

The New Documentation Paradigm

Julia Forjanic Klapproth and Barry Drees of Trilogy Writing & Consulting GmbH discuss how the paradigm of clinical documentation is shifting to a model in which the medical writer is a strategic partner on the clinical team

Clinical drug development has been in a state of change over the last 15 years, as the pharmaceutical industry strives to reduce the time for drug development and make the process more cost-efficient. In the course of determining how to achieve this, it has become clear that pharmaceutical companies must learn to stop development of unpromising candidate compounds sooner, improve patient recruitment, enhance the protocol design process, control development costs, and focus on areas of high therapeutic need (1). The question is: how?

An important key to this challenge is to use strategic goals as the drivers for decisions in the drug development process. This means bringing together an understanding of core competencies, diverse new factors for tailoring clinical programmes (for example, adaptive study designs and the use of biomarkers to steer how a new drug can be most effectively applied), and the expertise of key stakeholders to develop a model that moves drug development in a new direction. The scenario of statically designed, randomised, controlled clinical studies, performed to answer the sequential questions of Phase I, II, or III is being replaced by one of flexible design that merges phases, and shifts and reacts based on the results obtained (2). The resulting model for clinical development is an iterative process that requires the input of key stakeholders at each decision-making stage.

The solution thus lies in leveraging the experience and skill sets of these stakeholders to avoid pitfalls before they happen, finding creative solutions to complex problems, and ultimately to optimise the efficiency of the whole programme. A comparative study by Tufts CSDD in 2009 found that several pharmaceutical companies who consistently performed better-than-industry-averages commonly reported an emphasis on core competencies and higher usage of strategic functional

service provider (FSP) outsourcing, which enabled the high performing companies to better allocate and prioritise resources (1,3,4).

THE IMPORTANCE OF THE MEDICAL WRITER

One of the key stakeholders in this model is the medical writer. The need for a clear presentation of clinical study results that can aid rapid decision making is becoming ever more critical, and companies are looking to medical writers to help optimise the process. As a result, expertise in medical writing has become a competency that companies either develop as a core activity or for which they select a FSP that has the medical writing experience and proven ability to optimise the process of clinical development (5,6).

The evolution of the medical writer into a more valued cog in the machine of drug development has been accompanied by an increased demand for medical writers. Between 2003 and 2008, the medical writing market grew by 15 per cent each year (6). Both the increased demands and responsibilities taken on by medical writers have been driven, in part, by the growing volume of documentation needed to comply with increased regulations for clinical studies. As regulatory bodies continue

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to add to the amount and type of data to be presented and to develop more regulatory documents to communicate this information (for example, the Paediatric Investigational Plans or the Risk Management Plans in Europe and the Risk Evaluation and Mitigation Strategy in the United States) the amount of work continues to increase. To be able to provide documents that fulfil the intentions of the many new guidelines being issued, medical writers have had to become intimately familiar with the details of these guidelines. As a result, medical writers have begun to take on an essential function in clinical teams – namely, to provide an understanding of the needs and contexts of the documents to be written.

A NEW FUNCTION: MOVING BEYOND EDITORIAL

Whereas medical writers previously tended to perform an editorial role essentially, today's medical writer has a strategic function that is a critical part of the clinical development process (6). Their contribution to clinical teams represents a functional expertise that is similar to that of the statistician, the marketing representative or the clinician. From designing the clinical study protocol through to writing the submission dossiers for marketing applications, an experienced medical writer helps teams to think about what data will be collected and how these will funnel together to be able to support the intended claims of the target marketing profile for a product.

The skill of a professional, experienced medical writer to quickly recognise the key messages from a complex data set and effectively integrate these into a consistent storyline helps accelerate development programmes and ultimately can reduce time to market approval.

Furthermore, the role of the strategic medical writer goes beyond helping teams crystallise all the messages that need to be communicated. They also serve as team coordinators and as strategic advisors. Strategic medical writing results from a combination of several capabilities based on strong interpersonal skills and a broad range of experience documenting clinical studies and communicating with various regulatory agencies. The skill set that enables a medical writer to function as a strategic contributor is multifold (see skill set of a strategic medical writer, page 28). By building on these skills, the medical writer provides clinical teams with strong project management that combines proactive communication, ongoing coordination of review cycles for project-wide documentation, mediating of the multiple agendas of different team members, and experience-based consulting to foresee potential obstacles and work with teams to pre-empt these.

The fact that the industry is beginning to recognise the importance of the strategic medical writer for regulatory documentation and is actively seeking this function is

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evident in the job descriptions for medical writers found in position advertisements by pharmaceutical companies. As part of the expected responsibilities for a position as senior medical writer, a recent pharmaceutical job advertisement gave the following description: “Provide technical expertise for the research, writing, editing, and preparation of clinical and/or preclinical documents. Contribute to development of strategic plans for regulatory submissions and labelling. Prepare protocols and other regulatory documents. Ensure the production of accurate high quality documents in compliance with regulatory requirements. Participate on project teams. Provide training as necessary”. The qualifications required from an applicant for this position were: “Sound knowledge of the drug development process, descriptive statistics, and experimental design. Excellent communication skills.”

The company is clearly seeking someone who has a broad experience base and who will be able to perform a multifaceted function that goes far beyond making sure the grammar is correct in their documents. The job description makes it clear that the writer will be required to provide strategic input into how to effectively present and communicate messages in submission dossiers and product labels to make these messages clear to the regulatory reviewers and thereby shorten the review process.

EFFECTIVE COMMUNICATION

The critical importance of clear communication in science and the consequences of its absence have long been championed by Edward Tufte, Professor of Political Science, Statistics, and Computer Science at Yale University, and author of a number of books on scientific data presentation (7,8,9). Professor Tufte has famously attributed the loss of the space shuttle Challenger to poor data presentation; in effect, the lack of expert scientific communicators such as medical writers. Tufte’s analysis of the disaster notes that Thiokol (the makers of the solid-rocket booster that exploded) prepared PowerPoint presentations for NASA, which due to their complexity (individual slides contained up to six different levels of headings) actually managed to conceal rather than communicate the link between cold temperature and O-ring damage on prior flights (10). He referred to the slides as “a PowerPoint festival of bureaucratic hyperrationalism” which did not communicate that damage to the left wing might have been significant.

In clinical research, poor presentation of trial results might not lead to explosions, but it can just as surely obfuscate messages and conclusions, resulting in the costly waste of time and resource usage that is frequently seen during drug development. We still see ‘key message’ documents, prepared to inform corporate decision makers that are over 20 pages long and packed with lengthy and complex tables.

Skill set of a strategic medical writer

- Strong interpersonal skills
- Confidence in handling data
- Understanding how to structure thought and presenting data effectively
- Experience in preparing clinical documents for regulatory submission, including clinical protocols, study reports and clinical summaries
- Detailed knowledge of European, US, and international pharmaceutical regulations, requirements and guidance associated with document preparation and submissions to regulatory agencies
- Good overall knowledge of clinical development and GCP regulatory requirements for the conduct of clinical studies
- Proven ability to think creatively, meet deadlines and manage multiple tasks simultaneously

CONCLUSION

In clinical research, poor presentation of trial results might not lead to explosions, but it can just as surely obfuscate messages and conclusions, resulting in the costly waste of time and resource usage that is frequently seen during drug development. We still see ‘key message’ documents, prepared to inform corporate decision makers that are over 20 pages long and packed with lengthy and complex tables. In contrast, good documentation with clear presentation of key results can facilitate the decisions necessary for rapid and successful drug approval. Good medical writing is not only required for the submission documentation itself, but as part of the strategic process of drug development, ensuring that development decisions are made with a complete understanding of the available data.

Out of the relentless need to streamline drug development, the industry is driving the paradigm of clinical documentation towards a model in which the medical writer is a strategic partner on the clinical team. In a kind of runaway evolution, as clinical programmes become more adaptive and tailored to specific populations, the role of the strategic medical writer will become ever more essential to help teams recognise the messages to be gleaned from what will certainly prove to be complex data sets at each stage of

the process, and to keep the teams focused on how the data can support target product profiles.

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About the authors



After receiving her PhD in developmental neurobiology, [Julia Forjanic Klapproth](#) started her career as a Medical Writer in the pharmaceutical industry at Hoechst Marion Roussel (later Aventis) in 1997. Since then she has been President of the European Medical Writers Association (EMWA) twice (2001-2002, 2007-2009). Julia is also an

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