AI for medical writing: assistance, acceleration and augmentation

The promise of AI for the field of medical writing has been apparent for some time and a number of teams have created tools of varying effectiveness and scope. Dr Barry Drees, senior partner at Trilogy Writing & Consulting, believes that the best AI tool for medical writing will assist, accelerate and augment the job of the medical writer.

The use of computers to assist the medical writing of documents for regulatory purposes has a surprisingly long history, stretching far past the use of AI as a jargon word for computer-assisted text creation. Back in the early 1990s, I was involved in discussions at the pharmaceuticals division at Hoechst in Frankfurt, Germany, about streamlining the writing of subject narratives for participants in clinical trials who experienced serious adverse events. At the time, the entire subject narrative was written by a medical doctor, including basic information about the subject's age, sex and medical history, using the original line listings.

This was an arduous, mistake-filled, time-consuming and expensive procedure that was estimated to cost major pharmaceutical companies millions of euros. It occurred to me and several of my colleagues that they could make this process much faster and less error-prone if they simply imported the subject's basic information directly from the database. This presented the medical doctor, who was writing the subject narrative, with a small table showing all of the baseline information as well as everything about the adverse events – time, duration and intensity, for example – and study status. The doctor then only had to write their medical opinion about the course and how it related to the event in question. This reduced the time of writing by two-thirds, as well as considerably improved the accuracy. Clearly this was a question of both assisting and accelerating the writing process. These days, most medical writing projects use computer-created data tables – the old days of painstakingly searching through pages and pages of subject listings are thankfully largely ancient history.

Augmentation, however, is an entirely different matter. Most people understand augmentation as actual improvement – can an AI system actually improve the quality of regulatory documents above and beyond finalising them more rapidly, and with fewer mistakes? What would true augmentation actually look like? In fact, augmentation implies that there are things that can – and possibly even should – be improved, but what part of clinical documentation needs to be improved?

If it's not broke, don't fix it

It is a poorly kept secret that reviewers at major regulatory agencies have complained about the poor quality of study report writing for many years. Some organisations still seem to see medical writing as mostly following a style guide and putting the data in the correct place in the ICH template. One can see this in what passes for regulatory writing in many of the study reports submitted to regulatory agencies – where the data from tables are simply repeated in the text with no attempt to say what they mean. I have long felt that this was not medical writing but rather medical repetition. Early in my career, when I asked a colleague about this, I was told that putting the same information in a table and the text ensured that the reader would have the data in whatever form they preferred, for example, tables or text. Laughing at this, I wondered whether there was even a single person on earth that preferred to read numbers in text rather than a well-designed table. Once told that it was important to describe the

numbers in tables in text, I agree that describing the data is good but that this was different from merely repeating it.

It is only relatively recently that the movement known as 'lean writing' has come to be recognised and adopted by organisations. The goal of lean writing is to make the writing, reviewing and reading of regulatory documents more efficient by eliminating pointless repetition, excessive wordiness and a style more appropriate for novels than technical documents. Nevertheless, it has not been adopted everywhere and I often find myself in heated discussions trying to convince academics and clinical research scientists to adopt a leaner writing approach. It seems that, despite the obvious advantages of lean medical writing in terms of time and cost, not to mention readability, there is still a long struggle ahead before it is universally adopted.

Clearly, as has been noted by many observers, what would greatly facilitate the general adoption of lean medical writing techniques would be the proposal and acceptance of standard text. A standard structure has been adopted for clinical study reports in the ICH E3 guidelines in 1995, which defined how such reports should be organised. This greatly streamlined report preparation and writing as – finally – a definitive document structure was available and most groups happily followed it. Unfortunately, despite a number of attempts, no generally agreed text has ever been accepted. These failures were usually ascribed to the great variability of clinical research with a wide range of products and study designs in different disease indications.

It was clear to many medical writers, however, that many parts of a clinical study report are similar, regardless of the test substance or population. Sections on demographic variables and baseline characteristics or treatment-emergent adverse events, for example, often describe similar kinds of data sets and would appear to be ideal for standardised text. I have always felt that it was not the inherent variability in clinical studies, but instead it was the reluctance of many authors to relinquish control over what is still considered a personal thing – writing style – to a 'standard'. This is a common mistake in technical writing, where people use techniques and a style more appropriate for fiction than a scientific document. I have even heard some medical writers describe with pride a piece of writing as being 'beautifully written'. This is wonderful for literature but hardly appropriate for clinical documentation. Thus, large-scale attempts to create standardised text in the pharmaceutical industry have never been successfully adopted, even within organisations.

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The true potential of AI

Here is where I believe that the use of AI software for clinical documents can truly be augmented in a way that, so far, has not been achieved. In developing an AI tool for study report writing with the software programmers, Trilogy defines the rules that should be followed to interpret the data and creates standard text to be used, depending on the results. Why do I think that this time will be different and that there will be wide acceptance of such standard texts when they have often have failed in the past? It is because, rather than appearing as a document that will be seen by many as demanding compliance and submission, the standardised text will be suggested as almost an afterthought to a system designed to save the writer time and tedious effort. Writers who might object to being forced to write a certain way, will find that a computer providing suggestions based on data might be much simpler to accept than rewriting everything from scratch.

The introduction and wide use of AI tools for medical writing will definitely lead to large savings in time and money – assistance and acceleration – in the process of preparing clinical documentation. Whether it will also lead to the wide adoption of standardised texts to make these documents clearer and easier to understand is, of course, impossible to predict with any certainty. However, my more than 30 years of experience in the field makes me think that using such a 'back door' approach might finally be the opportunity for the field to take its long overdue step of using standardised texts and true augmentation in clinical document writing. ●

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