Assistance, acceleration and augmentation

AI is set to play a significant role in regulatory and medical writing in the very near future. **Dr Barry Drees** of Trilogy Writing & Consulting, using his more than 30 years of experience, discusses the history of medical writing, the challenges facing his company in implementing AI industry-wide, and why computer-augmented reports are necessary.

For the field of medical writing, the promise of AI has been apparent for some time now, and a number of teams – including Trilogy Writing & Consulting – have created tools of varying effectiveness and scope. Nevertheless, the actual aim of these various programmes, whether it is to assist, accelerate or augment the job of the medical writer, remains unclear. I actually believe that the best AI tool for medical writing will do all of these things. Let me explain.

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 jargon for computer-assisted text creation.

Back in the early 1990s, I was involved in discussions at the pharmaceuticals division of Höchst, a company based in Frankfurt, Germany, about streamlining the writing of subject narratives for participants in a clinical trial that experienced serious

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adverse effects. 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. It occurred to me and several of my colleagues that we could make this process much faster and less error-prone if we 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 their adverse events (time, duration, intensity, etc) and study status. The doctor then only had to write their medical opinion about the course and relatedness of the event in question.

This reduced the time of writing by two-thirds, and 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, and the old days of painstakingly searching through pages of subject listings is, thankfully, largely consigned to 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?

Changing something that isn't broken?

It is a poorly kept secret that reviewers at the major regulatory agencies have complained about the low 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 data from tables is simply repeated in the text, with no attempt to say what it means.

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 text paragraph ensured that the reader would have the data in whatever form they preferred – tables or text. I laughed and wondered whether there was even a single person on the planet that preferred to read numbers in text rather than a well-designed table. I was once told that it was important to describe in text the numbers in tables. I agreed that describing the data was good but that this was very different from merely repeating them.

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 much 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 was adopted for clinical study reports in the ICH E3 guidelines in 1995, defining 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.

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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 very similar, regardless of the test substance or population. Sections on demographic variables and baseline characteristics, or treatment-emergent adverse events, for example, often describe very similar kinds of data sets, and would appear to be ideal for standardised text. I always felt that it was not the inherent variability in clinical studies, but instead the reluctance of many authors to relinquish control over what is still considered a very personal thing, their writing style. ▶

Dr Barry Drees

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The adoption of computer-assisted writing should make medical reports easier to read as well as write.

This is a common mistake in technical writing, where people use techniques and a style more appropriate for fiction than for 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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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, together with the software programmers, Trilogy defines the rules that should be followed to interpret the data, and creates standard texts to be used, depending on results.

Thus, it is creating standardised texts.

Why do I think this time will be different, and that there will be wide acceptance of such standard texts where they have so often 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 texts will be suggested as almost an afterthought to a system designed to save the writer time and tedious effort.

Writers that might object to being forced to write a certain way, will find that a computer providing suggestions based on the data might be much simpler to accept than rewriting everything from scratch.

The introduction and more wide-scale 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 wider adoption of standardised texts to make these documents clearer and easier to understand is, of course, impossible to predict with any certainty. However, my 30-plus 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 the long overdue step of using standardised texts, and thereby achieve true augmentation of clinical document writing. ●

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