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TOPICAL FEATURE

Value of Medical Writing—Using the Regulator's Perspective (2021 Survey Results) to Educate and Empower Medical Writers

Lisa Chamberlain James,[1] **Julia Forjanic Klapproth,**[2] **Rona Claire Grunspan,**[3] **Wayne Beazley,**[4] **Brian Bass,**[5] **Joan Affleck,**[6] **Julia Cooper,**[7] **Caroline Lilley,**[8] **and Amy Wollish**[9] **/** [1]Trilogy Writing and Consulting, Cambridge, UK; [2]Trilogy Writing and Consulting, Frankfurt, Germany; [3]Medical Writing, ICON plc, Leawood, KS; [4]Medical Writing, Astellas, Northbrook, IL; [5]Bass Global Inc, Fort Myers, FL; [6]Medical Writing, Merck and Co, Inc, Rahway, NJ; [7]Global Medical Writing Services, Parexel International (IRL) Limited, Dublin, Ireland; [8]Regulatory Writing, Amgen, Thousand Oaks, CA; [9]Medical Writing, Jazz Pharmaceuticals, Palo Alto, CA

ABSTRACT

In 2021, an American Medical Writers Association (AMWA) working group conducted a survey to gain an understanding of how regulatory agencies perceive the value of medical writing. The survey showed that document quality is extremely important to the timely and efficient review of an application and identified key factors affecting document quality that negatively impact application approval. In response to this, a working group ran a series of roundtables at the AMWA and European Medical Writers Association conferences to gather opinions from medical writers about this survey and how we can best communicate these ideas to authoring teams. This article discusses the feedback obtained in those roundtable sessions and presents the working group's proposal for a set of resources to empower medical writers to implement change.

INTRODUCTION

Medical writers bring value across the health sciences, driving efficient approaches for the delivery of high-quality medical communication documents targeted at diverse audiences including regulators, payors, physicians, and patients.[1–3] The results of the American Medical Writers Association (AMWA) 2021 regulators survey[3] demonstrated that regulatory reviewers recognize the value of medical writers in the preparation of regulatory documents submitted to obtain new drug approvals worldwide. Of the regulators surveyed, 70% agreed or strongly agreed that medical writers improve the quality of documents, and 87% agreed or strongly agreed that sponsor companies with established medical writing functions and rigorous document development processes and standards produce higher quality submissions. Importantly, 87% confirmed that poor document quality impedes regulatory assessment, and 77% of the regulatory reviewers agreed or strongly agreed that poor document quality delays the approval process.

Thus, the impact of poorly written documents can be substantial. The survey showed that poor document quality negatively affects the applicant's goals, which in most cases would be the approval of a drug or expansion of indication. When the regulators were asked which one document quality issue they encounter most frequently, the 3 top answers were excessive length/repetition/verbosity, poor explanation of rationale, and nonadherence to guidance. These are all things that medical writers can have a direct impact on if their authoring teams agree to using common ideas considered to be good medical writing practice (eg, lean writing and effective review processes).

The current working group was formed to educate medical writers about the importance of these regulator-conveyed issues with document quality and to empower writers by proposing evidence-based resources they can use to advise and convince their authoring teams about what good medical writing practice is and why it is essential for successful regulatory documents.

EDUCATING AND EMPOWERING MEDICAL WRITERS

The survey revealed that regulatory reviewers appreciated and recognized the contributions and value of trained medical writers. The AMWA Value of Medical Writing workstream focusing on the regulator's perspective concluded that "Training must equip medical writers to lead teams that create documents that are concise and clearly present the messages supported by the data."[4] Moreover, recognizing the regulator's appreciation for the medical writer's contribution is a powerful tool to guide the industry toward more streamlined writing practices that will ultimately aid and streamline drug approvals. Making the writing community and their teams aware of this feedback should be a priority for the profession.

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To this end, the data from the AMWA Value of Medical Writing workstream were presented at roundtable sessions at the European Medical Writers Association conference in May 2022 and the AMWA conference in November 2022. The medical writers who participated in the roundtables were informally surveyed to assess what their opinions were about the survey results. We also sought their input on how they thought a set of resources would help to implement change in the specific areas of improvement identified and what they felt would be useful to include in such a set. The feedback from these sessions was formative for developing the concept of the set of resources to help implement change. The key ideas are summarized below.

First and foremost, it was recognized that the medical writing community needs to be made more aware of the 2021 article. Of approximately 20 medical writers who attended the roundtable sessions, only 2 had read the article and were aware of it prior to the session. This made it clear that there is a very low awareness of the article among medical writers. There was general consensus that, for people to actively use a set of resources based on the data from the article, they need to be well-versed in the upstream survey and results.

Beyond that, we asked for input on what participants felt a set of resources should be to aid in educating their teams. Based on the responses, it was understood that the resources should provide material to help medical writers understand and raise awareness about the following key topics:

- Having a clear, strategic presentation of rationale
- Streamlining the writing process
- Demonstrating value for management from using good medical writing practices

To help teams understand the need and methodology for a *clear, strategic presentation of rationale*, the set of resources should

- provide examples and arguments for explaining the rationale for study design and in-text data selection,
- present arguments for having the medical writer actively participate in kickoff and strategy meetings and lead comment resolution meetings, and
- describe and explain how professional reviewers review documents.

To help with *streamlining the writing process*, the set of resources should

- present arguments that a medical writer can share with their team to support the use of lean writing and demonstrate that it is not necessary to repeat all the data in text (eg, the regulators clearly expressed a preference for lean and concise writing; lean writing needs less quality control time),
- contain examples of what non-lean writing looks like compared with lean writing and include simple examples of how streamlining the language can be achieved, and
- provide a list of good writing practices based on the results.

To demonstrate *value for management*, the set of resources should provide arguments that can be used to convince management of the importance of well-written, lean documents. In addition, the participants of the roundtable sessions felt that the set of resources should be useable for training medical writers and include visual aids that can be embedded in other materials.

Ultimately, the goals of the set of resources are to raise awareness and highlight the importance of

- delivering succinct documents with clear and concise reporting of results and messaging,
- educating teams on how professional reviewers review documents, and
- empowering medical writers to act as strategists and key drivers of their documents.

The topics associated with these goals are outlined in Table 1 on the next page. Based on this, a set of resources will be created comprising a set of documents and slides that can be used with different audiences, depending on the setting and document types.

We hope that disseminating this set of resources will help spread the important message of the regulators survey and give medical writers effective arguments to show their teams that by applying good medical writing practice to reduce length/repetition/verbosity, increase clarity, and provide a better explanation of rationale, we can accelerate the drug approval process and deliver medicines to patients faster.

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Author contact: *Lisa@trilogywriting.com*

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Table 1. Goals and Topics of the Resources Set for Medical Writers

Goals of the Resources Set	Resources Set Topics
Delivering succinct documents with clear and concise reporting of results and messaging	Good writing practices How to avoid poor explanation of rationale and unclear key messaging Removing repetition: give examples Increasing the use of cross-referencing both within and between documents Using succinct bulleted lists or tables to convey key information, as appropriate, instead of long paragraphs Contemporary abbreviation rules (not defining at first use: explain how this saves time in multiple areas) Reducing excessive length The value of using a single template for study reports and other documents (for uniform structure and data presentation)
Educating teams on how professional reviewers review documents	If time is of the essence, what should the team focus on first to ensure the document will help them easily find the answers to the questions they have—what are the key messages, and have we made sure a reviewer sees these in each section? Help teams understand the importance of effective cross-referencing to guide reviewers to supporting information. Giving the assessors the messages in succinct text that aids them to prepare their assessment reports. If they do not have to slog through writing those reports from scratch and can copy over well-written text that has clear messages, it can save days of time in completing the assessment.
Empowering medical writers to act as strategists and key drivers of their documents	MW is present at kickoff and strategy meetings so they properly understand the rationale behind the messaging: only in this way can they effectively communicate the message. MW should lead the comment resolution meetings—they know best where the unanswered questions are in the document and where there are gaps that need filling. MW should be proactive in referring to relevant guidances, agency websites, and primary source references to tailor and suggest text within the dossier. Provide a strong argument for explaining the rationale for selection of the data. The MW should have a clear vision of how the data work together to build the overall story—and should advise the team on optimal ways of presenting these data (in figures, tables, text) to best communicate the flow of logic that leads to the conclusions. Clarification of roles on teams: no one person owns the content of a document; there is a team of authors who all contribute to a document. Yet, the medical writer owns the master version of the file and is responsible for making sure comments are all addressed and applied consistently throughout. There cannot be a free-for-all, or the MW will lose oversight of document integrity and what has been changed.

MW, medical writer.