AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V37 N4 / 2022

THEME ARTICLE

The Future of Medical Writing: A Panel of One

Lisa Chamberlain James, PhD / Senior Partner, Trilogy Writing & Consulting, Cambridge, England

Of all the points in the evolution of the medical writing profession, I believe we are at the pinnacle of what promises to be the most exciting and biggest paradigm shift in medical writers' roles and responsibilities. With an accompanying leap in the introduction and use of technology in ways we have only dreamt of until now, this is a huge opportunity for all of us. However, it will also require medical writers to expand and hone their already extensive skill sets, and for their managers to embrace new technology and empower their teams to really grow and flourish into their new roles. For those forward-thinking companies, the rewards—including increased job satisfaction, faster and more effective submissions and approvals, increased general public engagement, and productivity from their teams—promise to be significant.

GLOBALIZATION OF MEDICAL WRITING

Collaboration Among Professional Organizations

Collaboration and harmonization have to be the key aims and the buzz words for this next phase of medical writing evolution. Each region doing slightly different things in slightly different ways is not only inefficient, but ripe for increased human error. There is an increasing demand for more and better medicines and information delivered more quickly to patients and the general public, and, coupled with a lack of highly trained medical writing professionals, the only way to meet this demand is to collaborate and harmonize as much as possible. This plea extends not only for collaboration and harmonization among professional organizations, but among regulatory agencies. Let's take one document—the Clinical Study Report (CSR)—as an example: imagine a utopian situation in which all CSRs were written and data were presented in the same way. Not only would these documents be much easier and quicker to produce and review, but much of the first draft at least could be automated, freeing medical writers to focus on their higher value skills of discussing key messages and key data points with their clinical and regulatory teams, and honing and crafting the final documents to be the concise and accurate representations of data that currently can take months to prepare (see comments on the shared technology question).

Harmonization of document templates and guidelines could also positively impact the dearth of skilled medical writers. Not only could they leverage their knowledge and experience more easily between regions, but it would open up more career opportunities for them geographically, making the profession more attractive and increasing retention of talent.

Defining the Profession Along Agreed Lines

With collaboration and harmonization across the industry come the added benefits of common training and educational aims and needs. This would allow certification systems to be put into place with meaningful outcomes and measurements and allow and encourage medical writers to expand their skill sets to meet the growing demands of the profession without relying solely on an individual company's commitment to and expertise in their training.

Expansion to Other Professional Associations/ Professions With Venn Diagram Overlap

Of course, the benefits of harmonization extend beyond the medical writing sphere. There are many areas of overlap with organizations such as SCOPE, the International Committee of Medical Journal Editors, TransCelerate, and the Patient Information Forum. If the medical writing community can engage and collaborate more with these organizations, we can pool resources and knowledge and make a much larger impact on the guidelines and templates and information available to the general public. Such organizations could also potentially contribute to aspects of any certification schemes for medical writing, bringing their specialist knowledge of their areas and offering specialist training opportunities. This can only benefit medical writers and the profession as a whole.

Shared Technology

There is no doubt that the industry is ripe for an explosion

ISSN 2163-5315

of shared and new technology, including etemplates, virtual and real time clinical trials, etc. TransCelerate has already made huge strides in producing and making freely available some excellent templates for medical writers to use, which will hopefully encourage harmonization of documents across the industry. Beyond that, software and technological advances are already taking shape, and regulatory agencies are preparing themselves (the United Kingdom has proposed a new pro-innovation framework1 for regulating artificial intelligence). Some initial offerings have been in place for several years now, and these are being expanded with new technologies to automate initial drafts, bringing the benefits and advantages already mentioned.

Common Lexicons

The general public are increasingly demanding more understandable and better information about their medicines and therapies. This is essential not only to engage the public in clinical development, but to help them better use their medicines. If we are truly to ask the general public to be involved in the decision making about their treatment or involvement in trials or in any stage of clinical development, we must clearly explain the benefits and potential harms, along with the context surrounding the need for the treatment, therapy, or intervention.

However, it is an extremely difficult and highly skilled task to convert complex clinical and medical information into plain language. The first step is to find suitable vocabulary! Excellent and ground-breaking work has already been done by organizations such as the Clinical Data Interchange Standards Consortium and the Multi-Regional Clinical Trials Plain Language Glossary Group. A common lexicon is essential to be able to communicate with the general public to reduce the confusion created when different wording is used to explain the same disease or procedure. Sharing the lexicons and making them freely available is a huge service not only to the medical writing profession but to the general public as a whole, and the continuation and expansion of these initiatives will allow medical writers to connect with audiences that have been out of reach for them until now.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

Author contact: *Lisa@trilogywriting.com*

Reference

1. Mulryne J, Schildkraut PJ. UK proposes new pro-innovation framework for regulating AI. Arnold & Porter website. Published July 26, 2022. Accessed October 14, 2022. https://www.arnoldporter.com/en/perspectives/blogs/enforcement-edge/2022/07/uk-proposes-framework-for-regulating-ai

BIOSUMMARY

Lisa Chamberlain James, PhD, is a senior partner and CEO of Trilogy Writing & Consulting. Aside from management activities, she leads client projects with extensive experience in a variety of documents. Lisa has a special interest in writing for the public and in patient information. Following a PhD and post doctorate in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then, she has been involved in EMWA as a member of the Educational Committee, as a mentor, leader, and assessor of workshops, and teaches and reviews workshops for AMWA. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated and chaired the EMWA Pharmacovigilance and Communicating with the Public Special Interest Groups, and is also chair of the Geoff Hall Scholarship Committee, section editor of the "Medical Communications and Writing for the Public" section of *Medical Writing*, and a Fellow of the Royal Society of Medicine.