ISMPP University

Review and Approval of Scientific Publications: Processes, Practices and Execution

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OCTOBER 11-12, 2018 • SAN DIEGO, CA

ISMPP International Society for Medical Publication Professionals

OCTOBER 11-12, 2018

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SAN DIEGO, CALIFORNIA, USA

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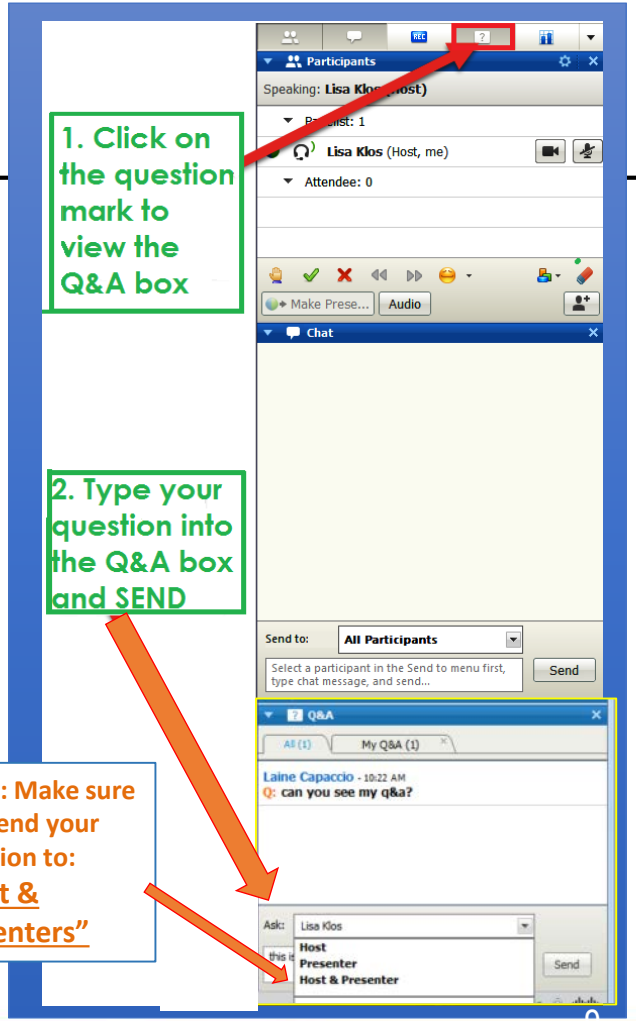

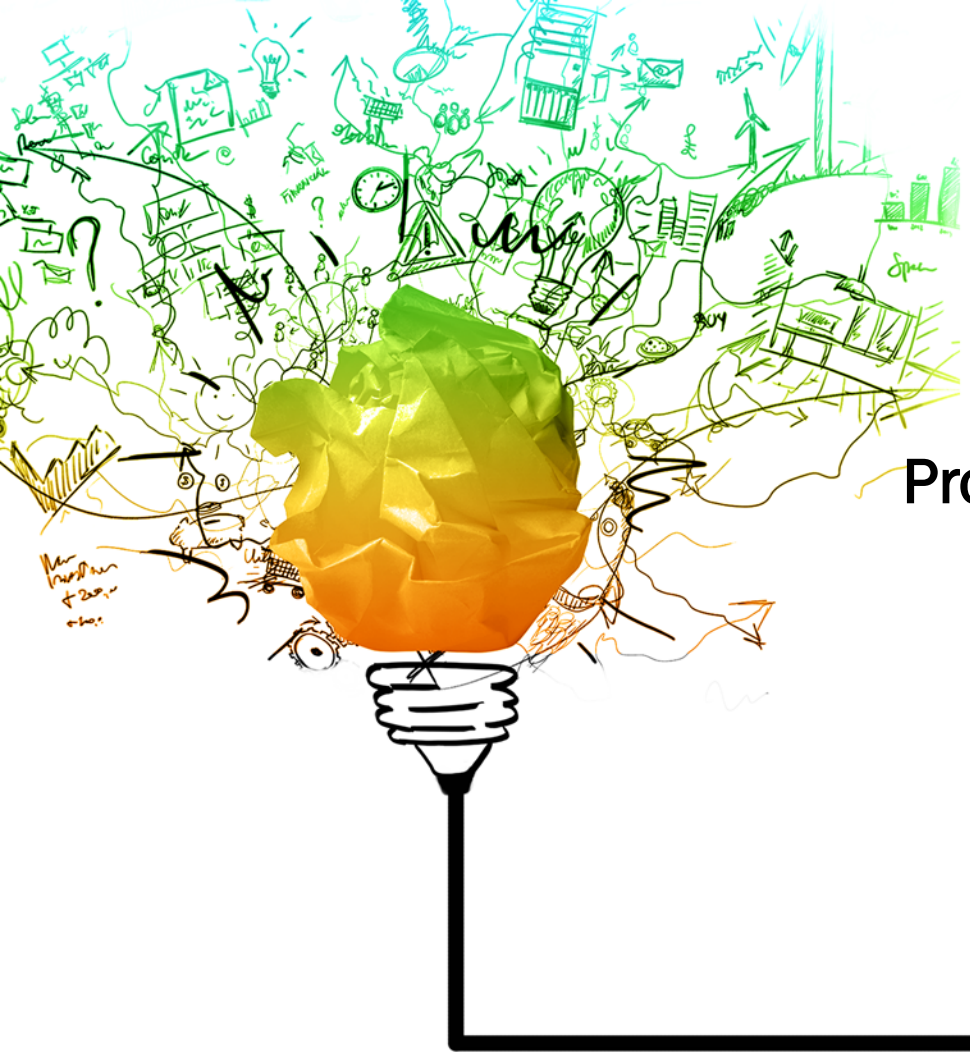

Review and Approval of Scientific Publications

Processes, Practices and Execution

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Susan Nastasee, MS, ISMPP CMPP™

Susan Nastasee has more than 20 years' experience as a publication professional. She is currently a Publication Advisor at Bristol-Myers Squibb, where she develops publication policy and guidelines, and provides training and subject matter expertise to internal colleagues and agency partners involved in publication planning and development. Prior to this role, Susan was a medical writer supporting virology and immunoscience at Bristol-Myers Squibb and Wyeth. Susan is an ISMPP-certified medical publication professional, having served for several years on the ISMPP Ethics committee and the Standards Working Group. She has been an author and presenter on multiple ISMPP presentations, and has served as a Roundtable moderator during ISMPP annual meetings. Susan is also a steering committee member of Medical Publishing Insights and Practices (MPIP).

Mary Beth DeYoung, PhD

Mary Beth DeYoung is a Global Publications Lead in Cardiovascular, Renal and Metabolic Medicine at AstraZeneca. She has more than 18 years of publications experience, and has coordinated >200 publications sponsored by industry. She worked as a publications professional at Bristol-Myers Squibb, Amylin Pharmaceuticals and PAREXEL-MMS, has worked in alliance with Eli Lilly&Co, Astellas and Fibrogen, and her clients have included Schering AG, Bayer Healthcare, GE Healthcare, and Alkermes . In addition to her industry experience, Mary Beth authored her own biomedical publications at the University of Pennsylvania, Case Western Reserve University, the Cleveland Clinic Foundation, and the University of California at San Francisco. Mary Beth has previously presented at ISMPP, the ISMPP University, and TIPPA.

Moderator:
Ann L. Davis, MPH, ISMPP CMPP™

Ann Davis is Manager of Global Scientific and Medical Communications at Pfizer, where she supports execution of publication plans for the vaccines portfolio. Ann has more than 30 years of experience in the medical communications field, including prior content development roles at Centocor Ortho Biotech (now Janssen Pharmaceuticals) and Bristol-Myers Squibb. At BMS, she also served as a Global Publication Advisor, developing publications policies and practices, as well as advising and training internal stakeholders and agency partners.

An ISMPP-certified medical publication professional, she has served as workshop leader for ISMPP and the American Medical Writers Association, author of multiple ISMPP poster presentations, faculty for the ISMPP U webinars, and a member of various ISMPP committees. She has been an invited speaker at TIPPA and other publication planning seminars, Ann completed her graduate studies at the University of Texas Houston Health Science Center.

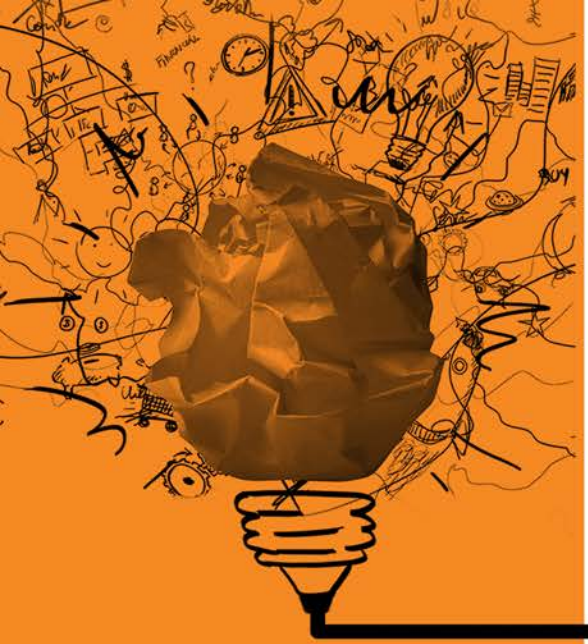
Disclaimer

The opinions expressed in this presentation are those of the presenters and do not necessarily reflect the views or policies of current or former employers, nor those of ISMPP

Learning objectives

At the end of this session, participants should be able to:

- Demonstrate knowledge of appropriate models for review and approval of publications
- Understand the roles and responsibilities of each stakeholder in developing publications
- Identify issues that affect the scientific value, integrity, and readability of a publication
- Understand the components of a critical evaluation of a publication, including constructive feedback that optimizes the final output



Designing a Process for Review and Approval of Publications

Susan A. Nastasee, MS, ISMPP CMPP™

Publication Advisor

Bristol-Myers Squibb

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Considerations

- Ensure processes are aligned with industry standards (eg, GPP) to ensure compliant, transparent, and ethical publication development
  - Lack of alignment and compliance places the company at risk
- Authors retain ultimate control and responsibility for the content of the publication
  - Input on content before writing begins
  - Critical review, comments, and input throughout publication development
  - Final approval of the version to be published prior to submission or presentation

Considerations (cont)

- Identify relevant internal stakeholders and appropriate reviewers
  - What is scope of publication?
  - Who is the data owner?
  - Does company require legal, regulatory review

- Set expectations
  - Transparent review process – ensure stakeholders are trained on review process
  - Timelines for development, review, submission
  - Discuss at Author Kickoff

What Is the Risk(s) of Not Having Internal Review of Company-Sponsored Publication?

a. Inappropriate disclosure of intellectual property
b. Inappropriate context of data interpretation
c. Lack of scientific objectivity, fair balance of safety and efficacy
d. Understating or overstating the conclusions
e. Company liability
f. All of the above

Role of Internal Reviewers

- Medical accuracy, objective interpretation of data
  - ✗ Over-reaching conclusions
  - ✗ Cherry-picking of data
  - ✗ Marketing or promotional messages or statements
- Adherence to scope of publication
  - Ensure primary objectives are met
  - No overlap with other planned pubs
- Ensure reviewer comments are appropriate
  - All reviewer comments are “discoverable” in audit
- Pub Lead/Manager may provide more granular review, including a broad scope and thorough editorial review
  - Quality of writing, content flow
  - Ensures authors’ comments and input are reflected in each draft

Publication Development Overview

Authors Contribute, Review, and Approve

Publication Lead Drives Process and Comment Resolution

Planning

Internal Alignment
Author Identification & Invitation

Initiation

Author Kickoff
Data Disclosure
Author Input

Development

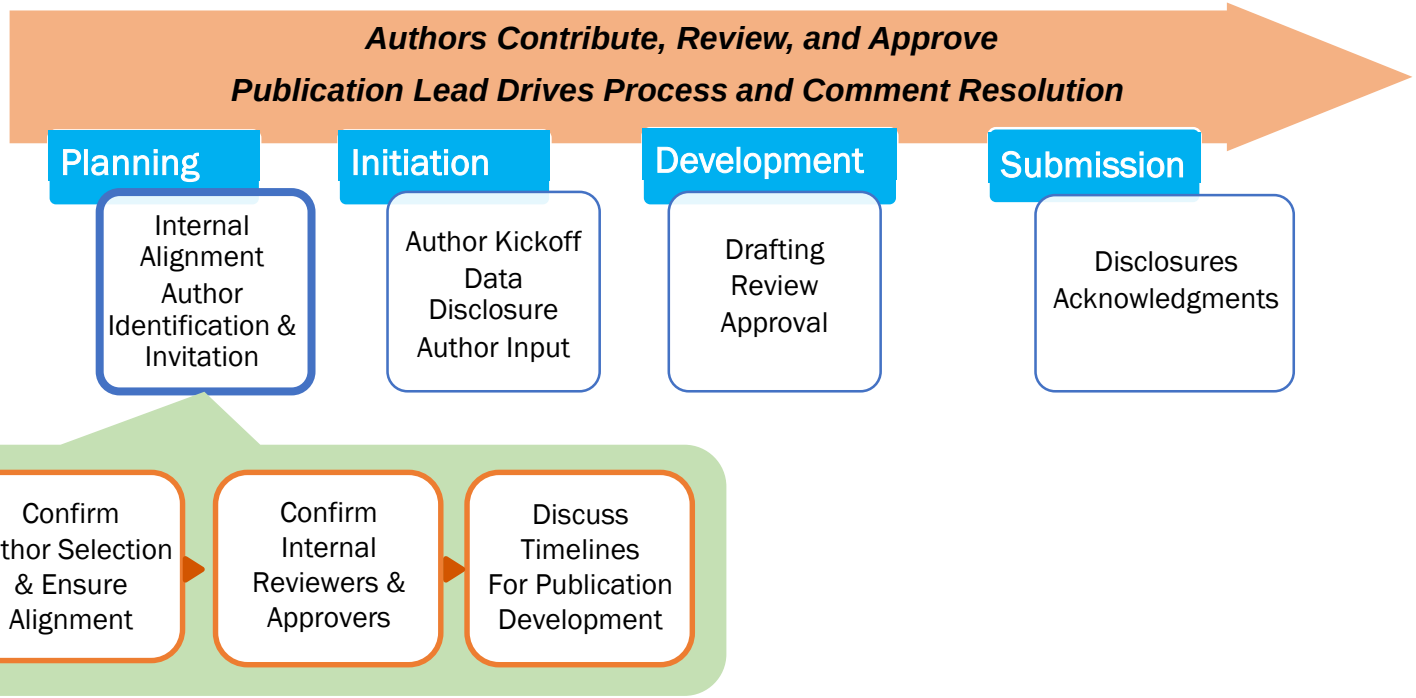
Drafting
Review
Approval

Submission

Disclosures
Acknowledgments

Documentation!

Planning: Internal Alignment

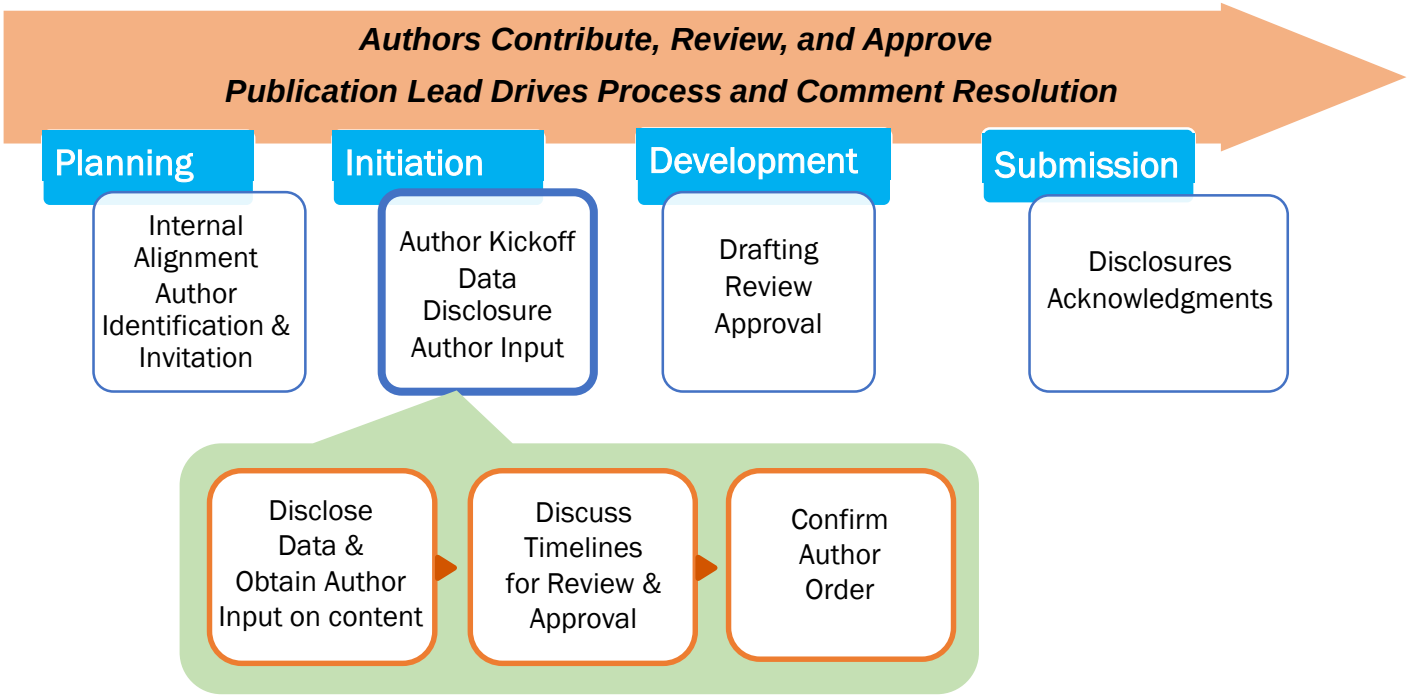


Identifying Appropriate Reviewers

- Internal Reviewers (usually 1 per functional area)
  - Publication Lead/Manager
  - Data owner
  - Statistician
  - Medical
  - R&D
  - Approver (if high-priority pub)
  - Others (based on scope of publication)
    - Safety Lead
    - Biomarker/pharmacology
- Internal Approvers (approval to submit/present company data/information)
  - Legal (Intellectual Property)
  - Senior-level manager

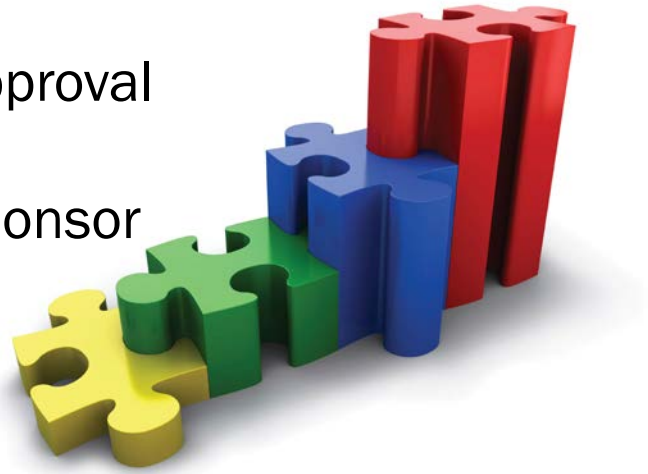
- External reviewers
  - Alliance partners
  - CRO
- Considerations
  - Minimal non-author input
  - Functional area representation
  - Internal reviewers ensure accurate, comprehensive, objective interpretation of data
  - Discuss publication development process – including required reviews and approvals and timeline for each step

Initiation: Author Kickoff



Initiation: Author Kickoff

- Set expectations – discuss process & timelines
  - GPP recommends informing the authors of the publication process to be followed
    - Describe required review steps (eg, outline, 1st draft, 2nd draft) and approvals (final draft)
  - Define timelines for review and approval
  - Author agreement defines roles & responsibilities for authors and sponsor
  - Confirm author order



Development: Review & Approval

Authors Contribute, Review, and Approve

Publication Lead Drives Process and Comment Resolution

Planning

Internal Alignment
Author Identification & Invitation

Initiation

Author Kickoff
Data Disclosure
Author Input

Development

Drafting
Review
Approval

Submission

Disclosures
Acknowledgments

Prepare Drafts

Reviewed by All Authors and relevant Internal stakeholders

Approval All Authors Internal Approvers

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Development: Review & Approval

- Early review (eg, at 1st draft step) is crucial to ensure timelines are adhered to and major changes are discussed early in publication development
  - Suggest delegate if reviewer not available
- Substantive changes late in publication development
  - Impact submission timeline
  - Disrespect authors' "ownership" of content
  - May affect relationship with authors (eg, harm KOL relationships)
- Internal reviewers' comments
  - Clearly delineate for authors' consideration
  - Consider appropriateness of comments: all reviewer comments are discoverable in audit

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Development: Review & Approval

- Approval to disclose (submit/present) company-owned data and/or information
  - Consider timing vs. author approval, (eg, may occur after author approval of final version)
  - Align with legal/compliance to ensure appropriate reviewers/approvers are included (eg, regulatory or legal review required)
  - Intellectual Property (IP) review strongly recommended for company-owned data
  - Many companies have a senior-level manager provide final approval before public disclosure
  - No surprises at this stage
    - Include approver at draft review to avoid surprises and/or major changes at end of process

Summary

- Design a publication review and approval process that is aligned with GPP
  - Embed process in quality and training documents
- Include relevant and appropriate internal reviewers
- Obtain alignment with internal reviewers and all authors on defined review process and timelines for review and approval
- Ensure all relevant stakeholders understand the process and their roles

Critical Manuscript Review

Mary Beth DeYoung, PhD
Global Publications Lead
AstraZeneca

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- What Does Good Look Like?
- Roles and Responsibilities
- Best Practices for Reviewers

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A “Good” Medical Publication

- Optimal definition: A trusted, frequently read, frequently cited manuscript
- Earlier definition: A paper rapidly and easily accepted for publication by journal reviewers
- Earliest definition: A paper that all authors and reviewers endorse after reviewing every word and number

General Characteristics of a Good Publication

- The paper can be understood by an intelligent non-expert
  - Appropriate background information provided
  - Well-written, Logical flow/structure provided
    - Figures and Tables give insight into the data
- Aligned with best scientific/medical thought
- Fair-balanced
  - All relevant medications mentioned
  - All key results mentioned
- Timely and relevant to the audience
  - Cites recent references and treatment guidelines

Journal Club

Perspectives on Treatment of Alzheimer's Disease: A Closer Look into EphB2 Depletion

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Details Matter

Appropriate background

Clear Aims

Clear Conclusions

Well-chosen references

Timely

Well-written

No typos

Complete Tables

Clear Figures

Well-structured

Thorough Supplementary Material

Good transitions/flow

Consistent with Protocol, SAP

Appropriate descriptors

All Endpoints

Perspectives on Treatment of Alzheimer's Disease: A Closer Look into EphB2 Depletion

Follows Publications Guidelines

Appropriate Analyses

Thorough Safety Info

Mention relevant treatment guidelines

Concise

Answers Medical Questions

Balanced discussions of other products

Clinically relevant

Easily Understood

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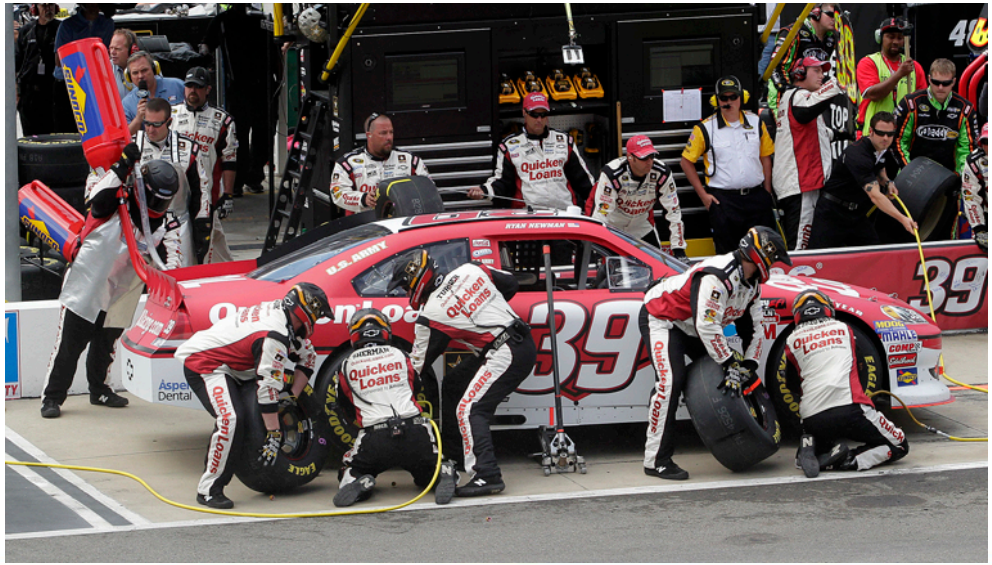
Manuscript Review: It Can Take a Village

- Extensive review from multiple people with different experiences and specialties improve a paper

Clear Roles Improve Efficiency

- A well-established, documented process will guide the team
  - Be aware of the primary responsibilities of others
  - Avoid overlapping/duplicating effort

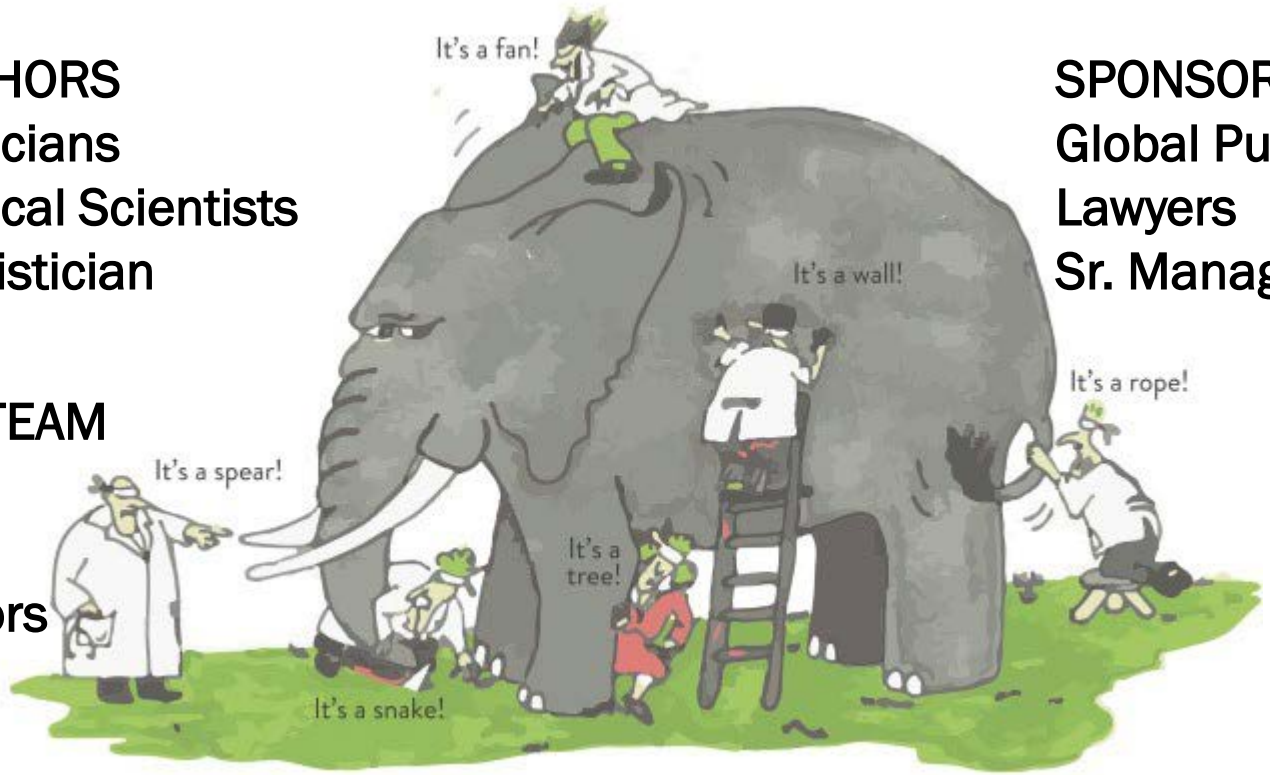


Key Reviewers

AUTHORS
Clinicians
Clinical Scientists
Statistician

SPONSOR
Global Publications Lead
Lawyers
Sr. Management

WRITING TEAM
Writers
Reviewers
Copy-Editors



JOURNAL
Editors
Reviewers
Copy-Editors

A Publications Expert Should Review It All

AUTHORS
Clinicians
Clinical Scientists
Statistician

SPONSOR
Global Publications Lead
Lawyers
Sr. Management

WRITING TEAM
Writers
Medical Director
Copy-Editors

JOURNAL
Editors
Reviewers
Copy-Editors

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Expert Publications Reviewers Can Improve Quality and Journal Reviews

- From a reader's perspective: Verify clarity and readability
- From an author's perspective
  - Identify ambiguities or errors that others may have missed
  - Look for inconsistencies
- From the sponsor's perspective
  - Ensure that accurate and complete information is provided
  - Relate this work to other publications on the therapy
  - Avoid inappropriate claims or controversial statements
- From a journal editor's perspective
  - Follow the journal's guidelines to the letter
  - Ensure consistency with the structure and style of other papers in the journal

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Who Writes and Who Reviews?

- A medical writer or physician may prepare the original draft
- Most other authors review but all may rewrite
  - Investigators ensure that the data presented is clinically important, interpreted appropriately and presented in context
  - Clinical Development team: Verify conclusions, check inclusiveness of data, check consistency with regulatory submissions
  - Statistician to verify methods, check accuracy of data
- Non-authors review but do not write

Reviewer Guidelines Over Time

Beginning

Time

End

MOST IMPORTANT

LEAST IMPORTANT

- Draft 1: Address major issues
  - Data in figures, tables, text okay?
  - Are analyses complete?
  - Are there any gaps in the information?
  - Approximately right length?

  <<Last opportunity to request analyses>>
- Draft 2: Focus on data interpretation
  - Work on discussion

  <<Last opportunity for new ideas>>
- Final draft: Minor changes

  <<Last opportunity to polish the paper>>

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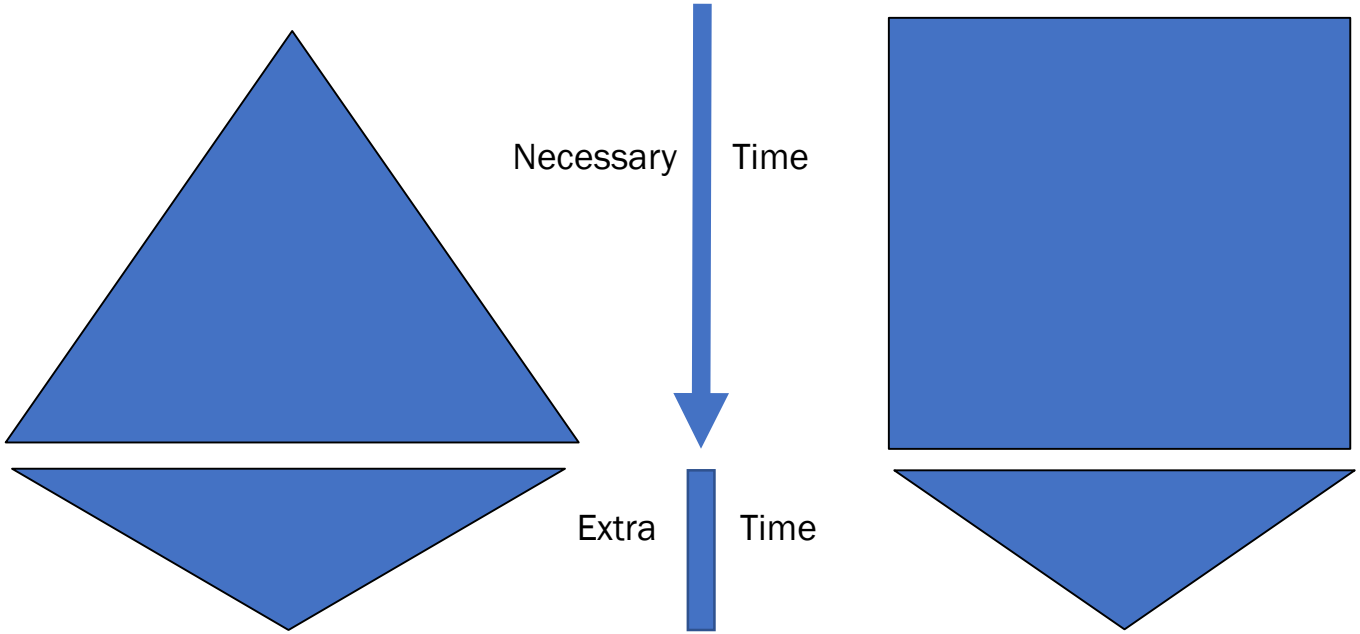
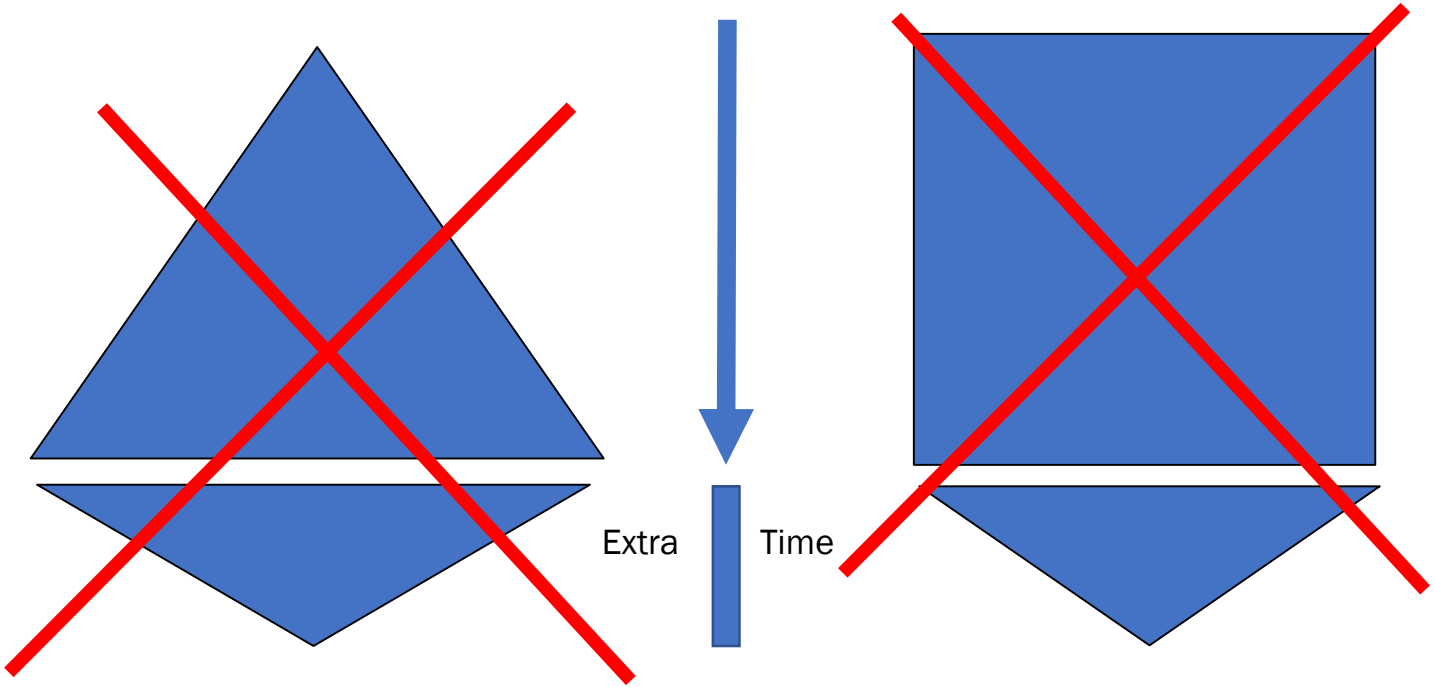
Different Review Patterns Cost Time



For Efficiency, Avoid These Review Patterns!



Best Practices for Reviewers

- Provide **Specific Comments** that
  - **define problems** and/or
  - **suggest actions**

Examples:

NOT: Hate the title!!!

NOT: This makes no sense!!!!!!

NOT: “You are missing a key reference”

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Best Practices for Reviewers

- Provide **Specific Comments** that
  - **define problems** and/or
  - **suggest actions**

Examples:

NOT: Hate the title!!!
Good: Add the study design to the title.

NOT: This makes no sense!!!!!!
Good: What two groups are being compared? Please add.

NOT: “You are missing a key reference”
Good: For completeness, cite Doe et al, Journal Name, 2012

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Best Practices for Reviewers

- **State the Importance** of your comment
  - REQUIRED—often used for compliance-or accuracy-related issues
  - Recommended—there is room for negotiation
  - Editorial, which means grammatical or preference (Vanilla vs chocolate)

Examples:

NOT: Consider adding information on adverse events

NOT: Who are the patients?

NOT: DO NOT USE RELATIONSHIP!!!!

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Best Practices for Reviewers

- **State the Importance** of your comment
  - REQUIRED—often used for compliance-or accuracy-related issues
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Examples:

NOT: Consider adding information on adverse events

Good: REQUIRED: Safety data is missing. Must include all safety endpoints.

NOT: Who are the patients?

Good: Recommended: Add more comorbidities and use of key medications to baseline demographics to more fully define the patient population

NOT: DO NOT USE RELATIONSHIP!!!!

Good: Editorial: Globally change every “relationship” to “relation”

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Best Practices for Non-Authors

- Word your comments carefully to minimize influence but support quality
  NOT: "I needed to rewrite this entire section!"
  GOOD: "Please find suggested additions for the author's consideration"
- Keep in mind that the work needs to be owned and shaped by the authors
  - Raising questions is best such as "Have the authors considered their results in light of x paper?"
  - "The authors may want to consider the alternative of.."
- If your changes are substantial, an acknowledgement may be appropriate

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The Red-Face Test for Non-Authors

NOT:

Pharmaceutical Company Hides Negative Endpoints!

Pharmaceutical Company Removes Safety Data!

INSTEAD:

Pharmaceutical Company Requests Clarification of Methods

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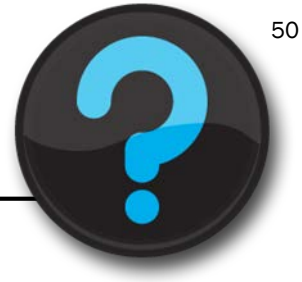
For Sponsor Reviewers: Fair-Balance and Claims

- Are discussions of other drugs balanced?
  - Are all relevant drugs in the class or for the indication mentioned?
  - Are all pertinent data presented?
- Are claims avoided?
  - Claims are often broad statements in present tense
    - Example: “Miracle drug cures horrible disease”
  - Specific past events supported by numbers are less likely to be claims
    - Example: “In a double-blind randomized controlled study of 1000 patients with horrible disease, the incidence of death per 5 yr was Y% in patients given standard therapy and half that in patients treated with miracle drug.”

For Sponsor Reviewers: Claims, Causality, Characterization

- Are any claims inferred by association or based on poor quality data?
  - Example: Reducing blood pressure reduces death. Newdrug reduces blood pressure so…
  - *No statement about Newdrug and death can be made until an adequate outcomes study is complete*
- Are unsupported statements of causality made?
  - Did a treatment cause something else, or was the result "associated with" treatment?
- Are descriptors appropriate?
  - Do the data support "Powerful, stable, long-term, best"? …
- Consider stating when use is investigational or approved

Which Issue Is Most Important to the Sponsor (1)?



a. The tables are not well-organized
b. One of the authors rewrites the paper at every draft, correcting her own corrections
c. The authors included a huge paragraph in the Discussion detailing irrelevant preclinical data
d. The authors' interpretation of the data is not completely consistent with the numbers given

Which Issue Is Most Important to the Sponsor (2)?

a. The writing style is difficult to read
b. All efficacy endpoints in the SAP are not included
c. The safety data should be reported for the pre-specified timepoint
d. The study data do not support statements of comparison with competitors
e. The wording on the indication used in regulatory documents is not followed

Summary

- Publications professionals may assist in identifying and solving issues that others may not recognize or know how to solve
- Agreement on best practices for review from the beginning of a project can assist authors and reviewers in completing their work efficiently
  - Give most comments at the beginning; least at end
  - Provide specific comments describing the problem and offering a solution
  - State the importance of comments
  - Write comments suitable for all to read

Questions

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- To ensure anonymity, before sending please choose the drop-down box option, "Hosts and Presenters." Otherwise, **ALL** audience members will be able to see your submitted question
- Due to the nature of this particular ISMPP U topic and the fact that it is an overview of many individual presentations, we may not be able to answer all questions. We are happy to follow up with specific faculty after the ISMPP U if needed

Upcoming ISMPP U

DATE	TOPIC	FACULTY
October 2018	ICMJE Guidelines for Data Sharing and EU GDPR Privacy Regulations	Karen Mittleman Brian Sharkey

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- We hope you enjoyed today's presentation.
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- We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!