Strategic Benefits

Julia Forjanic Klapproth of Trilogy Writing and Consulting elucidates how strategic medical writing can help communicate key messages across development programmes and make sure teams stay focused on a common goal

I am going to pose a rhetorical question. How early should there be clear and effective crystallisation and communication of a company's clinical development strategy? Hopefully your answer is 'at the time of writing the initial clinical development plan,' and ideally, you were imagining that the plan would be written at the start of the clinical development programme. Now, here is another question: how many times have you seen a medical writer involved in the writing and development of a clinical development plan? How often is a medical writer an integral part of the clinical team at that stage of development? My guess in answer to that is 'close to never'. But why?

EVOLUTION OF MEDICAL WRITING

The answer lays in the perception of the medical writer's role on clinical teams. Many medical writers, together with publishers, play a rather secondary role on clinical teams helping to tidy up documents and get them ready to send out to the world at large. For many, medical writing is a function that merely brings data correctly to paper and makes sure that documents are formatted correctly and compliant with ICH guidelines. They are often not an integral part of the core clinical team and do not offer strategic support to the documentation process.

This is, in part, because medical writing evolved out of an editorial and language correcting past. It originally developed as a profession in its own right after World War II (1). At that time, the medical field was expanding rapidly and the need to communicate the science grew beyond what physicians could write on their own. With an increasing number of journals, writers and editors were brought on board to help write the manuscripts to ensure dissemination of the wealth of data being gathered.

Then, as regulatory guidelines and regulations developed and became more complex, clinicians working in the pharmaceutical industry were confronted with a similar situation. Numerous, often complex documents were needed and there wasn't enough time to get them all written. In line with the assistance writers had been giving physicians for decades to write manuscripts, in the 1980s the industry recognised the benefit of having writers assist in preparing these regulatory documents (2).

So medical writing as a professional service has served the medical world for over half a century as a means of providing editorial input, making sure documents are compliant with journal or regulatory formats, and taking data and changing it into text or figures for the authors to refine. This has been a successful model and for many this continues to be what a medical writer offers.

This is the world of standard medical writing and is the foundation of what medical writing has to offer. In general, standard medical writers are happy to sit in the back seat of the writing process, waiting for the authors to tell them what should be done next with the storyline. Which means the documents will have all the necessary basic elements, they will communicate within the realm of what the authors are able to conceive of on their own, and they will get done when the authors find the time to coordinate each stage of review within their busy schedules.

STRATEGIC MEDICAL WRITING

However, medical writing can offer the industry more. It can take the communication of the data from a data dump to something that tells a story, clearly and quickly. Good medical writers understand that – contrary to the old adage – data do not speak for themselves. Through discussions with authors, medical writers can help tease out the strands of the story a data set may have to tell, and weave them together in such a way that they build upon each other. As a result, the reader is not only able to follow the flow of thought and naturally understand the messages; they also see how the authors arrived at their conclusions. This is effective communication, arising out of the teamwork between authors and a medical writer, and it is the product of strategic medical writing (3).

But what is strategic medical writing, and how does high-end medical writing work? In a nutshell, it is the culmination of a multifaceted skill set. It arises partly from knowing how to tell a story, how to build an argument using logical building blocks. But the real strategic element comes from how a medical writer interacts with a clinical team to tease out those building blocks and drive the whole process to get clearly written documents done when they are needed. Sometimes also called a 'communication specialist', strategic medical writing is a constellation that emerges from the writer's ability to do many different things, which together produce a synergy

that not only improves the document but also streamlines the writing process as a whole (see Figure 1) (4).

A large part of the strategic element comes from an understanding of the big picture of clinical development: where it starts, where it is going, and the possible hurdles to be expected along that road. A strategic medical writer has the experience and knowledge to advise a clinical team on how to accommodate for potential hurdles in advance and how to communicate about them afterwards. For example, a medical writer who has helped several clinical teams address the lack of certain, relevant data that would have been informative in the context of their submission dossiers could suggest to future teams to consider ways of collecting this data when writing the protocols for a future programme in similar indications. From the experience of discussing the gap in the storyline of the original dossiers made by the missing data, the strategic medical writer is already thinking about how to avoid similar gaps in future dossiers while designing new protocols.

TEAMWORK & STAYING FOCUSED

Another strategic element comes from the medical writer's ability to guide a team to have discussions about challenging topics, highlighting and elucidating risks, benefits, weaknesses and strengths of a clinical programme. The ability to pull these topics together and develop a well synthesised discussion is critical to communicating the benefit/risk evaluation of a clinical programme, and is a key indicator of a good and experienced medical writer (5).

The strategic medical writer will also strive to eliminate topics that are tangential to the main story of a document, or the label of a submission dossier. If a team is spending time considering issues that are not relevant to the document – for example exploratory subgroup analyses that show no trends and have no impact on the content of the planned label – the medical writer can guide them back to those topics that are critical to the document storyline and will give a reviewer what is needed to understand the big picture. The strategic medical writer keeps the team focused on their target and helps them from getting too far off track.

Another important role of the strategic medical writer is to ensure that input is obtained from all functions on a team (marketing, regulatory, statistics, clinical, pharmacovigilance) while helping to mediate cross-functional differences of opinion on what messages the data have to say. Writing scientific documents as a truly collaborative process is not the way most academics learned to write about data and, as a result, does not come naturally to many members of clinical teams (6). Experienced medical writers often serve as a kind of glue on clinical teams. They pull team members together by focusing them on the common goal of channeling all their ideas to produce a unified document (see Figure 2). This is achieved partially by suggesting effective data presentations and clear texts that make the meaning easy to understand and partially by having appropriate and effective interpersonal skills. Strong argumentation and leadership skills are necessary to challenge and guide a team to find the best way to present what can be complex data sets and tell the story consistently and clearly, sometimes across multiple documents.

PROJECT MANAGEMENT & DOCUMENT REVIEW

A further cornerstone of strategic medical writing is the ability of the medical writer to keep the process of writing documents from losing momentum or stagnating by means of effective project management. The strategic medical writer develops clear timelines with their team from the kick-off meeting, with realistic dates and time for review cycles. By planning the stages of the writing and reviewing process in advance, the whole team can schedule in each stage and be sure to set aside enough time to deliver their input in a timely fashion.

Another aspect of strategically managing the projects is to help teams understand how to review a document.

Figure 1: Standard medical writing versus strategic medical writing

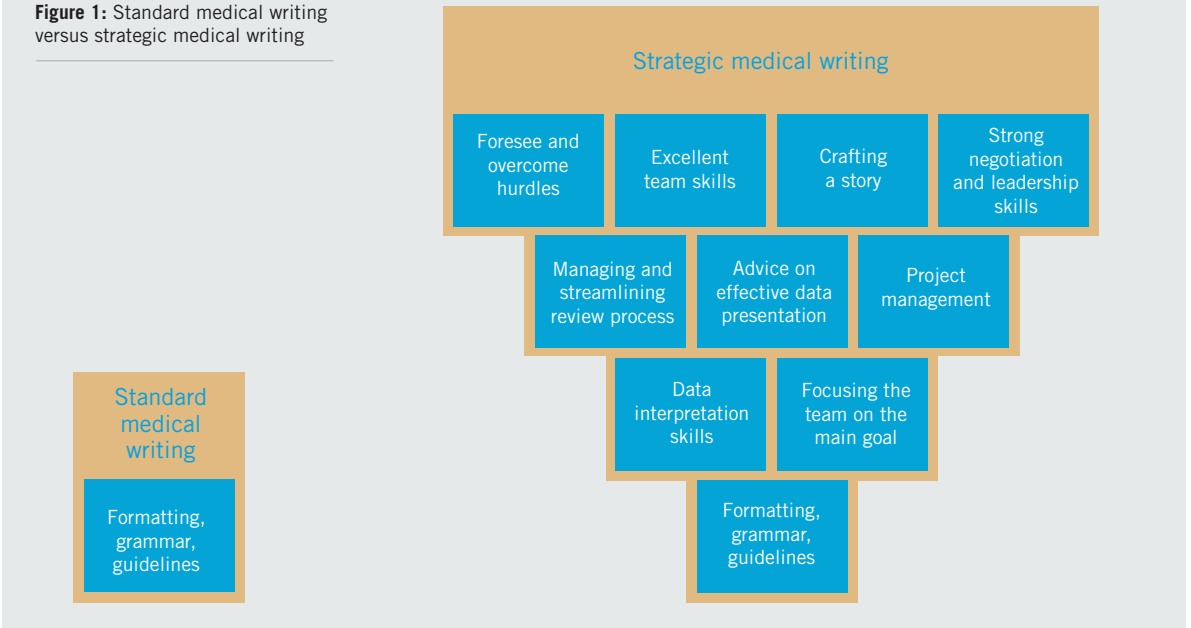
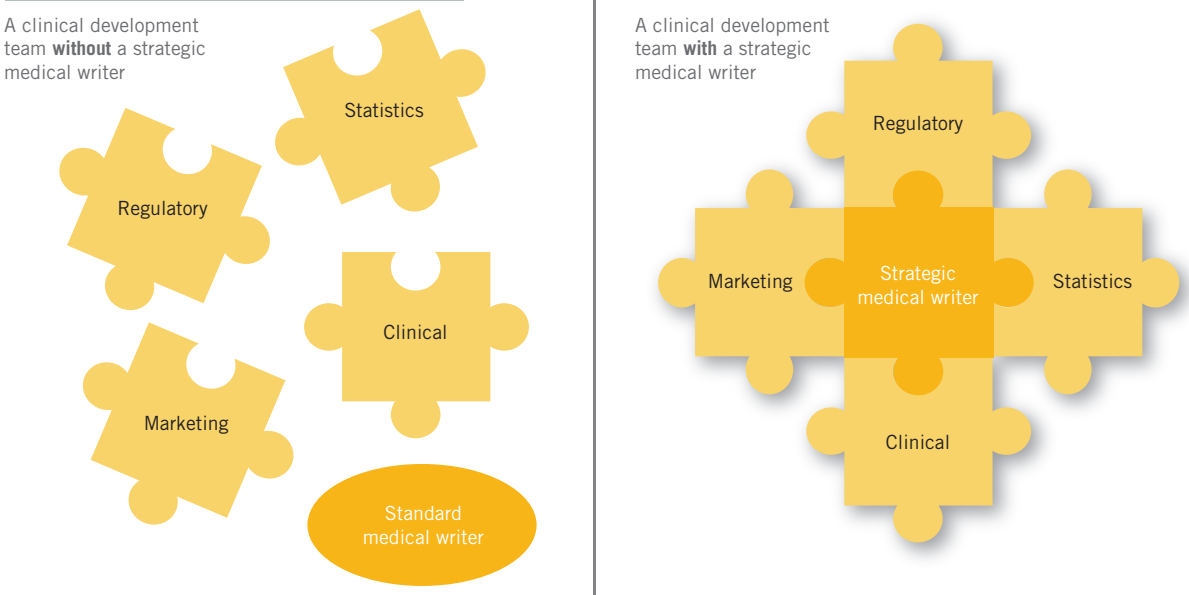


Figure 2: Strategic medical writers pull teams together



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The medical writer can advise each function exactly where their input is needed, and thereby save team members from focusing on things that are unnecessary or have already been agreed on by the team. For example, an effective tool is to apply a lockdown to portions of a document that the team has already reviewed and agreed on. This will prevent the team from reviewing such sections again, later in the process, when their time is needed to concentrate on newly written sections.

By offering clinical teams solutions to what can be an unwieldy and often an anxiety-ridden endeavour, strategic medical writing is ultimately about developing functional teams who can work together to achieve a common goal. It turns what can be a quagmire of poorly communicated, unclear data and endless review cycles into a structured and guided experience to craft effective documents.

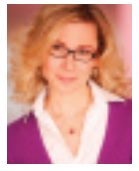
CONCLUSION

Standard medical writing is an essential, first building block in the writing process, but strategic medical writing brings many more building blocks together to create a more effective process of producing consistent, well-crafted documents that communicate clear messages. With the rapid increase in the number of development programmes and the ever stricter and more complex regulatory requirements, this is no longer just a nice to have (7,8). An FDA-commissioned report has indicated that a key reason for the failure of new drug applications is the poor quality of the dossiers submitted: 10 per cent of dossiers had inconsistencies and did not adequately help the reviewer find information (9). Strategic medical writing is thus essential to maximise the likelihood of the success of any clinical development programme, by making sure that the reviewers get documents that help them understand the full scope of the product they are assessing.

References

1. **Lang T, Medical writing: where it's been, where it's going, *AMWA Journal* 15(2), 2000**
2. **Korieth K, Medical writing market appreciation, *The CenterWatch Monthly* 11(7):113, 2004**
3. **Forjanic Klapproth J and Drees B The New Documentation Paradigm *International Clinical Trials* Spring 2010**
4. **Ford JD, Bernhardt SA, and Cuppan G, From medical writer to communication specialist: expanding roles and contributions in pharmaceutical organizations, *AMWA Journal* 19(2), 2004**
5. **Limaye N, Outsourcing medical writing: the evolution of a niche domain, *Pharma Times* 42(8), August 2010**
6. **Bernhardt SA and McCulley GA, Knowledge management and pharmaceutical development teams: using writing to guide science, *Technical Communication*, February/March 2000**
7. **Donaghy M, Investor Awareness for Effective Clinical Development: The Tie between Clinical Development and ROI, *ScianNews*, 2010**
8. **Tufts Center for the Study of Drug Development, Management Implications of the Global Regulatory Environment, 9 August 2011**
9. **Booz Allen Hamilton Inc, Independent evaluation of FDA's first cycle review performance – retrospective analysis final report, 2006, available at: www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/Studies/ucm201004.htm#ProductApp**

About the author



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