: Recommendations from an Expert Task Force of Medical Publication Professionals"



# Meera Kodukulla

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- Over 20+ years of experience in scientific publications and communications across Medical Affairs and R&D
- Provides leadership in developing and shaping publications and communication strategies
- Current member of the ISMPP Authorship Algorithm Steering Committee and Task Force
- A coauthor on a recent publication entitled "Building Consensus on Author Selection Practices for Industry-sponsored Research: Recommendations from an Expert Task Force of Medical Publication Professionals"



# Robert Matheis

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- Integral part of ISMPP for more than a decade, including previous Chair and Credentialing Committee roles
- Workstream Lead for the ISMPP Authorship Selection Best Practices Task Force
- Chair of the ISMPP Global Transparency and Trends Committee



# Scott Thompson

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- ISMPP Strategic Partner who designed, developed, and hosts the new Authorship Algorithm tool
- Has worked with many of the top teams in medical affairs
- Company provides the first KOL Social Monitoring Platform built specifically for medical affairs, provides operational outsourcing, and consulting