President's Message

Navigating the new era of clinical trial transparency

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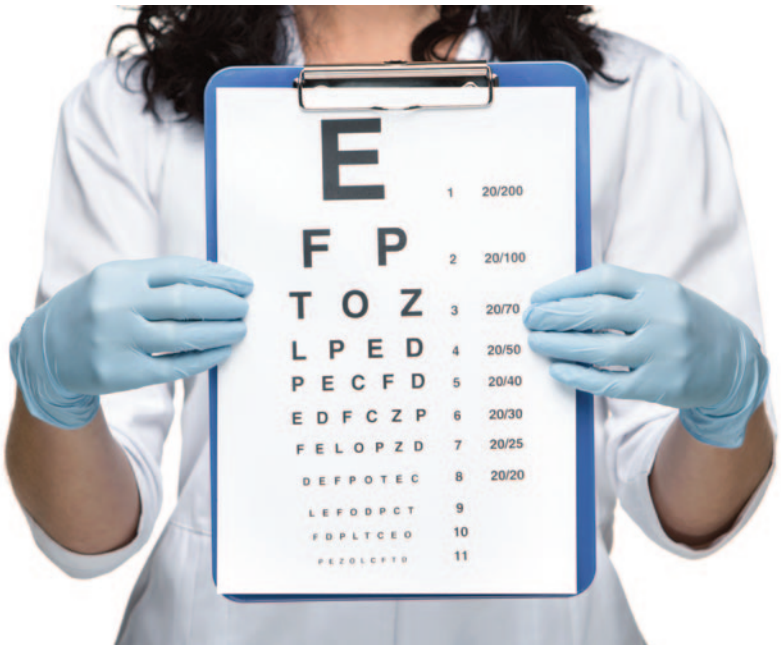

Dear EMWA Colleagues,

This September's issue of *Medical Writing* comes at a time when the summer holidays are behind us. Here's hoping it has been a relaxing and rejuvenating time for all. As we get back to our day-to-day work, our fellow EMWA colleagues bring us an expert insight into the latest requirements in clinical trial transparency and disclosure. As medical writers, this has been on our agenda for many years now, but as we look to the future, transparency in clinical research is emerging as more than just a regulatory requirement – it is a cornerstone of public trust and ethical responsibility. Yet navigating this terrain is not always straightforward. With new regulations, evolving expectations, and the ever-present need to protect sensitive information, it can feel like we must add yet another string to our bow.

In force since January 2022, the European Union's Clinical Trials Regulation (EU No 536/2014) has been a significant and long needed evolution, designed to increase transparency. But as with any regulation, it comes with its share of challenges. The recent revisions to the EMA's Clinical Trials Information System (CTIS) transparency rules remind us that our work was never about ticking boxes; it is about finding that delicate balance between openness and protection. We are expected to make clinical trial data available to the public while safeguarding personal data (PD), of the people who participate in a trial, and the commercially confidential information (CCI).

For those of us dealing with trials transitioning from EudraCT to CTIS, the pressure is on. Not only do we need to ensure a smooth transfer of data, but we also must be meticulous about how we present this information. What exactly constitutes PD or CCI can sometimes be a grey area, and it is our job to navigate these decisions with care. The goal is transparency, but never at the expense of privacy or commercial sensitivity. It is a challenge and we, as medical writers, are uniquely placed to drive forward best practice.

One such document that has been gaining momentum is the plain language summary (PLS). I am sure you are already familiar with the push to make clinical trial results more accessible to the public, especially to patients. Again, this is not just a regulatory requirement; it is a genuine effort to engage and empower those who stand to benefit from clinical research. Should patients have a say in how these summaries are written? Absolutely. They can provide insights that we, as professionals, might miss. And what about AI? It is a tool, as any other, but one that may help us craft clearer, more concise summaries that resonate with a broader audience.

As we work globally, the challenge of transparency grows even more complex. Each region has its own set of rules and expectations, and it is our job to ensure that we are not only compliant but also consistent across borders. Certain companies have shown that it is possible to meet these challenges head-on, maintaining a commitment to transparency while navigating a web of global regulations.

In this digital age, we have more tools than ever to reach people where they are, but with that comes an increased dimension to our responsibility to ensure that the information we provide is accurate, accessible, and meaningful.

Staying up to date requires continuous learning. The results of the 2023 CORE Reference Utility Survey are presented in this issue (see pages 38). We need to keep evolving, refining our skills, and staying informed about best practices. This is a task for our EMWA specialists and volunteers and is a timely reminder to keep coming to our EMWA conferences and attending our very professional educational workshops and seminars. Do not forget to register for the November online conference when registration opens and do think about joining one of the local hubs to participate in the face-to-face networking activities.

We have a journey ahead of us. It is complex, sometimes challenging, but undeniably crucial. Let us continue to work together to uphold the highest standards of transparency, all while protecting the privacy and integrity that our work demands.

Continually learning,
Sarah