



THANK YOU FOR JOINING ISMPP U
TODAY!

The program will begin promptly at 11:00 am EDT

January 27, 2016

ISMPP WOULD LIKE TO THANK . . .

. . . the following Titanium and Platinum Corporate Sponsors
for their ongoing support of the Society:



An ICON plc Company



ISMPP ANNOUNCEMENTS

- Registration now open for the **12th Annual Meeting of ISMPP, April 11-13th**; register soon to take advantage of early bird pricing and discounted room rate www.ismpp.org
- Interested in taking the March CMPP exam? Don't miss the **February 1st deadline**.
- Get social! Follow us on **Twitter (@ISMPP)** or join the conversation at **ISMPP's LinkedIn** group page.
- This program qualifies for **.5 credit** towards recertification

CMPP™: COULD YOU BE A MENTOR?

ISMPP is seeking volunteers to provide mentorship to individuals considering sitting for the exam or who have questions related to recertification

- Must be CMPP™ certified and willing to be listed on the ISMPP website
- Please email cmpp@ismpp.org to register your interest



FOR YOUR BEST ISMPP U EXPERIENCE . . .

To optimize your webinar experience today:

- Use a hardwired connection if available
- Use the fastest internet connection available to you
- If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers

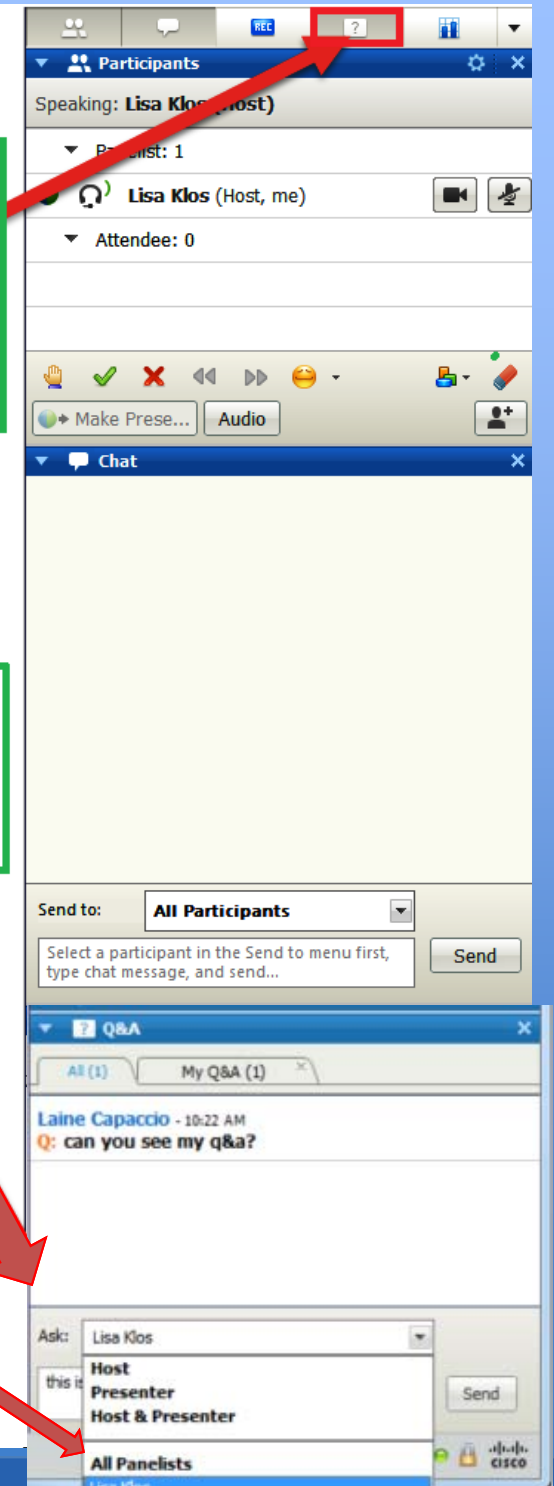
QUESTIONS...

- To ask a question, please type your query into the Q&A box
 - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, **"ALL Panelists"** Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions

1. Click on the question mark to view the Q&A box

2. Type your question into the Q&A box and SEND

NOTE: Make sure you send your question to "ALL Panelists"



The background features a stylized, abstract design with large, overlapping geometric shapes. A prominent green shape occupies the upper left, a blue shape is in the upper right, and a large orange shape curves across the middle and bottom. The shapes have a faceted, crystalline appearance with visible edges and some internal shading.

ADVENTURES IN MANUSCRIPT DEVELOPMENT: GOOD PUBLICATION PRACTICE IN THE REAL WORLD

INTRODUCTIONS

- **FACULTY:** **Ann L. Davis** is a Scientific Director at StemScientific, an Ashfield Healthcare Communications company, where she develops and oversees execution of publication plans. She has been in the medical education field for more than 20 years, including content development roles at Centocor 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™ (CMPP), she has served as presenter at TIPPA and other publications seminars, workshop leader for the American Medical Writers Association, co-author of multiple ISMPP presentations, and member of the ISMPP Credentialing Committee. Ann completed her graduate studies at the University of Texas Houston Health Science Center.

INTRODUCTIONS

- **FACULTY:** **Godfrey Lisk** is a Senior Scientific Specialist at PAREXEL International GmbH. He graduated from Imperial College, London with a PhD in Biochemistry and joined PAREXEL International GmbH as a medical writer in 2010. Prior to joining PAREXEL, Godfrey worked for the United States Department of Health and Human Services at the National Institutes of Health, Bethesda, Maryland, USA, as an infectious disease fellow. At PAREXEL he is responsible for developing medical education and external expert engagement programs, and publications planning. Godfrey is a member of the Royal College of Science, the American Society of Tropical Medicine and Hygiene and an active ISMPP committee member (ISMPP-U).

INTRODUCTIONS

- **FACULTY:** **Bianca B. Ruzicka** is a medical communications specialist with 19 years' medical communications and publications experience. She is currently the Director of Medical Affairs – Oncology at Gilead Sciences. Bianca began her career in medical communications as an Assistant Director-Scientific Communications at Bayer Pharmaceuticals. Until recently, Bianca was the Director of Medical Communications and Director of Global Publications for Onyx Pharmaceuticals (an Amgen Subsidiary). She has also held positions on the agency side, including Sr VP-Scientific Services at ApotheCom and Managing Director of Helix Medical Communications; during this tenure, she spear-headed the publication of good publication practice guidelines for medical communication agencies. Bianca received her PhD in pharmacology from Queen's University in Ontario, Canada, and completed her postdoctoral training at the University of Michigan in Ann Arbor.

INTRODUCTIONS

- **MODERATOR:** **Lisa Baker** is a Medical Director at inScience Communications, part of Springer Healthcare, in New York, NY. She has been an agency-based medical writer since 2006, including five years at Envision Pharma Group. Lisa's work has included publication development and strategic publication planning for varied clients and therapeutic areas. Lisa received her PhD in research psychology from McGill University. She is an ISMPP CMPP™ and a member of the ISMPP U committee since 2013.

DISCLAIMER

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

OBJECTIVES

At the end of this presentation, attendees should be able to:

- Identify commonly followed publication guidelines and applicability to manuscript development
- More effectively manage strategically timed publications
- Establish best practices for author selection for scientific papers
- Understand and manage the pitfalls that may arise from compressed timelines (accelerated publication)

MANUSCRIPT DEVELOPMENT IN A PERFECT WORLD

Ann L. Davis, MPH, ISMPP CMPP™
Scientific Director, StemScientific
Ashfield Healthcare Communications

PUBLICATION PROFESSIONAL'S ROLE IN MANUSCRIPT DEVELOPMENT

- Eschew the assembly-line mentality!
- Understand what is happening with all moving parts at all times
- Ensure all the rules are being followed
- Ensure authors and other stakeholders are kept in the loop



Designated keeper of quality control

PUBLICATION PRACTICE GUIDELINES

- International Society for Medical Publication Professionals (ISMPP)
Good Publication Practice (GPP) (<http://www.ismpp.org/>)
 - Communication of industry-sponsored research
 - Integrity, completeness, transparency, accountability

PUBLICATION PRACTICE GUIDELINES

- International Society for Medical Publication Professionals (ISMPP)
Good Publication Practice (GPP) (<http://www.ismpp.org/>)
 - Communication of industry-sponsored research
 - Integrity, completeness, transparency, accountability
- International Committee of Medical Journal Editors (ICMJE)
Recommendations/Publication (<http://www.icmje.org/>)
 - Manuscript formatting, ethics, principles
 - Gold standard for authorship criteria

PUBLICATION PRACTICE GUIDELINES

- International Society for Medical Publication Professionals (ISMPP)
Good Publication Practice (GPP) (<http://www.ismpp.org/>)
 - Communication of industry-sponsored research
 - Integrity, completeness, transparency, accountability
- International Committee of Medical Journal Editors (ICMJE)
Recommendations/Publication (<http://www.icmje.org/>)
 - Manuscript formatting, ethics, principles
 - Gold standard for authorship criteria

PUBLICATION PRACTICE GUIDELINES

- International Society for Medical Publication Professionals (ISMPP) Good Publication Practice (GPP) (<http://www.ismpp.org/>)
 - Communication of industry-sponsored research
 - Integrity, completeness, transparency, accountability
- International Committee of Medical Journal Editors (ICMJE) Recommendations/Publication (<http://www.icmje.org/>)
 - Manuscript formatting, ethics, principles
 - Gold standard for authorship criteria
- World Association of Medical Editors (WAME) (<http://wame.org/>)
 - Fosters international cooperation among journal editors
 - Conflicts of Interest (COI) guidelines
- Committee on Publication Ethics (COPE) (<http://publicationethics.org/>)
 - Publication ethics for journal editors
 - How to report misconduct

PUBLICATION PRACTICE GUIDELINES

- Medical Publishing Insights and Practices (MPIP) Initiative (<http://www.mpip-initiative.org/>)
 - 10 Recommendations for Closing the Credibility Gap in Industry-Sponsored Research
 - Author Submission Toolkit
 - Five-Step Authorship Framework
- Consolidated Standards of Reporting Trials (CONSORT) (<http://www.consort-statement.org/home/>)
 - Ensure adequate reporting of RCTs
 - Patient disposition diagram, manuscript submission checklist
- EQUATOR Network for guidelines related to all study types (<http://www.equator-network.org/>)

ISMPP'S GPP3: OVERVIEW

- GPP establishes standards to:
 - Increase transparency
 - Prevent publication bias
 - Standardize relationship between pharmaceutical companies, investigators

ISMPP'S GPP3: OVERVIEW

- GPP establishes standards to:
 - Increase transparency
 - Prevent publication bias
 - Standardize relationship between pharmaceutical companies, investigators
- Signed agreements between sponsor, authors/investigators
 - Clearly spell out roles, responsibilities, obligations
 - No *honoraria* for authorship; GPP3 clarifies payment is allowed for work related to publication development

ISMPP'S GPP3: OVERVIEW

- GPP establishes standards to:
 - Increase transparency
 - Prevent publication bias
 - Standardize relationship between pharmaceutical companies, investigators
- Signed agreements between sponsor, authors/investigators
 - Clearly spell out roles, responsibilities, obligations
 - No *honoraria* for authorship; GPP3 clarifies payment is allowed for work related to publication development
- Authors' access to data
- Role of professional medical writers
- Acknowledgment of contributions by authors, non-authors
- Checklist to ensure adherence to guidelines

ICMJE AUTHORSHIP CRITERIA

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
2. Drafting the work or revising it critically for important intellectual content
3. Final approval of the version to be published
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

ICMJE AUTHORSHIP CRITERIA

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
2. Drafting the work or revising it critically for important intellectual content
3. Final approval of the version to be published
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

ICMJE AUTHORSHIP CRITERIA

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
2. Drafting the work or revising it critically for important intellectual content
3. Final approval of the version to be published
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

➤ **Authors must meet all 4 criteria**

➤ **All who meet the 4 criteria must be listed as authors**

MPIP: FIVE-STEP AUTHORSHIP FRAMEWORK

Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications

Ana Marušić^{1*}, Darko Hren², Bernadette Mansi^{3,4}, Neil Lineberry^{4,5}, Ananya Bhattacharya^{4,6}, Maureen Garrity^{4,7}, Juli Clark^{4,8}, Thomas Gesell^{4,9}, Susan Glasser^{4,10}, John Gonzalez^{4,11}, Carolyn Hustad^{4,12}, Mary-Margaret Lannon^{4,13}, LaVerne A Mooney^{4,14} and Teresa Peña^{4,15}

1. Establish authorship working group early in trial
2. Determine substantial contribution criteria
3. Document trial contributions
4. Determine those making substantial contribution
5. Ensure authors meet remaining ICMJE criteria

PAYMENT TO AUTHORS

- GPP2¹: No honoraria for authors
 - Many thought that meant no payment to authors under any circumstances

PAYMENT TO AUTHORS

- GPP2¹: No honoraria for authors
 - Many thought that meant no payment to authors under any circumstances
- GPP3²: Authors may be paid for work conducted in connection with publication (e.g., writing, statistical analysis)
 - *Details of payment must be fully disclosed*
 - *No payment for purpose of enticing someone to be an author or influence author's opinion*

INTERACTIONS WITH AUTHORS

- Authors direct development of publication
 - Lead author is driver of manuscript

INTERACTIONS WITH AUTHORS

- Authors direct development of publication
 - Lead author is driver of manuscript
- Ensuring authors' involvement
 - ICMJE requires authors to (write or) review, approve

INTERACTIONS WITH AUTHORS

- Authors direct development of publication
 - Lead author is driver of manuscript
- Ensuring authors' involvement
 - ICMJE requires authors to (write or) review, approve
- Writer develops draft under authors' direction
 - May offer suggestions
 - Provides guidance on publication guidelines, practices

INTERACTIONS WITH AUTHORS

- Authors direct development of publication
 - Lead author is driver of manuscript
- Ensuring authors' involvement
 - ICMJE requires authors to (write or) review, approve
- Writer develops draft under authors' direction
 - May offer suggestions
 - Provides guidance on publication guidelines, practices
- All authors must be aware of – and accept – writing support

INTERACTIONS WITH AUTHORS

- Authors direct development of publication
 - Lead author is driver of manuscript
- Ensuring authors' involvement
 - ICMJE requires authors to (write or) review, approve
- Writer develops draft under authors' direction
 - May offer suggestions
 - Provides guidance on publication guidelines, practices
- All authors must be aware of – and accept – writing support
- *Set realistic expectations upfront*

AUDIENCE QUESTION



Why isn't a medical writer usually considered an author?

- A. Writer is paid for his/her contribution
- B. Writer is usually not involved in the research
- C. Writer cannot help to resolve questions related to the accuracy of the publication
- D. Writing is not the same as critically revising the manuscript

WHO SHOULD BE ACKNOWLEDGED?

- Substantial contributors not meeting full authorship criteria, including individuals providing writing/editorial assistance
- Journal instructions and journal editors should ask authors to declare assistance with manuscript preparation, disclose identity of individuals and supporting entity

WHAT SHOULD BE SPECIFIED IN A CONTRIBUTORSHIP MODEL?

- Specific author and/or sponsor contributions:

- Study conception and design
- Conducting or managing study
- Collecting, interpreting data
- Designing, conducting statistical analysis
- Drafting, reviewing, approving manuscript
- Funding

Author contributions; for example, "Authors A and B designed the study. Authors A and C analyzed and interpreted the study data. Author A reviewed the literature. All authors critically reviewed the manuscript and approved the final version for submission."

WHAT SHOULD BE SPECIFIED IN A CONTRIBUTORSHIP MODEL?

- Specific author and/or sponsor contributions:

- Study conception and design
- Conducting or managing study
- Collecting, interpreting data
- Designing, conducting statistical analysis
- Drafting, reviewing, approving manuscript
- Funding

Author contributions; for example, "Authors A and B designed the study. Authors A and C analyzed and interpreted the study data. Author A reviewed the literature. All authors critically reviewed the manuscript and approved the final version for submission."

- Specific contribution of writers
- Acknowledgment of statisticians, key research personnel

"Under the direction of the authors, Writer D (ST Medical Writing) drafted the initial version of the manuscript . . .

- Investigators, patient participants (as group)
- Permission to acknowledge contributors should be obtained, as readers may infer endorsement of data and conclusions

WHAT IF...?

- After submitting a manuscript, the journal editor insists the medical writer qualifies for authorship. The medical writer was paid for developing the publication. Is the medical writer an author?

WHAT IF...?

- After submitting a manuscript, the journal editor insists the medical writer qualifies for authorship. The medical writer was paid for developing the publication. Is the medical writer an author?
 - Journals following non-ICMJE authorship criteria may require person who drafted the manuscript to be an author
 - For review articles, writer may meet ICMJE criterion #1
 - Payment by sponsor should be disclosed
 - GPP3 clarifies that authors can be paid for work associated with publication development

ANATOMY OF A MANUSCRIPT: IMRaD STRUCTURE

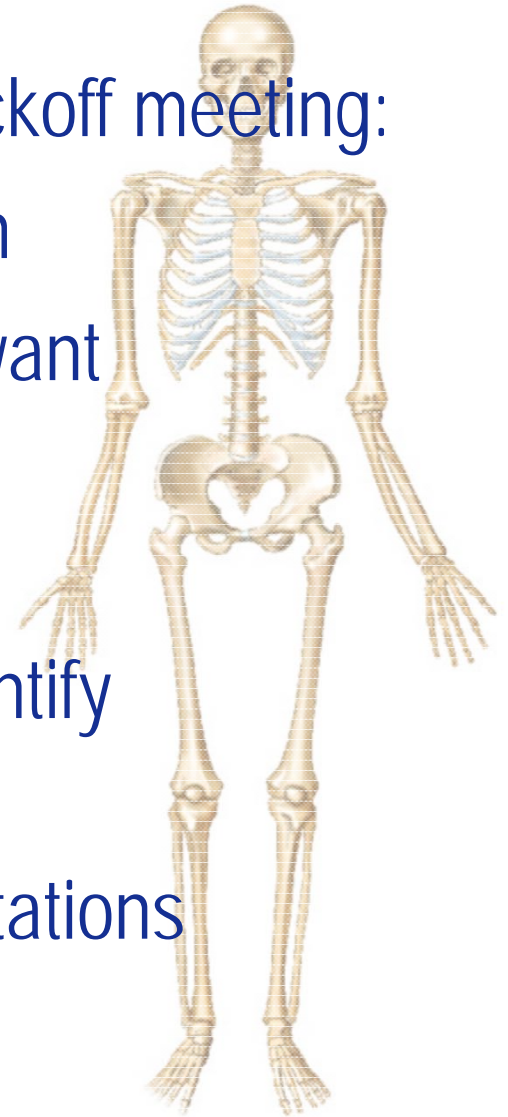
- Introduction
- Methods
- Results
and
- Discussion/Conclusions
- Section titles, order may vary by journal
 - Conclusions may be separate section following Discussion



GETTING STARTED: MANUSCRIPT OUTLINE

Based on information exchange during author kickoff meeting:

- Understand scope, objectives, publication plan
- Determine how much detail authors/sponsor want
 - Skeleton vs bulleted first draft
 - May include full tables, figures
- Literature search – therapeutic landscape, identify appropriate references
- Overview of target journal's requirements, limitations



STORY FLOW ORGANIZES THE FACTS IN MEANINGFUL, RELEVANT WAY

- Throwing list of scientific facts into a paper \Rightarrow disjointed, illogical
- Story flow helps reader understand, appreciate those facts
 - Makes us care
 - Makes us want to know more

STORY FLOW ORGANIZES THE FACTS IN MEANINGFUL, RELEVANT WAY

- Throwing list of scientific facts into a paper \Rightarrow disjointed, illogical
- Story flow helps reader understand, appreciate those facts
 - Makes us care
 - Makes us want to know more
 - *Increases likelihood of acceptance*



STORY FLOW: INTRODUCTION SETS THE STAGE

Typical Order	Example (Outline)
Introduce the issue/unmet need (make us care)	Glophitis affects 2 million patients; no approved treatment available

STORY FLOW: INTRODUCTION SETS THE STAGE

Typical Order	Example (Outline)
Introduce the issue/unmet need (make us care)	Glophitis affects 2 million patients; no approved treatment available
Introduce new treatment, how it may help (make us want to know more)	Novel mechanism of Amazinex inhibits production of glophix-20 proteins Amazinex has demonstrated efficacy, tolerability, low discontinuation rates in short-term Phase 2 trials

STORY FLOW: INTRODUCTION SETS THE STAGE

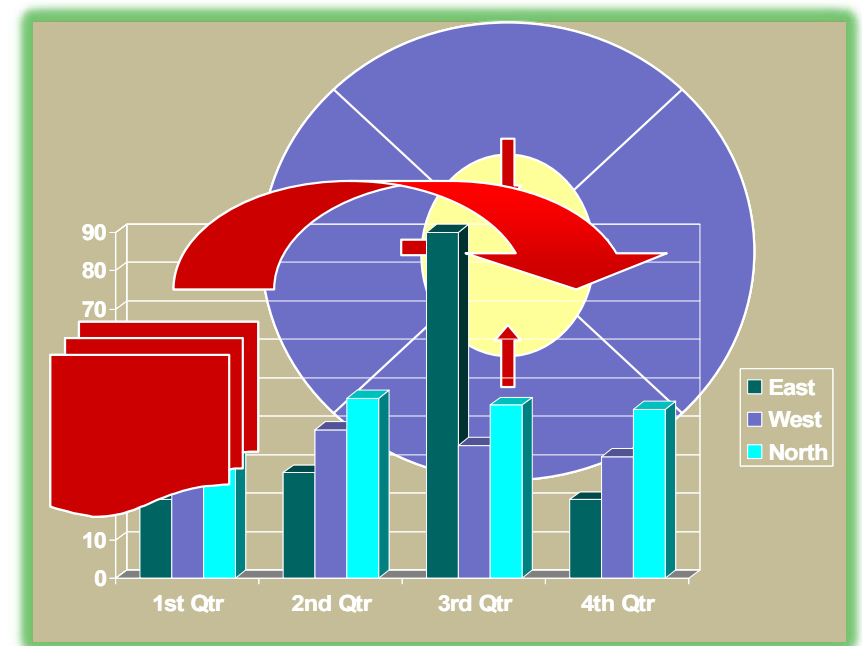
Typical Order	Example (Outline)
Introduce the issue/unmet need (make us care)	Glophitis affects 2 million patients; no approved treatment available
Introduce new treatment, how it may help (make us want to know more)	Novel mechanism of Amazinex inhibits production of glophix-20 proteins Amazinex has demonstrated efficacy, tolerability, low discontinuation rates in short-term Phase 2 trials
What this study will tell us (and reminder of who you're trying to help)	Phase 3 trial to evaluate Amazinex as long-term treatment option for patients with mild-to-moderate glophitis

OVERALL COMPOSITION

- Methods section includes critical components of study design
 - Demonstrates validity, integrity of study
- Results address primary (and key secondary) efficacy and safety outcomes

OVERALL COMPOSITION

- Methods section includes critical components of study design
 - Demonstrates validity, integrity of study
- Results address primary (and key secondary) efficacy and safety outcomes
 - Figures, tables emphasize, enhance understanding of results
 - Avoid excessive duplication in text



REFERENCES

- Primary references only
 - Ensures your statement is accurate

REFERENCES

- Primary references only
 - Ensures your statement is accurate

"Glophitis is considered one of the most challenging diseases of the 21st century" (cites Smith 2013)



"Diagnosing and managing glophitis can be challenging" (what Smith 2013 actually said)

REFERENCES

- Primary references only
 - Ensures your statement is accurate

"Glophitis is considered one of the most challenging diseases of the 21st century" (cites Smith 2013)

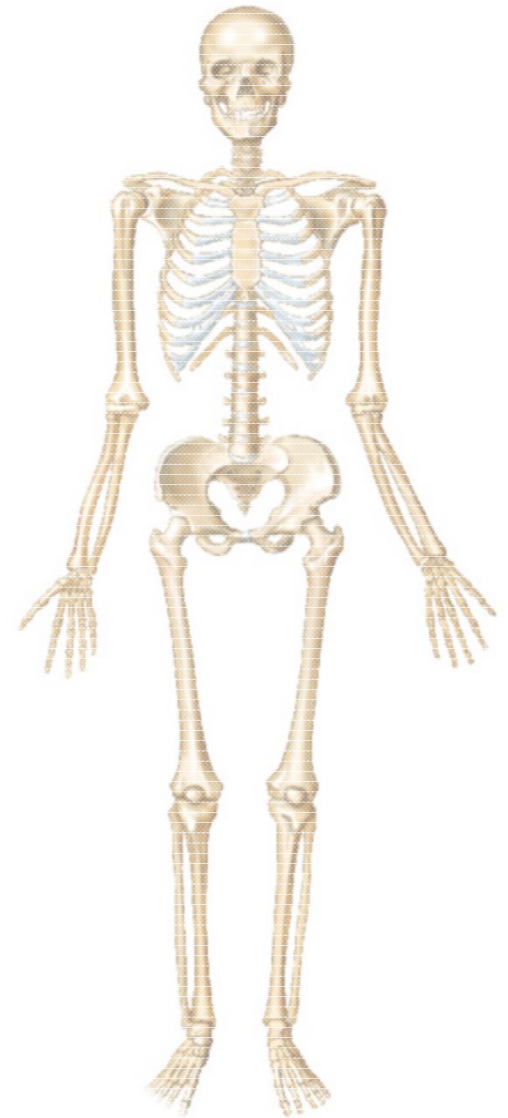


"Diagnosing and managing glophitis can be challenging" (what Smith 2013 actually said)

- Verify every reference provided by other sources
 - Authors/sponsors may tell you to use reference that does not support statement

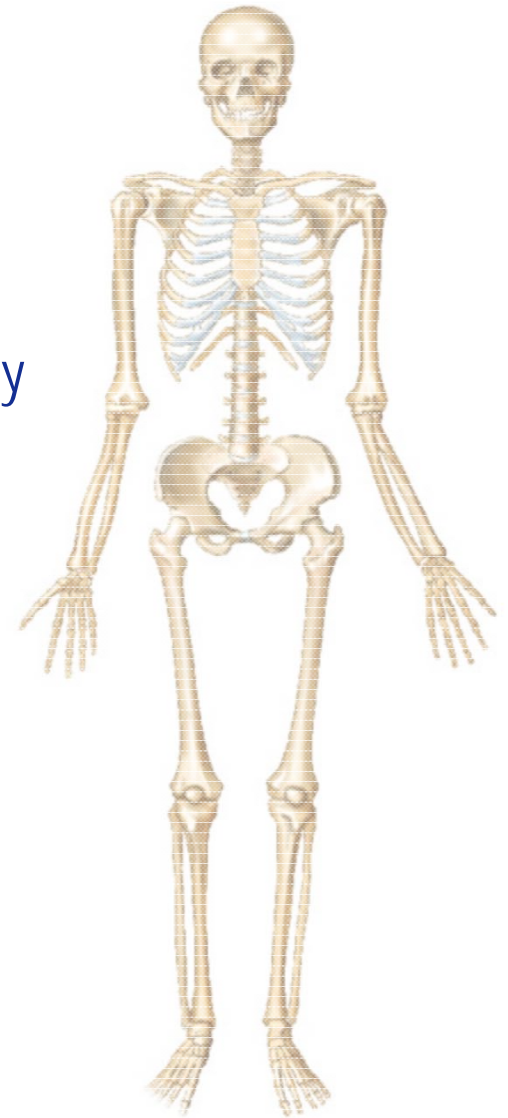
KEY POINTS OF MANUSCRIPT DEVELOPMENT

- Abstract must be consistent with manuscript text
 - Wait to write until after authors review first draft



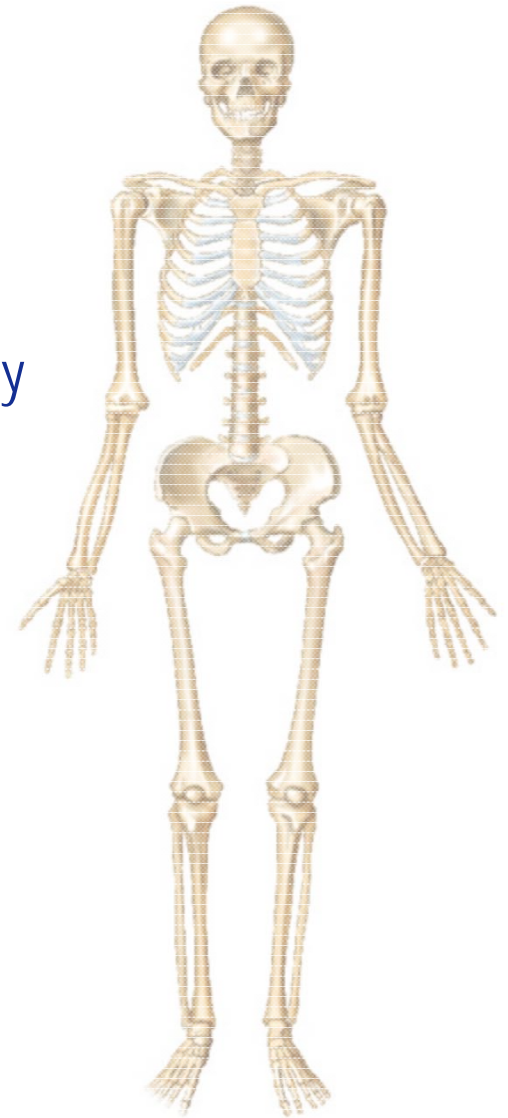
KEY POINTS OF MANUSCRIPT DEVELOPMENT

- Abstract must be consistent with manuscript text
 - Wait to write until after authors review first draft
- Do not overstate efficacy or understate safety issues
 - “Generally well tolerated” is not a sufficient summary of safety



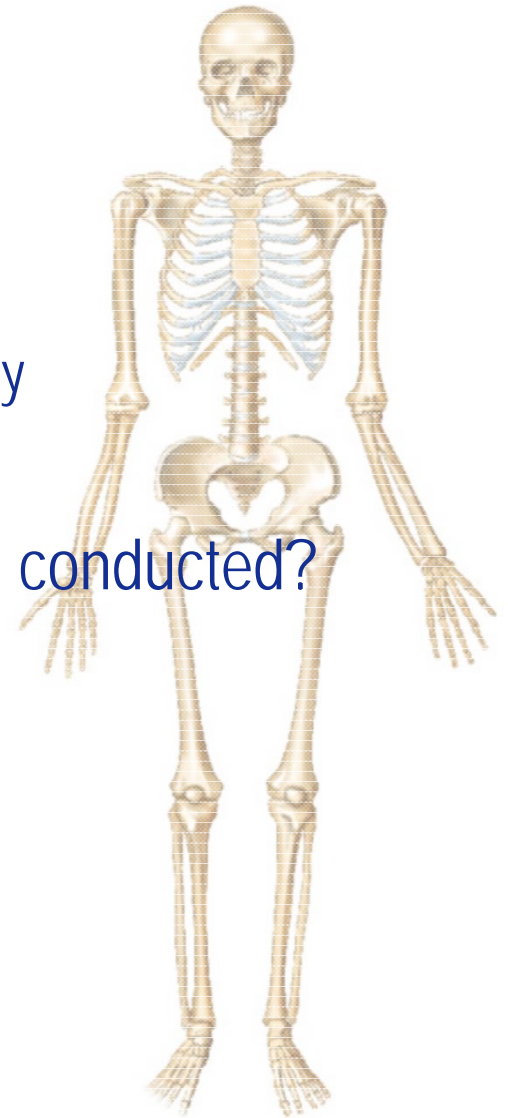
KEY POINTS OF MANUSCRIPT DEVELOPMENT

- Abstract must be consistent with manuscript text
 - Wait to write until after authors review first draft
- Do not overstate efficacy or understate safety issues
 - “Generally well tolerated” is not a sufficient summary of safety
- No interpretation in Results section



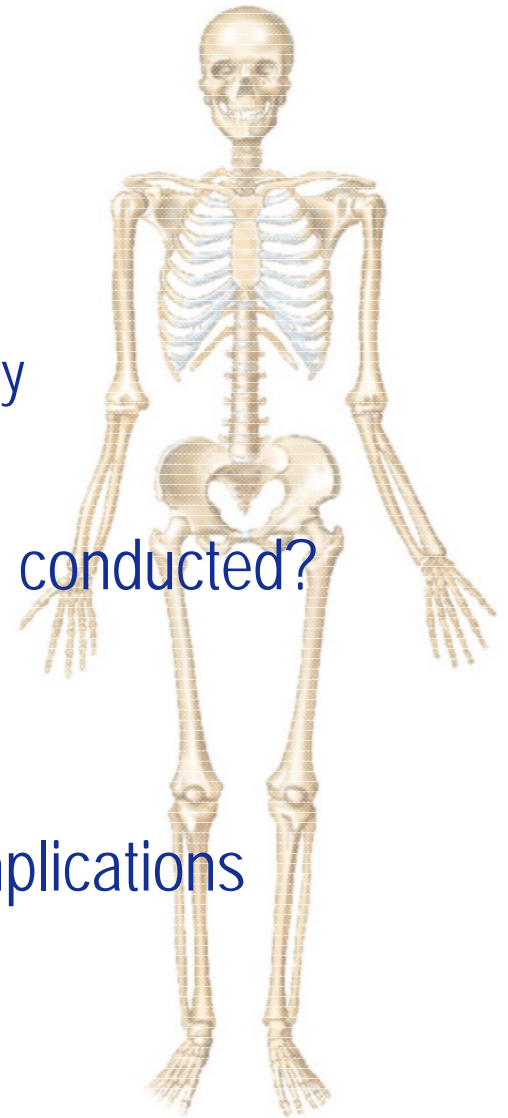
KEY POINTS OF MANUSCRIPT DEVELOPMENT

- Abstract must be consistent with manuscript text
 - Wait to write until after authors review first draft
- Do not overstate efficacy or understate safety issues
 - “Generally well tolerated” is not a sufficient summary of safety
- No interpretation in Results section
- Methods or Results: Did you know it before study was conducted?
 - If yes \Rightarrow Methods
 - If no \Rightarrow Results



KEY POINTS OF MANUSCRIPT DEVELOPMENT

- Abstract must be consistent with manuscript text
 - Wait to write until after authors review first draft
- Do not overstate efficacy or understate safety issues
 - “Generally well tolerated” is not a sufficient summary of safety
- No interpretation in Results section
- Methods or Results: Did you know it before study was conducted?
 - If yes \Rightarrow Methods
 - If no \Rightarrow Results
- Conclusion is statement of overall study outcomes, implications
 - What the results mean to target audience



SECOND DRAFT... THIRD DRAFT...

- Keep record of authors' comments
- Merge comments, considering objectives, scope of manuscript
 - Consult with lead/senior authors on diverse directions
 - Tell authors privately why significant changes were not made ("Please advise if you feel strongly...")
 - Be forthcoming, transparent about what was done and why
 - Revisions, additions can be called out with tracked changes, highlighting
 - *Document all communication with authors*

SECOND DRAFT... THIRD DRAFT...

- Keep record of authors' comments
- Merge comments, considering objectives, scope of manuscript
 - Consult with lead/senior authors on diverse directions
 - Tell authors privately why significant changes were not made ("Please advise if you feel strongly...")
 - Be forthcoming, transparent about what was done and why
 - Revisions, additions can be called out with tracked changes, highlighting
 - *Document all communication with authors*
- Remember the authors own the content!

AUDIENCE QUESTION



You are told to add an author after second-draft review. What is the BEST way to ensure the individual merits authorship?

- A. Have new author review data and second draft to ensure participation
- B. Have new author review and approve final version
- C. Request documentation of new author's research contribution and review of manuscript
- D. Consult with publication manager for permission to add new author

APPROPRIATE TARGET JOURNALS

- Journal should be peer-reviewed *and* indexed
 - If it's in PubMed database, it's indexed
- Journals that claim to be peer-reviewed but are not indexed are *not* appropriate submission targets

APPROPRIATE TARGET JOURNALS

- Journal should be peer-reviewed *and* indexed
 - If it's in PubMed database, it's indexed
- Journals that claim to be peer-reviewed but are not indexed are *not* appropriate submission targets

The screenshot shows the PubMed website interface. At the top, there's a navigation bar with 'NCBI', 'Resources', and 'How To'. Below this is the 'PubMed.gov' logo and the text 'US National Library of Medicine National Institutes of Health'. A search bar contains the text 'PubMed' and 'journal of clinical oncology[jour]'. To the right of the search bar are links for 'RSS', 'Save search', and 'Advanced'. Below the search bar, there are links for 'Show additional filters', 'Display Settings: Summary, 20 per page, Sorted by Recently Added', and 'Send to:'. The main content area displays 'Results: 1 to 20 of 20435'. The first result is a checkbox followed by the title 'Time to Diagnosis of Ewing Tumors in Children and Adolescents Is Not Associated With Metastasis or Survival'. Below the title is the author information 'Alonso L, Navarro-Perez V, Sanchez-Muñoz A, Alba E.' and the journal information 'J Clin Oncol. 2014 Nov 10. pii: JCO.2014.58.4466. [Epub ahead of print] No abstract available. PMID: 25385742 [PubMed - as supplied by publisher]'. There is also a link for 'Related citations'. The second result is a checkbox followed by the title 'Individual Patient Data Analysis of Progression-Free Survival Versus Overall Survival As a First-Line End Point for Metastatic Colorectal Cancer in Modern Randomized Trials: Findings From the Analysis and Research in Cancers of the Digestive System Database'. Below the title is the author information 'Shi Q, de Gramont A, Grothey A, Zalcberg J, Chibaudel B, Schmoll HJ, Seymour MT, Adams R, Saltz L, Goldberg RM, Punt CJ, Douillard JY, Hoff PM, Hecht JR, Hurwitz H, Diaz-Rubio E, Porschen R, ...'.

APPROPRIATE TARGET JOURNALS

- Journal should be peer-reviewed *and* indexed
 - If it's in PubMed database, it's indexed
- Journals that claim to be peer-reviewed but are not indexed are *not* appropriate submission targets

The image displays two screenshots of the PubMed.gov website interface. The left screenshot shows a search for "journal of clinical oncology[jour]" with results displayed, including a list of articles. The right screenshot shows a search for "European Infectious Diseases Review[jour]" with a message stating "The following term was not found in PubMed: European Infectious Diseases Review[jour]. No items found." The phrase "No items found." is circled in red.

JOURNAL SELECTION: CONSIDERATIONS

- Target audience
- Aims and scope
- Similar topics published
- Submission guidelines
- Impact factor (?)
- Timeline for decision, publication
- Rejection rate



JOURNAL SELECTION: CONSIDERATIONS

- Target audience
- Aims and scope
- Similar topics published
- Submission guidelines
- Impact factor (?)
- Timeline for decision, publication
- Rejection rate

Authors make final decision



JOURNAL EDITORS' EXPECTATIONS

- Submission/formatting guidelines are followed
- Manuscript is well organized, well written
- Topic is relevant to readers



LIAISING WITH JOURNAL EDITORS

- Presubmission inquiries, submission cover letters, post-submission revisions
- When contacting journal directly, always state you are working under authors' direction; cc lead author
 - Example: "assisting Dr. XYZ in preparing manuscript for submission"



SUBMISSION: CONSORT CHECKLIST FOR RCTs

- Provides clear, stepwise template for manuscript
- Many journals require completed CONSORT checklist to be submitted with manuscript

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	<u>1</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>2</u>
Introduction Background and objectives	2a	Scientific background and explanation of rationale	<u>3</u>
	2b	Specific objectives or hypotheses	<u>3</u>
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>4</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>N/A</u>
Participants	4a	Eligibility criteria for participants	<u>5</u>
	4b	Settings and locations where the data were collected	<u>5</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>6</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>7</u>
	6b	Any changes to trial outcome measures in the trial course	

POST-SUBMISSION PROCESS

- Journal response to corresponding author:
 1. Accepted
 2. Accepted pending minor revisions
 3. Needs major revision/will reconsider
 4. Rejected
- Formal letter (email) provides comments from reviewers, editors

REVISIONS, RESUBMISSION

- Journal provides instructions, specified time period for resubmission
 - Detailed summary addressing *all* comments must accompany revised manuscript
 - Authors can decide to submit to different journal
- Extreme courtesy in responding to peer review
 - “We thank the reviewer for this comment...”
 - “We respectfully disagree with the suggestion...”
- Expect >1 round of review for substantive revisions



AFTER ACCEPTANCE: IMPORTANCE OF REVIEWING PROOFS

- Simple typos may be critical data points
- Figures may be redrawn incorrectly
- Tables may be laid out incorrectly

tional review boards/independent ethics committees. All participants gave informed consent.

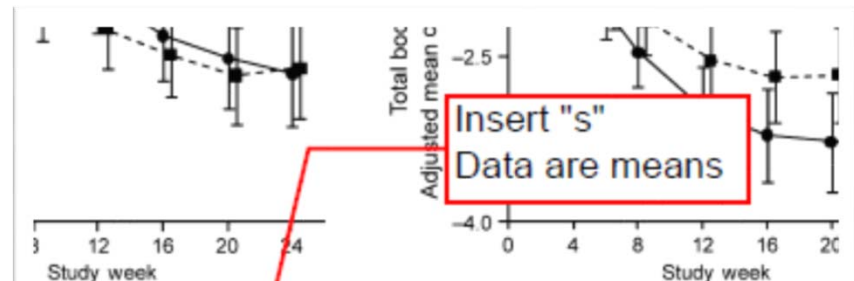
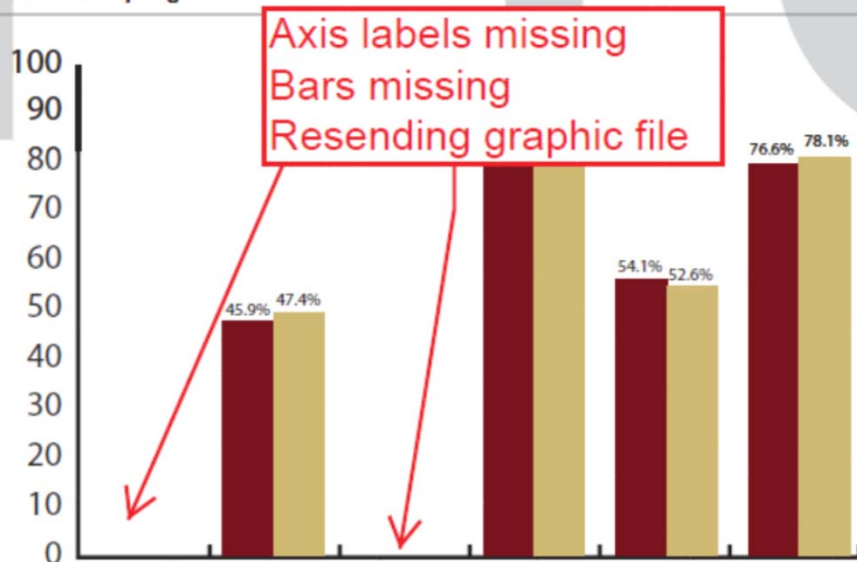
Lower case "c"
HbA1c

Patients

Patients were aged 18–77 years, with HbA1c (HbA1c) 7.5–12%, body mass index (BMI) ≥25 kg/m², C-peptide concentration ≥0.33 nmol/l and type 2 diabetes.

7.5 (add decimal point)


combined), the differences between treatment groups were not statistically significant.



baseline in haemoglobin A1c (HbA1c), fasting plasma glucose. Data are mean (95% confidence interval). Analyses are intention carried forward, excluding patients who were lost to follow-up. (C) Change from baseline (last observation carried forward),

THAT'S THE PERFECT WORLD

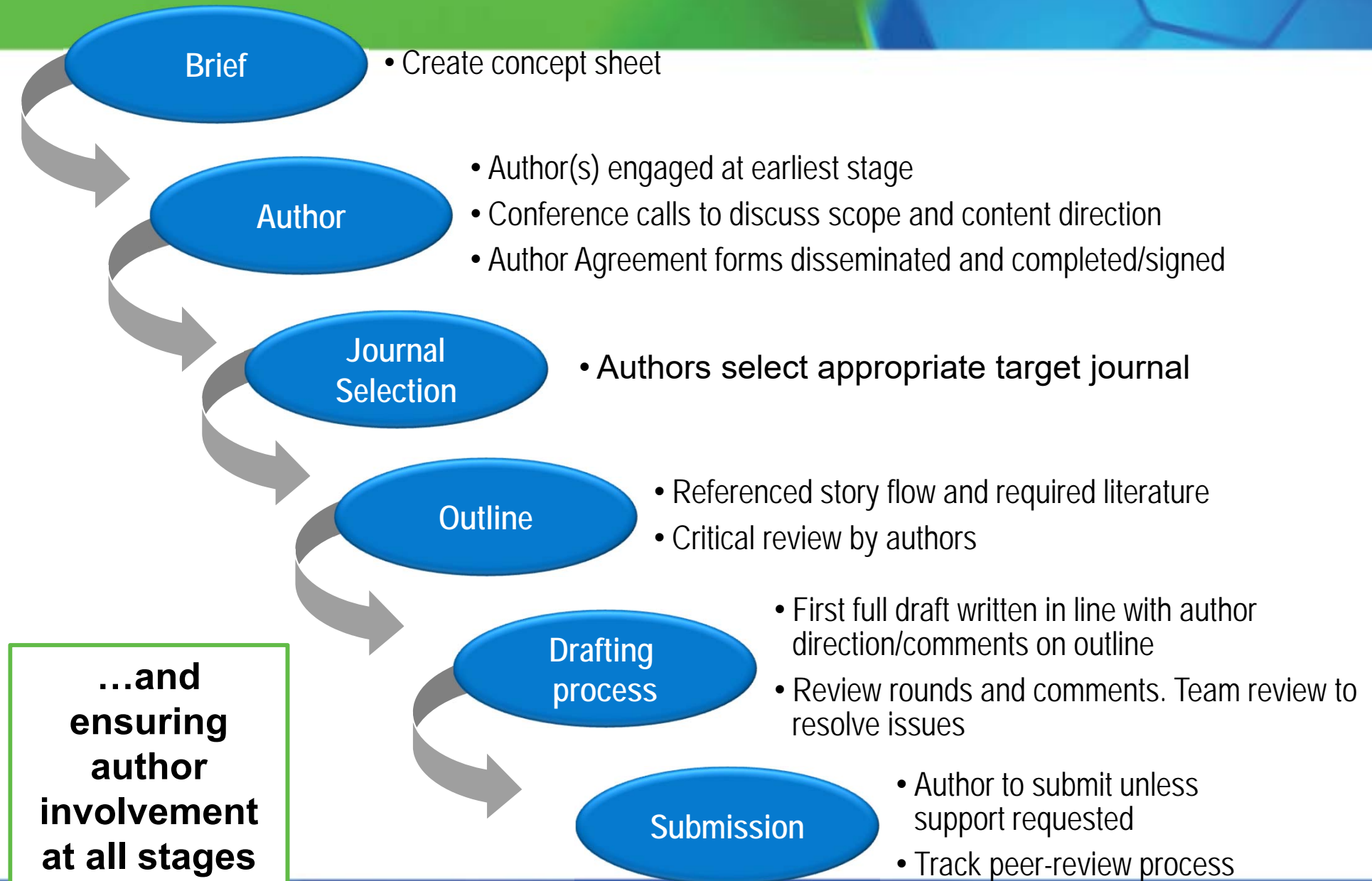
- But of course, stuff happens...



CASE STUDY #1: STRATEGICALLY TIMED PUBLICATION

Godfrey Lisk, PhD
Senior Scientific Specialist
PAREXEL

MAINTAINING COMPLIANCE: PROVEN PROCESSES AND PROCEDURES



AUDIENCE QUESTION



Have you have been involved in a simultaneous data release and manuscript publication?

- A. Yes
- B. No
- C. Just started working on it

STRATEGICALLY TIMED PUBLICATION

- Landmark trial of patients with COPD and one of the largest international COPD trials ever conducted
- *New England Journal of Medicine* agreed as an appropriate top-tier journal in which to publish the results
- Publication timed to coincide with data release at an international COPD congress

KEY DECISIONS TO BE MADE BEFORE COMMENCEMENT OF MANUSCRIPT

- Author selection
 - Lead investigator, steering committee members?, client leads
- Journal selection
 - Timeframe for publication to coincide with date of congress
 - Communications with editor to gauge interest
 - Agreement from editor for publication at ERS congress should manuscript be accepted; enabled fast-track journal review, acceptance and publication
 - Editor to identify reviewers and have them ready to review manuscript with rapid turnaround
 - Have a back-up journal

SPECIAL CONSIDERATIONS FOR *SELECTED JOURNAL*: DRAFT DEVELOPMENT (1)



There will most likely be more than 2 review rounds and will need to be accommodated in your Timings & Estimate document

SPECIAL CONSIDERATIONS FOR *SELECTED JOURNAL*: DRAFT DEVELOPMENT (2)

Complete client legal and medical review	Publications manager and PAREXEL	10 days
Prepare submissions package	PAREXEL/Publications manager	3 days
Submit manuscript	PAREXEL/Lead author	1 day
Journal review of manuscript	All authors	TBC
Respond to reviewer comments and resubmit revised manuscript	All authors	7 days
Acceptance???	Journal	TBC
Review of proofs	Lead author/PAREXEL	2 days
Return proofs and Manuscript to PRINT	Journal	TBC

There will most likely be more than 2 review rounds and will need to be accommodated in your Timings & Estimate document

POTENTIAL PROBLEMS AND SOLUTIONS (1):

- Adherence to agreed timelines
 - Publications manager and authors to agree on draft Timings & Estimate document during kick-off teleconference
 - Rapid follow-up with authors (ensure Pubs manager is aware of any delays)
- Author conflict

AUDIENCE QUESTION



How would you resolve a conflict among authors?

- A. Majority vote
- B. Lead author decides if all else fails
- C. Revoke authorship of dissenting author
- D. Keep your fingers crossed and hope for the best

POTENTIAL PROBLEMS AND SOLUTIONS (2):

- Adherence to agreed timelines
 - Publications manager and authors to agree on draft T&E during kick-off teleconference
 - Rapid follow-up with authors (ensure Pubs manager is aware of any delays)
- Author conflict
 - Proactively address conflicts
 - Lead author in conjunction with Pubs manager to have the final say if emerging problems threaten to derail the process?

SPECIAL CONSIDERATIONS FOR *SELECTED JOURNAL*: REVIEW PROCESS

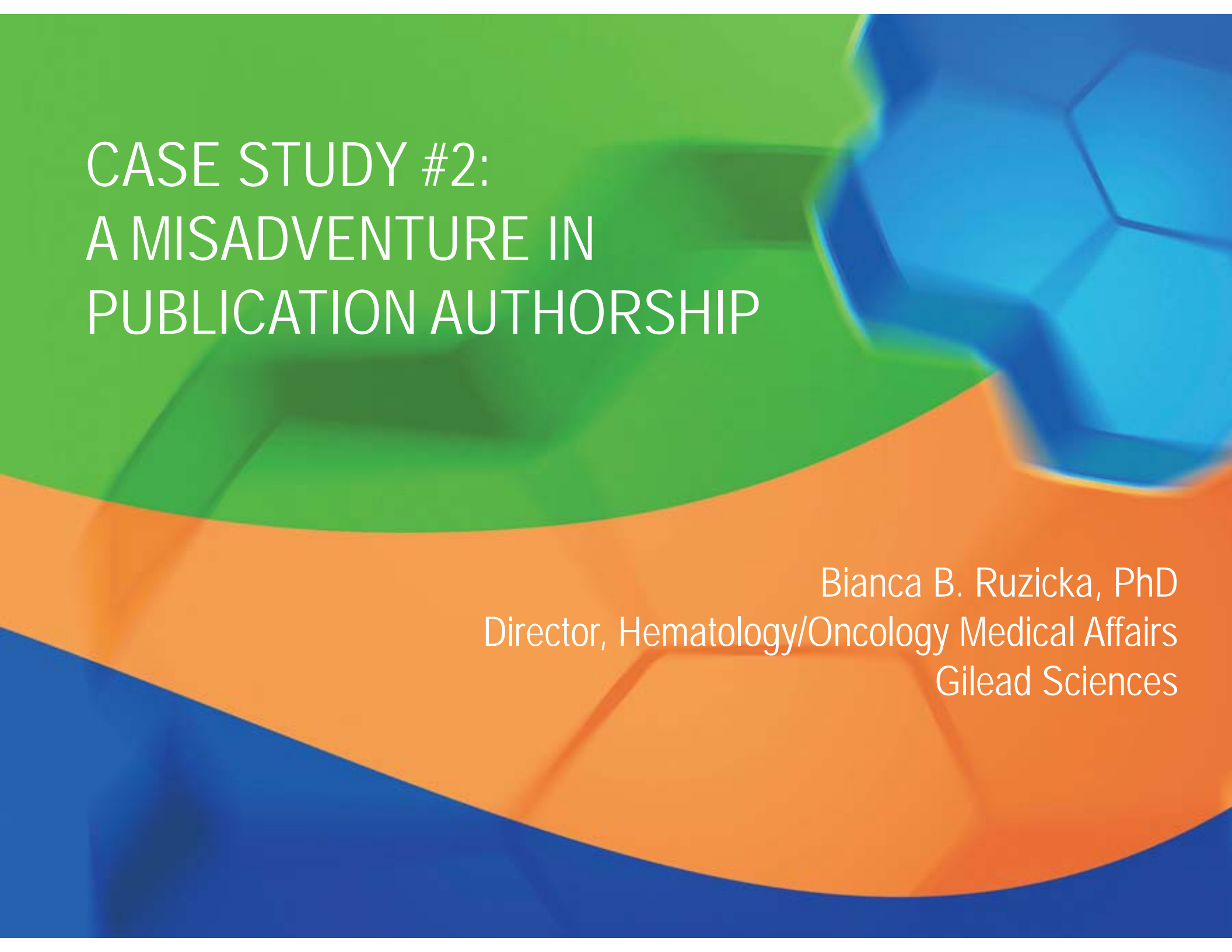
- Expect extensive reviewer comments with rapid turnaround
- Ensure all authors are available to address reviewer comments
 - Authors should be aware of submissions date and expected availability of reviewer comments
 - Face-to-face meeting if possible or a teleconference to address reviewer comments

SPECIAL CONSIDERATIONS FOR *SELECTED JOURNAL*: REVIEW OF GALLEYS/PROOFS

- Ensure project leads are available to review
- Agency writer to arrange for internal resource as required to ensure rapid turnaround

If all goes well.....



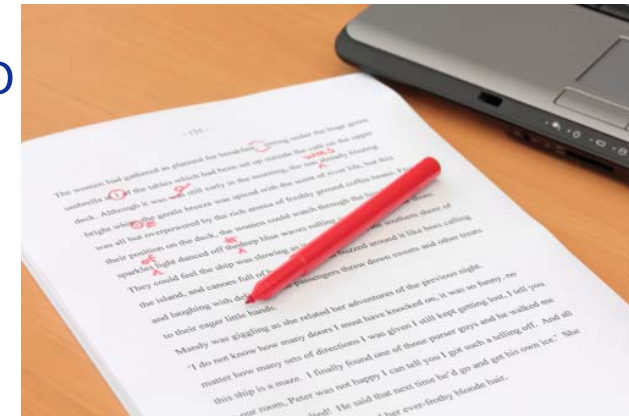


CASE STUDY #2: A MISADVENTURE IN PUBLICATION AUTHORSHIP

Bianca B. Ruzicka, PhD
Director, Hematology/Oncology Medical Affairs
Gilead Sciences

ICMJE REQUIREMENTS FOR AUTHORSHIP

- Authorship credit should be based on **all four ICMJE criteria**:
 - 1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data AND
 - 2) Drafting the article or revising it critically for important intellectual content AND
 - 3) Final approval of the version to be published AND
 - 4) Accountability for all aspects of content
- Acquisition of funding, collection of data (enrollment), or general supervision of the research group alone, does not justify authorship



AUTHOR SELECTION: BY THE NUMBERS

- Should author number be limited?
- What and who should determine what the cut-off number should be?

(What is the max number of authors you have seen on a publication?)

NUMBER OF AUTHORS

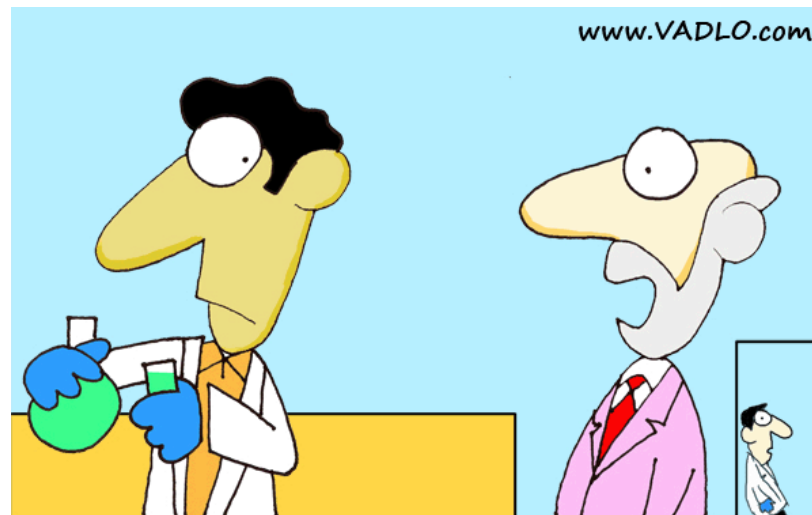
- There are no guidelines as to the number of authors on a publication
- The number of allowed authors varies by journal/congress
 - *J Clin Oncol*/limit is 20
 - *New Engl J Med* has no limit
 - Am Soc Clin Oncol (ASCO) limit is 10
 - Some associations include authors in the abstract character count



“You should spend the next week typing down names of all co-authors on your paper.”

AUTHORSHIP SELECTION: THE QUESTION OF SEQUENCE

- How should the order in which authors/contributors appear on a publication be determined?
 - First (lead) and senior author positions are the most coveted
- ICMJE requirements do not provide detailed guidance applicable to all situations: Investigators or corporate staff may qualify



“No, it’s my wife’s turn to be the first author
on **your** paper.”

AUTHORSHIP SELECTION CASE STUDY: THE BACKGROUND

- Two pivotal phase 3 trials, Study 1 and Study 2, are conducted to support related indications for the same product.
- Author Selection for Study 1:
 - Lead authorship is discussed only with the PI, who acts as lead author for the initial congress presentation and primary publication
- Presentation and Publication of Study 1:
 - Primary results are presented to great acclaim at an international congress
 - Primary results are published in the *NEJM* in a timing coincident with the initial data presentation
- Fall-out from Study 1:
 - Many investigators displeased about the authorship selection process and their exclusion from participating as authors

AUDIENCE QUESTION



How could the situation have been managed differently, to avoid the negative fall-out regarding authorship?

- A. Include all investigators as authors, regardless of number
- B. Utilize study metrics to help guide author selection
- C. Have the Study Steering Committee or related Publication Steering Committee identify potential authors based on investigator contributions
- D. Request that all investigators provide a list of contributions before deciding authorship

SAMPLE METRICS FOR INCLUSION ON AUTHOR SCORECARD

Potential Criteria	Weighting (example)	Score (example)	Potential Definition
Study Design/Concept	x2	2 = Heavily Involved 1 = Some Involvement 0 = No Involvement	Provided feedback to Study Concept Document or Protocol.
Patient Data Collection	x3	2 = Top 90 Percentile 1 = Top 80 Percentile 0 = Below 80 Percentile	Total number of patients randomized in study that completed treatment as defined in the SAP.
Steering Committee Participation	x5	3 = Chair / Co-chair 2 = Heavily Involved 1 = Some Involvement 0 = No Involvement	Contributions to steering committee meetings.
Data Analysis/ Interpretation	x2	2 = Heavily Involved 1 = Some Involvement 0 = No Involvement	Level of involvement in the data analysis and/or data interpretation for the Final Analysis, an Interim Analysis, or/and a Subgroup Analysis.

AN AUTHOR METRICS SCORECARD IS “IN THE EYE OF THE BEHOLDER”

- Scorecards, despite their objective focus and intent, remain inherently subjective, due to differences in:
 - Selection of criteria
 - Weighting of criteria
 - Definitions and interpretations of scoring
 - Definitions of criteria and their interpretations

LESSONS LEARNED: STUDY 2 AUTHOR SELECTION

- Study metrics are utilized to guide author selection
 - The formula for determining investigator score for authorship is presented to the Global Development Steering Committee
- The lead author is identified:
 - Highest patient enrollment number
 - “Clean” data
 - Patient follow-up
 - Protocol compliance
 - Contributions at Global Development Steering Committee meetings
- A total of 25 investigators are invited to act as authors (along with 3 internal corporate employees)
- The manuscript undergoes 4 rounds of drafting/revision
- The authors approve the final manuscript version for submission and the manuscript is submitted to *NEJM*

SO, NO PROBLEM...OR IS THERE...?

- Upon manuscript submission to the *NEJM*, two investigators come forward:
 - Investigator-1:
 - Currently is not included as an author on the manuscript, but learned of this exclusion only once receiving the manuscript from the *NEJM* for his peer review
 - Questions why he has not been included as an author
 - Investigator-2:
 - Currently is the second author on the manuscript
 - Takes the position that he be given lead authorship based on strongest overall contributions to the study, including having signed off on the protocol

AUDIENCE QUESTION



How would you handle the situation with Investigator-2?

- A. Explain that a metrics-based approach was taken to identify author sequence, and leave author sequence as is
- B. Offer senior authorship instead of the second-author position
- C. Consider joint lead authorship between first and second authors

WHAT HAPPENS NEXT?

- The Clin Dev team acknowledges the significant overall contributions made by the second author and supports co-lead authorship
- First and second authors agree to be listed on the byline as having shared equally in the work, and this co-lead authorship is (ultimately!) supported by all co-authors
- *NEJM* ultimately rejects a revised version of the manuscript
- The manuscript is next submitted to *Lancet Oncology*, which requests revisions

AND IT'S DÉJÀ VU, ALL OVER AGAIN....

- Investigator-3 comes forward based on having seen a congress presentation of the data and noting his exclusion as an author on the congress presentation
 - Currently is not included as an author on the paper
 - Requests that he be included on the manuscript byline based on having provided significant input to the study protocol and having signed off on the protocol as a PI
- Investigator-3 handed over responsibilities to a colleague at the institution who then actually participated in the study
 - The colleague ranked 158/174 investigators on the author metrics scorecard
 - Neither the colleague nor Investigator-3 reviewed any draft of the manuscript, nor approved it for submission to either *NEJM* or *Lancet Oncology*
- The Clin Dev team advocates strongly that the investigator should be added to the author byline because:
 - The investigator made significant contributions to the protocol and advised critically on the entire clinical development program for the molecule
 - The Clin Dev team assumes responsibility for the oversight of excluding this investigator in the first place

AUDIENCE QUESTION



Should Investigator-3 be added as an author?

- A. No
- B. Yes

AND SO THIS MANUSCRIPT ADVENTURE CONCLUDES...

- Investigator-3 was added as an author following:
 - A review of corporate compliance policy that would allow the late addition of an author under certain mitigating circumstances
 - Receipt of approval from all co-authors to add the investigator as a co-author
 - Investigator-3 review of the submitted manuscript, as well as review and approval of the manuscript revised per journal request
- The manuscript was accepted for publication by *Lancet Oncology*, and the publication was timed with a related congress presentation

IMPORTANT CONSIDERATIONS FOR ESTABLISHING BEST PRACTICES IN AUTHOR SELECTION

Five-Step Authorship Framework

1. Establish authorship working group early in trial
2. Determine substantial contribution criteria
3. Document trial contributions
4. Determine those making substantial contribution
5. Ensure authors meet remaining ICMJE criteria

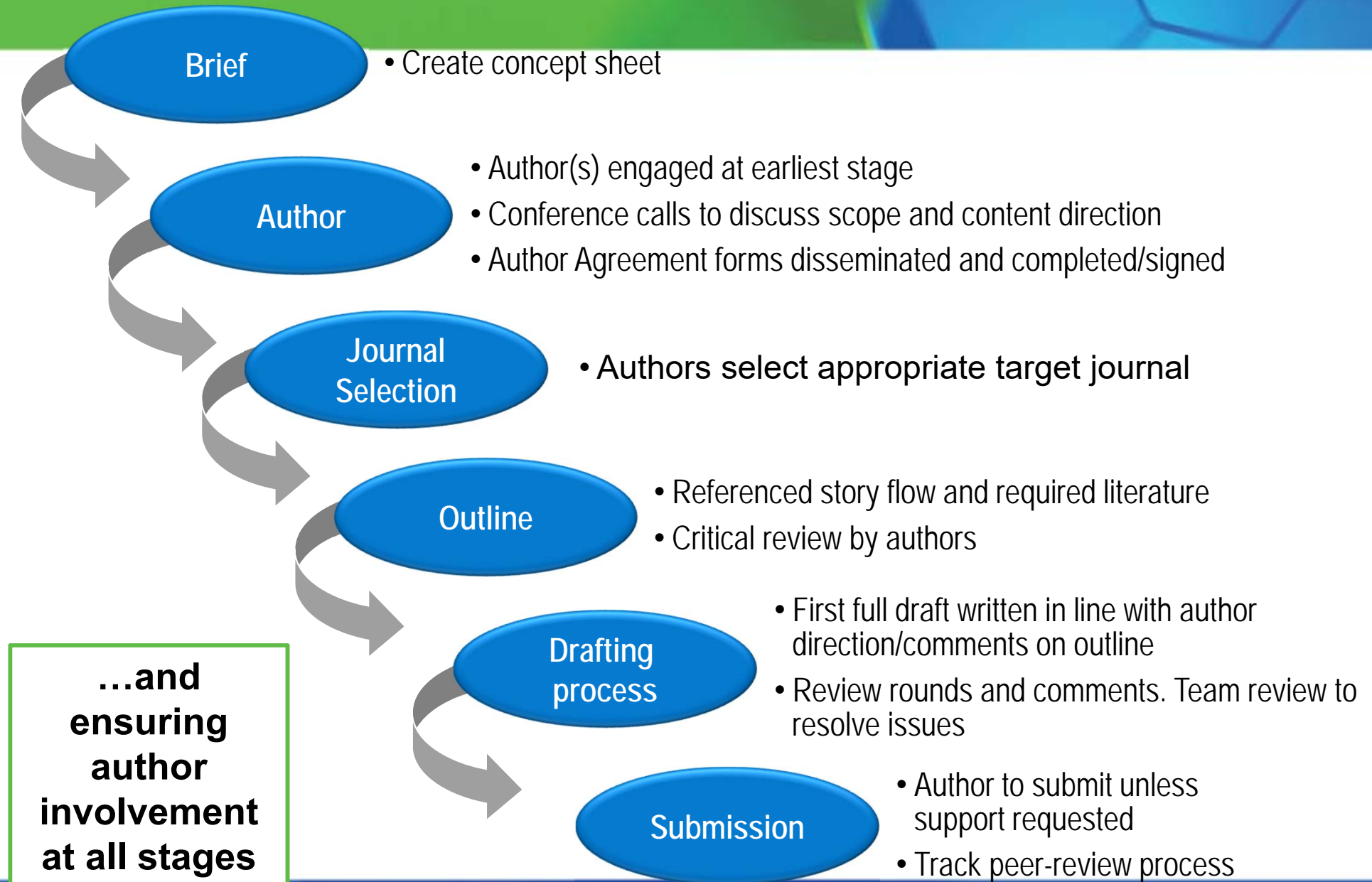
- Educate internal stakeholders about publication authorship: criteria, processes, compliance, etc
- Establish a corporate publication policy clearly defining authorship criteria and including scenario planning
- Use study metrics as a guide to select authors
 - Obtain internal alignment on the metrics scorecard
 - Recommend vetting with the Study Steering Committee or Publication Steering Committee
 - Authorship scoring is for internal use and guidance only – it should not be prescriptive
 - Subjective criteria may still contribute substantially
- Consider a proactive investigator communication plan to ensure understanding and to facilitate fulfillment of authorship selection criteria
 - Define and communicate authorship criteria at study initiation
- High patient enrollment should not guarantee lead authorship

The background is an abstract composition of large, overlapping geometric shapes. A large green shape occupies the upper left and center. To its right is a blue shape with a hexagonal pattern. Below the green shape is a large orange shape, also with a hexagonal pattern. The bottom left corner is a solid blue shape.

CASE STUDY #3: ACCELERATED PUBLICATION

Godfrey Lisk, PhD

MAINTAINING COMPLIANCE: PROVEN PROCESSES AND PROCEDURES

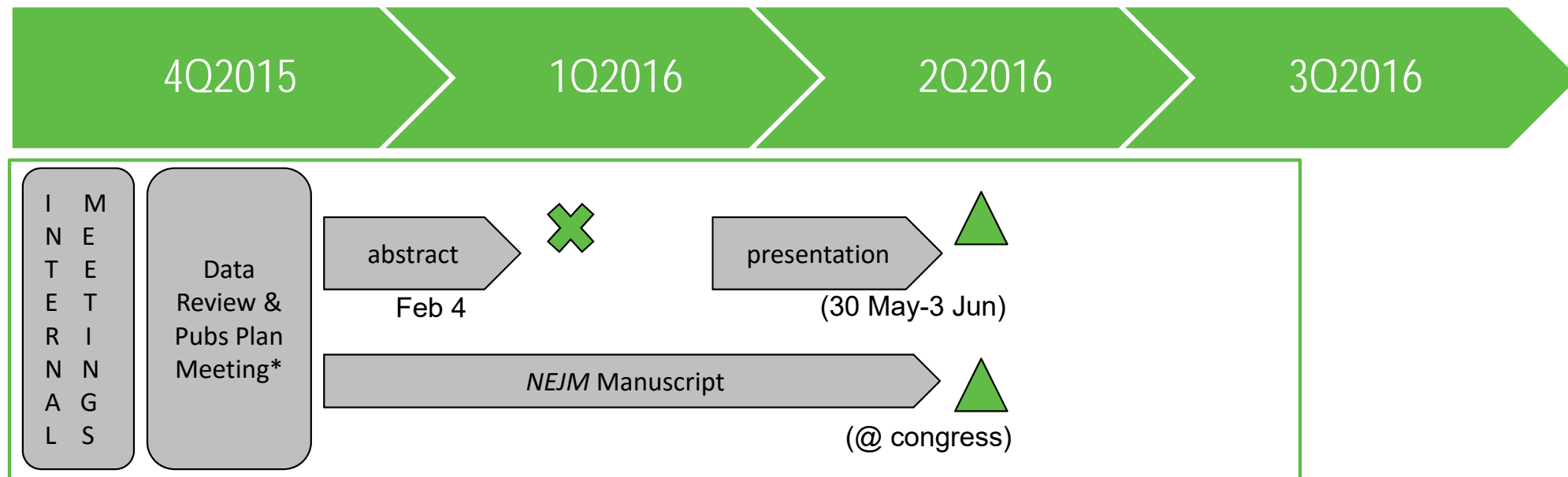


RAPID PUBLICATION AND COMMUNICATION OF LANDMARK TRIAL DATA IN TIGHT TIMEFRAME TO CREATE HIGH IMPACT

- Landmark trial: 17,000 COPD patients and one of the largest international COPD trials ever conducted
- Data available July 2013
- *New England Journal of Medicine* agreed as an appropriate top-tier journal in which to publish the results
- *NEJM* approached by lead author to determine interest to publish ... and to publish on the day data to be presented at a major international congress
- Author meeting in New York at end of July 2014, at which draft was prepared **over 2 days** – expert authors, pharma authors and PAREXEL
- Publication online achieved to coincide with symposium at European Respiratory Society (ERS) (September 2013), with release of data at congress booth and significant PR activities



OVERVIEW OF DEVELOPMENT TIMELINES



*Assumes data are already available;

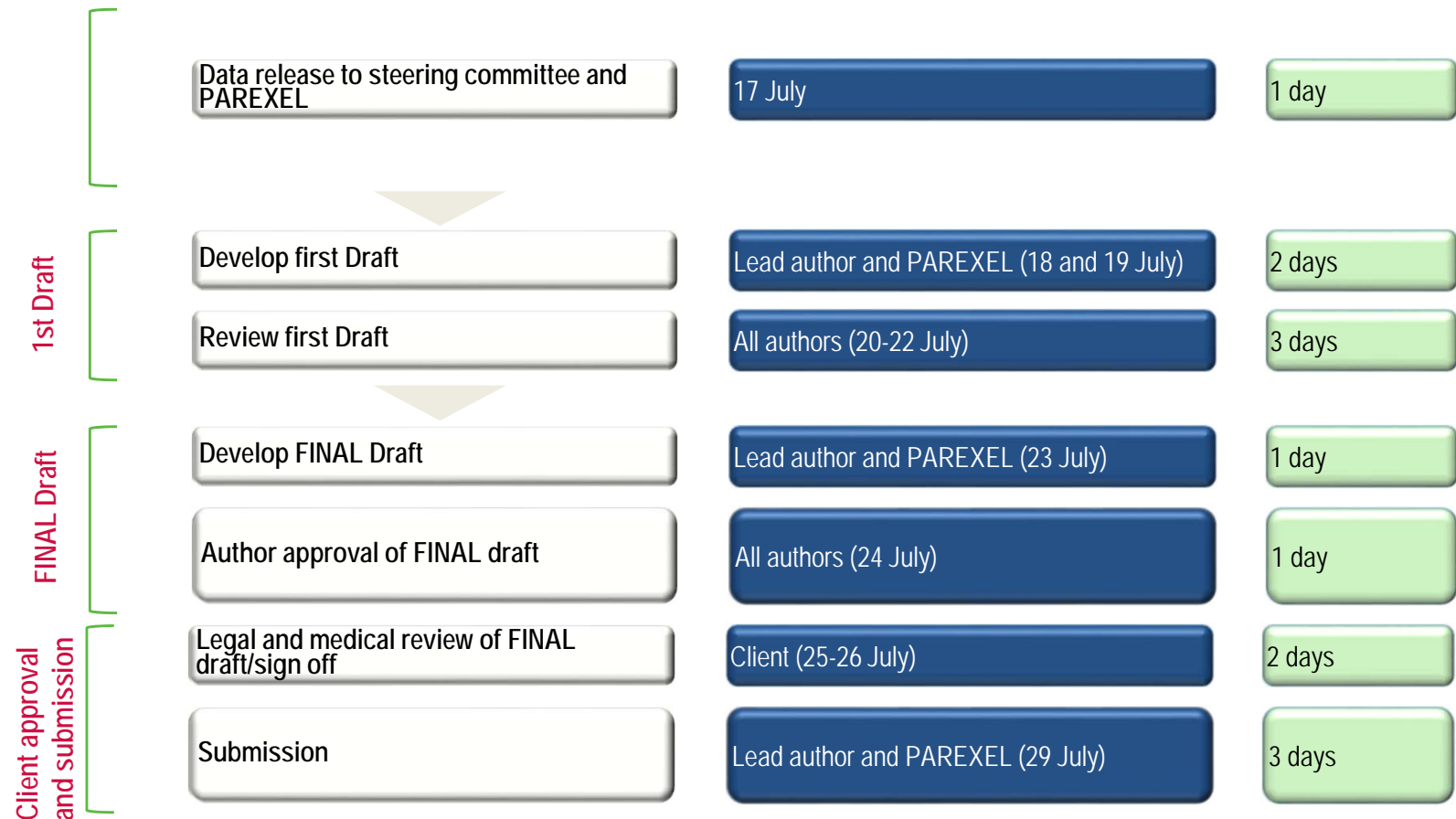
AUDIENCE QUESTION



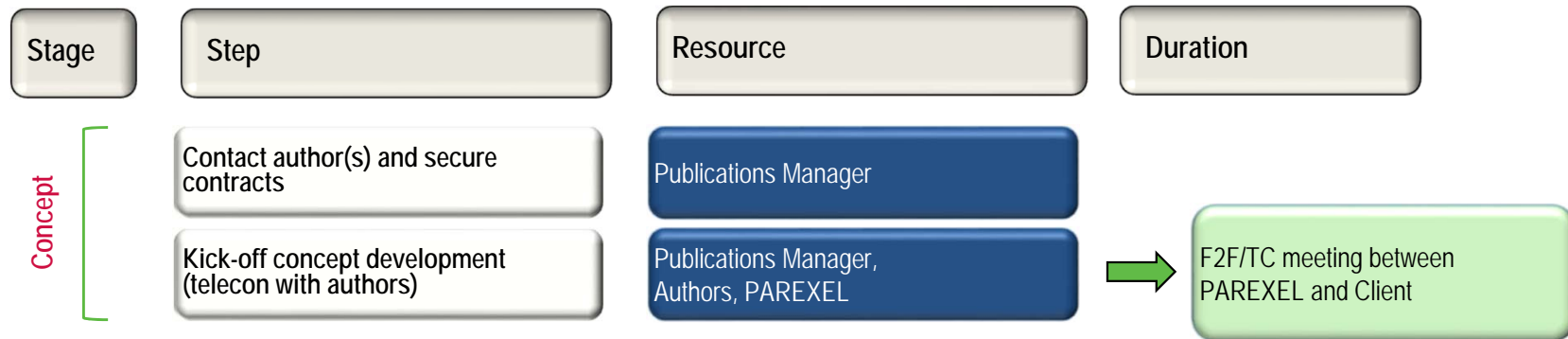
Which of the manuscript development processes do you believe can be shortened without jeopardising quality?

- A. Draft preparation
- B. Author review
- C. Client legal and medical review
- D. All of the above

ACCELERATED DEVELOPMENT OF DRAFT MANUSCRIPT



NEJM MANUSCRIPT: STAKEHOLDER ENGAGEMENT



Dual presentation/publication process will require commitment from internal stakeholders

- Agree on plan for engaging authors (particularly the lead) and driving dual development of abstract and manuscript
- Present redundancies and timelines and gain agreement

NEJM MANUSCRIPT: STAKEHOLDER ENGAGEMENT



Dual presentation/publication process will require commitment from authors

- Discuss publication plan at earliest stage
- Gain agreement on timelines/modify if required
- Agree on roles and responsibilities

- Engage lead author to initiate liaison with *NEJM*
- Discuss possible need for Fast Track option
- Determine alternative journal and “back-up” plan

NEJM MANUSCRIPT: EARLY CONTENT COMMITMENT



Authors/client may have differing viewpoints on appropriate content

- F2F discussion of content of manuscript and subsequent consensus
- Proactively address conflicts
- Potential of premeeting “shell” development to get head start on timelines

SPECIAL CONSIDERATIONS FOR *NEJM* MANUSCRIPT: SUBMISSION

Submission

Prepare submission package

Lead author and PAREXEL

3 days

Submit manuscript

Lead author and PAREXEL

1 day

Multiple materials required for submission

- Ensure adherence to journal guidelines
- Liaise with client to ensure availability of required items (eg, redacted protocols)

Potential for rejection

- Prepare “back-up” submission package in parallel

SPECIAL CONSIDERATIONS FOR *NEJM* MANUSCRIPT: REVIEWER FEEDBACK/PROOFS

Likely receipt of extensive reviewer feedback with need for rapid (~1 week) turnaround

- Ensure that lead author and publications manager are forewarned of impending feedback
- Use teleconferences to effectively manage process
- Provide advance notice to potentially allow for expedited approval of revised manuscript

Galley/page proofs will need careful attention

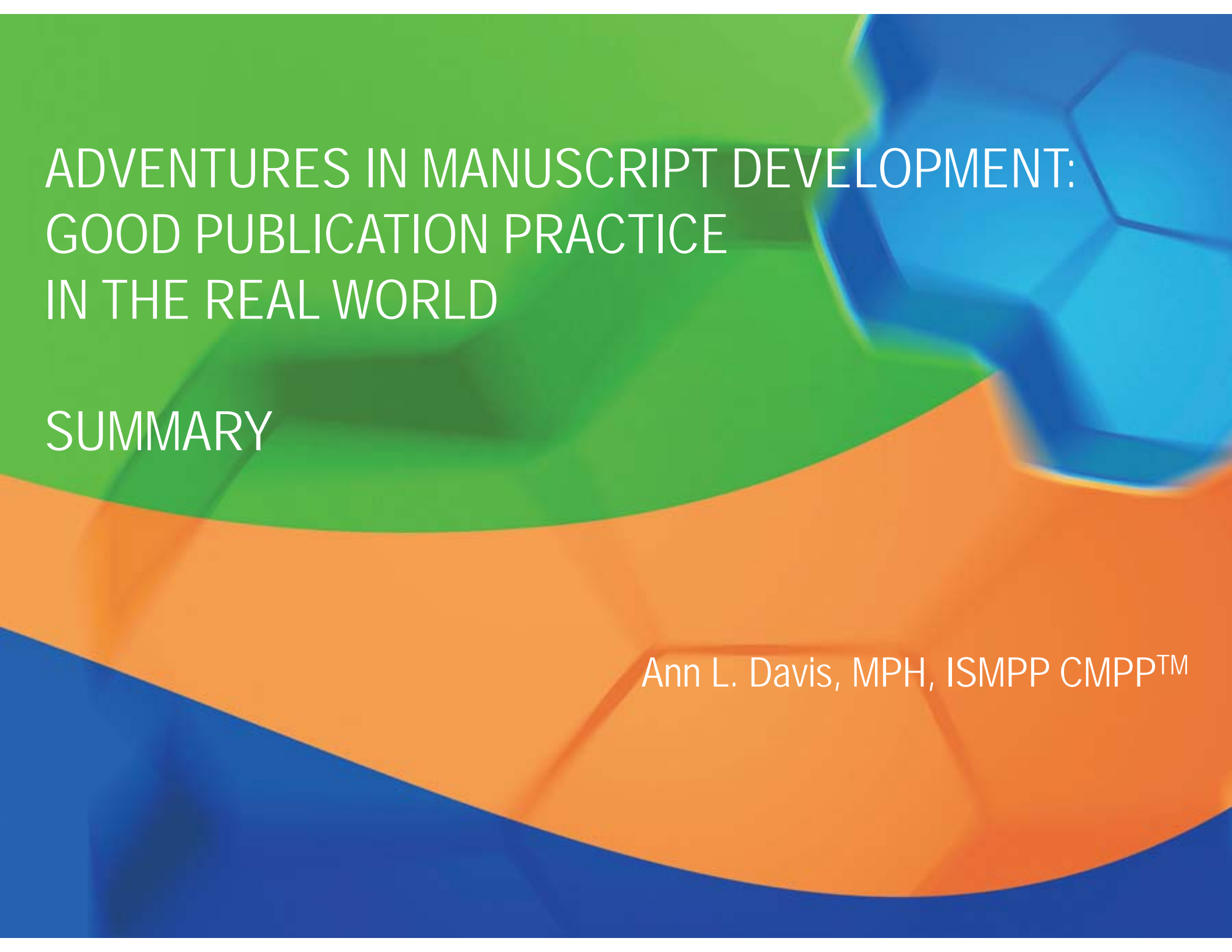
- Ensure that lead author and publications manager are forewarned of arrival of galley/page proofs
- Proactively determine need for approvals
- Arrange for full time zone coverage by PAREXEL writers

ACCELERATED DEVELOPMENT OF DRAFT MANUSCRIPT



REASONS FOR SUCCESS

- All Steering Committee (investigators/external authors), BI authors and other BI stakeholders including clinical trial team together with medical writer (PAREXEL) **onsite and fully engaged** for intensive working meeting
- All authors very committed to **sticking to timelines** (very short!) for manuscript preparation, review and approval. They all reviewed and commented very promptly
- Client review and approval teams **briefed upfront** and **responded promptly**
- **Lead author communication with journal editor** prior to manuscript submission and throughout the submission/peer review process, with the agreement for publication at ERS congress should manuscript be accepted
- Relatively limited journal peer review comments (by *NEJM* standards), likely due to the relatively simple and **solid trial design and clear, uncomplicated results**
- **Two PAREXEL medical writers** (one onsite/lead) plus program coordinator (admin assistant) prioritizing the manuscript throughout the process



ADVENTURES IN MANUSCRIPT DEVELOPMENT: GOOD PUBLICATION PRACTICE IN THE REAL WORLD

SUMMARY

Ann L. Davis, MPH, ISMPP CMPP™

STRATEGICALLY TIMED PUBLICATIONS

- Choose target journal wisely; gauge interest in timing of publication
 - Have a backup plan
- Timeline challenges
 - Swift resolution of author disagreement
 - Ensure availability of authors, internal reviewers for rapid response to journal review comments

MISADVENTURES IN PUBLICATION AUTHORSHIP

- Dealing with latecomers to the table
 - Alignment with ICMJE criteria
 - Sponsor publication policies
 - Target journal restriction on number of authors
- Gain advance agreement on criteria for author selection, order (consider MPIP Five-Step Framework)
 - Proactively advise all investigators of author selection criteria

ACCELERATED DEVELOPMENT

- Commitment to accelerated timeline, compressed process from authors, sponsor reviewers
- Target journal selection for rapid/likely acceptance
 - Lead author liaises with target journal to gauge interest
 - Agreement on backup plan; prepare backup submission in case of rejection by target journal
- Consider advance work (manuscript “shell”) to kick-start review process
- Address content issues early to avoid conflicts at deadline

LESSONS LEARNED

- Be proactive... be prepared for anything
 - Backup plans
- Set realistic expectations upfront with all authors, stakeholders
- Choose target journal wisely
- Authors own/drive the content
- Publication professional takes responsibility for knowing what is happening with all parties at all times
- Know the rules **AND** know the intent behind the rules

LESSONS LEARNED

- The three most important tenets of scientific publications:
 - *Transparency, Transparency, Transparency*

The background is an abstract composition of large, overlapping geometric shapes. A large green shape occupies the upper left and center. To its right is a blue shape with a hexagonal pattern. Below the green shape is a large orange shape, also with a hexagonal pattern. The bottom left corner is a solid dark blue. The text "THANK YOU!" is written in white, uppercase letters on the green background.

THANK YOU!

QUESTIONS . . .

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "**ALL PANELISTS**." Otherwise, **ALL** audience members will be able to see your submitted question

UPCOMING ISMPP U'S

- **February 2016**
 - Topic: ISMPP European Meeting Highlights
- **March 2016**
 - Topic: Biosimilars

THANK YOU FOR ATTENDING!

- We hope you enjoyed today's presentation. Please take a few moments to **complete the survey that will appear on your screen** immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings