

SPECIAL FEATURE:
Strategic medical writing:

Why settle for less

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WHY STRATEGIC MEDICAL WRITING IS THE NEW BUZZ PHRASE IN CLINICAL DEVELOPMENT.



Julia Forjanic Klapproth

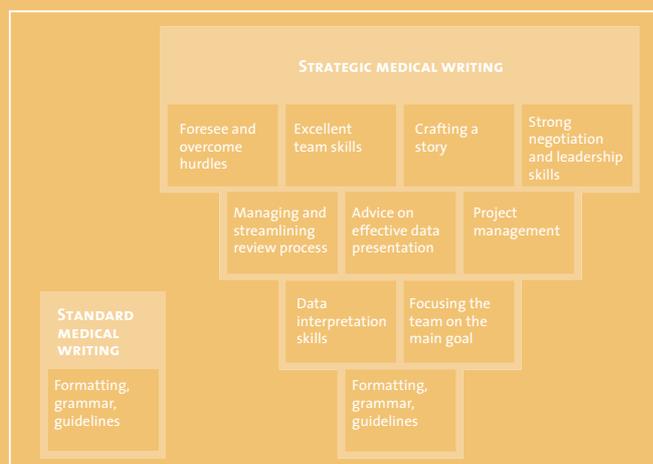
I'M GOING TO pose a rhetorical question. How early should there be clear and effective crystallisation and communication of a company's clinical development strategy? Hopefully your answer is at the time of writing the initial clinical development plan, and ideally, you were imagining that plan being written very early in 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 is the answer to that is close to never. But why?

The answer to that lays in the perception of the medical writer and their role on clinical teams. To begin with, the medical writer is often not

actually seen as an integral part of a core clinical team, but rather plays a secondary role, together with publishers, to help get documents tidied up and ready for sending out to the world at large. For many, medical writing is a function that brings data correctly to paper and makes sure that documents are formatted correctly and compliant with ICH guidelines. And in many cases, this is precisely the role it offers.

Medical writing evolved out of an editorial and language correcting past, developing as a profession in its own right after World War II¹. 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

| FIGURE 1: Standard medical writing versus strategic medical writing



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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. Paralleling 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 profession for over half a century as a means of providing editorial input, making sure documents are compliant

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.

Yet, medical writing can be so much 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. Authors need to interpret data and decide what they mean. Through discussions with the authors, medical writers can help tease out all different parts of the story a data set may have to tell, and weave them

“ HOW OFTEN IS A MEDICAL WRITER AN INTEGRAL PART OF THE CLINICAL TEAM ”

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: putting data on paper with little input regarding the most effective order or format of presentation, because of the belief that data speak for themselves. It is the foundation of what medical writing has to offer. The grammar is generally good, the right font styles are applied, and the documents are compliant with formats dictated by the applicable guidelines. In general, standard medical writers are

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 the conclusions. This is effective communication, arising out of the team work between authors and a medical writer, and it is the product of strategic medical writing.

And there it is, the buzz phrase, strategic medical writing. It is being talked about in the industry, thrown around at conferences as a desirable commodity, and used to describe the medical writing services on offer at

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several contract research organisations^[3, 4, 5]. But what is it, exactly? How does it work, this high-end medical writing? To sum it up, it is the culmination of a multifaceted skill set. One part of it depends on knowing how to tell a story, how to build an argument using logical building blocks. But that ability alone doesn't make medical writing strategic. The 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 out of the writer's ability to do many different things, which together produce a synergy that improves the document but also streamlines the writing process as a whole and offers so much more than can be achieved with standard medical writing (*Figure 1*)^[6].

A large part of the strategic element comes from an understanding of the big, long picture of clinical development: where it starts, where it is going, and the possible hurdles to be expected along that road. A strategic

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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, can suggest to future teams to consider ways to collect this data when writing the protocols for future programs 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.

Another strategic element comes from the medical writer's ability to guide a

issues that are not relevant to the purpose of a document, for example exploratory subgroup analyses that show no trends and have no impact on achieving the desired content of the planned label, the medical writer will guide them back to those topics that are critical to completing a document that will give a reviewer what is needed. The writer is always helping the team to remember their goal, whether it be acceptance by an editor or approval of a product label. The strategic medical writer keeps the focus on the target and helps teams from getting too far off track from that.

In addition, the strategic medical writer ensures that input is provided from all functions on a team (marketing, regulatory, statistics, clinical, pharmacovigilance) while helping to mediate cross-functional differences of

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team to have discussions about challenging topics, thereby highlighting and elucidating the core elements of 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 program, and this is a key indicator of a good and experienced medical writer⁷¹.

The strategic medical writer will strive to eliminate topics and argumentation that are tangential to the main story of a document, or the target label of a submission dossier. If a team is getting caught up in considering and discussing

opinion on what messages the data have to say. Writing scientific documents as a truly collaborative process – rather than the individual effort of a particular author – is not the way many clinicians and academics learned how to write up their data. As a result, it does not come naturally to many members of clinical teams⁶¹. Experienced medical writers often serve as a kind of glue on clinical teams (Figure 2). They pull team members together by focussing them on the common goal of funnelling all their ideas to produce a unified document. 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.

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 real dates and time for review cycles that are developing in agreement with the team members. By planning each stage of the writing process in advance, the whole team can schedule in each stage and be ready for them as they arrive, especially scheduling in review times to be sure they set aside enough time to deliver their input in a timely fashion.

In addition to project management, the strategic medical writer also helps keep the writing process moving forward by helping teams understand how to review a document. The medical writer

will let each function know exactly where their input is needed, and thereby save team members from focussing on things that are unnecessary or have already been agreed to by the team. For example, an effective tool is to apply a lock-down to portions of a document that the team has already reviewed and agreed to (e.g. the methods section). There is no need for the team to review such sections again, later in the process, when their time is now needed to focus on newly written sections.

Thus, in contrast to what standard medical writing provides, strategic medical writing tackles the many hurdles encountered in the communication process as a whole. It offers clinical teams solutions to what can be an unwieldy and often an anxiety-ridden endeavour. And ultimately it is about developing functional teams who can work together to achieve a common goal: a document that says what it should, in the way it should (tailored to the specific audience), and gets done on time.

Standard medical writing is an essential, first building block in this process. But strategic medical writing brings many more building blocks together to

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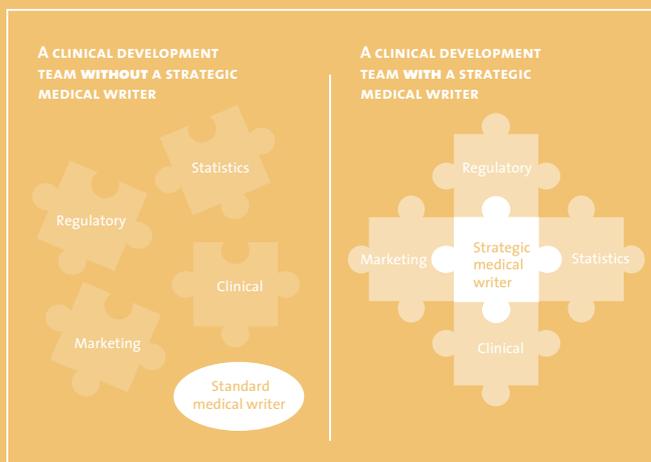


produce a larger, more effective process of producing consistent, well-crafted documents that communicate clear messages. With the rapid increase in the number of development programs running and the ever stricter and more complex regulatory requirements^{9, 10}, this is no longer just a nice to have. An FDA commissioned report indicated that a key reason for the failure of new drug applications is the poor quality of the dossiers submitted: 10% of dossiers had inconsistencies and did not adequately help the reviewer find information¹¹. Strategic medical writing is essential to maximize the likelihood of the success of any clinical development program, by making sure that the reviewers get documents that help them understand the full scope of the product they are assessing.

CONCLUSION

The term medical writing evokes different things for different people. Standard medical writing helps physicians bring data to paper and ensures that documents comply with guidelines. However, strategic medical writing goes beyond this in many ways and is becoming ever more sought after. Strategic medical writers serve as

FIGURE 2: Strategic medical writers pull teams together



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communication specialists and advisors who provide strategy to the documentation process. They help communicate key messages across dossiers and entire development programs and make sure teams stay focussed on a common goal. Ultimately, they help turn what can be a quagmire of communicating unclear data and endless review cycles into a structured and guided experience to craft effective documents. Given a choice between standard or strategic medical writing, which would you choose?

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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. Strategic Medical Writing Services offered by Beckloff Associates Inc. <http://www.cardinal.com/us/en/Beckloff/Services/Strategic+Medical+Writing+Services>
5. Writing Excellence for Healthcare Communications Professionals - one day workshop <http://writingexcellenceinhealthcare.eventbrite.com/>
6. 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
7. Limaye, N. Outsourcing medical writing: the evolution of a niche domain. *Pharma Times* 42(08) August 2010
8. Bernhardt, SA and McCulley GA. Knowledge management and pharmaceutical development teams: using writing to guide science. *Technical Communication* February/March 2000
9. Donaghy M. Investor Awareness for Effective Clinical Development: The Tie between Clinical Development and ROI. *ScianNews* 2010
10. Tufts Center for the Study of Drug Development. Management Implications of the Global Regulatory Environment. *News*, 9 August 2011
11. 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