37 TIPS FOR EFFICIENTLY WRITING SCIENTIFIC PUBLICATIONSS

Speaker
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Medical writers who work on scientific publications can improve their bottom line by adopting a productivity mindset and working more efficiently. During this session, Katherine Molnar-Kimber shared 37 efficiency tips for the planning, writing, and reviewing of scientific manuscripts.

Planning for Publication

Before writing, planning can save medical writers significant time and stress. At the start, you should obtain clear, specific details about the project, including timelines, your responsibilities, team members, and ultimate publication goals (Figure 1). By clearly defining tasks, determining priorities, and setting a tentative schedule, many common problems encountered during writing and revision can be avoided. Additionally, "you want to make sure you get buy-in from all stakeholders," explained Molnar-Kimber, to avoid delays during revision due to late reviewer input.

Figure 1. Specific details to clarify during the publication planning stage. ©www.gograph.com / artist: get4net, figure modified by Katherine Molnar-Kimber.

Delays can also be avoided by consulting relevant guidelines for determining authorship (eg, International Committee of Medical Journal Editors [ICMJE] recommendations) and reporting methods (the Enhancing the QUAlity and Transparency Of health Research [EQUATOR] network for clinical trials; Animal Research: Reporting of *In Vivo* Experiments [ARRIVE] for animal studies). If a target journal is known, its instructions should be examined to ensure the manuscript matches the journal's scope and to identify journal-specific requirements, such as word or figure/table limits. Journals often provide author checklists, and some, such as Radiology, even provide public access to peer review checklists. Molnar-Kimber advised consulting these checklists early and often.

Writing Your First Draft

Molnar-Kimber encouraged writers to begin with the Results section "because everything in the document is dependent on the presented results." The Methods should only include the steps taken to obtain the results. For the Introduction, sufficient information should be provided for the reader to grasp the rationale and understand the Methods and the Results. Finally, the Discussion should focus on the significance of the study's results to the larger field.

The Results section largely requires writing about numbers to describe comparisons or highlight differences that are statistically or clinically significant. To create clear sentences about numbers, Molnar-Kimber proposed using the "4 W's" of writing:

- **Who:** Groups or subgroups
- **What:** Units of measurement
- **When:** Duration of analysis or year
- **Where:** Study site location or geographic population
- **How much:** Magnitude/direction of the effect or response

After the Results are complete, the Methods can be written. Here, you may question what steps must be included and what can be left out. To avoid confusion, Molnar-Kimber suggested listing the reagents used and asking 2 questions:

- Is this essential to reproducing the study?
- Would most readers need this information to understand the results?

If the answer to both questions is "yes," this information belongs in the Methods. If the answer to the second question is "no," the information can be placed in the supplementary file.

When working on the Introduction and Discussion, you may struggle with which section should cite contradictory data described in published articles. To minimize this deliberation, Molnar-Kimber provided a decision tree (Figure 2). Briefly, if the article spurred the investigators to alter the design or

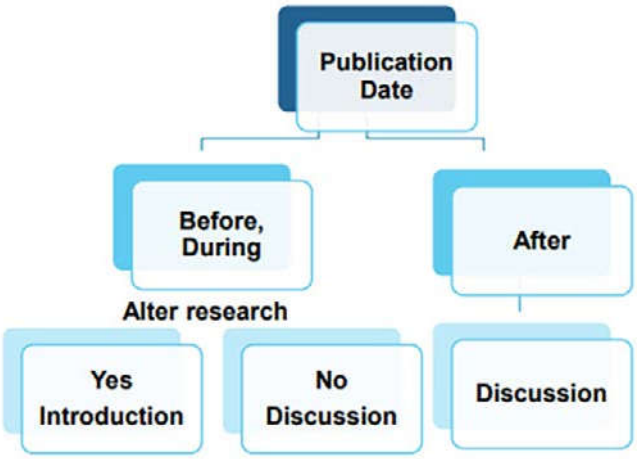

Figure 2. Decision tree for selecting where to cite an article of contradictory data. Copyright 2018, Katherine Molnar-Kimber.

interpretation of the research in the current study, it should be cited in the Introduction. If not, it can be cited in the Discussion.

To minimize writer's block and procrastination, Molnar-Kimber encouraged reading key references to gain context. She also cautioned against editing while writing, which can often hinder the flow of ideas. Instead, you should plan a time for editing separate from writing.

Reviewing the Manuscript

After writing is complete, you should spend time self-editing for structure, grammar, style, and consistency. Molnar-Kimber suggested using PerfectIt 3 software to save time during proofreading and help fix inconsistencies in hyphenations or abbreviations.

When multiple people review a document, version control can be difficult to maintain. Several software programs are available to help manage the review process. Some, such as PleaseReview, allow multiple reviewers to work on the same document simultaneously. However, if the program allows only a single reviewer, Molnar-Kimber recommends training the team to sign the manuscript back in when stepping away from the computer to avoid unnecessary delays between reviews.

Just like writing, implementing productivity tips into your daily work requires planning and review. To supplement this, Molnar-Kimber provided a handout for writers to list their top 6 tips and prioritize them by helpfulness. For maximum efficiency, writers should implement the highest-priority tip consistently for 1 month, then assess its advantages/disadvantages and determine whether to continue its use.

Online Resources

A document file summarizing the session slides and handout content is available online.

The *Radiology* checklist for peer reviewers can be found at https://pubs.rsna.org/page/radiology/reviewer-checklist. To learn more about the PleaseReview software, visit https://www.ideagen.com/products/pleasereview.

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CHALLENGES FOR BIOLOGIC AND BIOSIMILAR DEVELOPMENT: A CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC) PERSPECTIVE

Speakers

Teresa Chu, PhD, *Medical Writer and Consultant, Whitsell Innovations, Inc, Chapel Hill, NC*

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By Leslie Kowitz, MA, ELS

Welcome to the world of CMC—chemistry, manufacturing, and controls. Teresa Chu and Mary Ellis Bogden took the audience on an information-packed tour of biologic drug development, analytical chemistry, and the emerging space of biosimilars. For many, this was not only an introduction into the differences between biologics and biosimilars but also an exploration of the complexities and challenges in drug development and manufacturing processes—topics often challenging for medical communicators. This report provides a general overview of the session's focus on biosimilars. A more comprehensive article on biologic drug development and the analytical methods used to determine biosimilarity is planned for a future issue.

The Goal of CMC

To develop a new drug in the United States, a company must submit sufficient information to assure "the proper identification, quality, purity, and strength" of the product (21 CFR 312.23) in the form of an Investigational New Drug Application (IND). The CMC group is responsible for planning, driving, and overseeing studies and experiments that generate information required to write the Quality sections of the IND. In the case of biologics, Chu emphasizes that "the process is the product." The process is as much a part of a company's license as is the final drug product.

What Are Biologics and Biosimilars?

Before going further, we need a common lexicon to eliminate potential confusion (Table on next page).

Brief History of Biosimilars

Biosimilars are relatively new players to the US pharmaceutical industry, available only since 2015 (Zarxio from Sandoz, biosimilar to Neupogen), whereas the European Medicines Agency recorded their first biosimilar license in 2006 (Omnitrope from Sandoz, biosimilar to somatropin). Some of the early biologics approved in the 1990s saw their patents expire after 20 years in the early 2000s, making those fair game for other companies to try to create highly similar products. As of this writing, 13 biosimilars are currently available in the United States.