

CONFERENCE

Session Report

Plain Language With a Page Limit: Strategies for Writing Two-Page Protocol Synopses and Other Deliverables

Speaker

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Regulatory writers often work on lengthy technical documents tailored to an expert audience, such as investigator's brochures, clinical study protocols, and clinical study reports. But with recent regulation from the European Union (EU), a new deliverable—the plain language protocol synopsis (PLPS)—entered the picture. With it came questions: who is this document for? Is it required? And most importantly, how can a writer summarize a complex study protocol, using plain language, in just 2 pages? Zack Fey, a medical writer at the Center for Information and Study on Clinical Research Participation (CISCRP), has written countless PLPSs since the regulation took effect. At the 2023 AMWA Annual Conference, he shared his expertise, including best practices for writing in plain language, challenges introduced by the new regulation, and strategies for using plain language with a page limit.

PLAIN LANGUAGE BEST PRACTICES

Plain language, broadly defined as writing that is easy to read and understand, is increasingly implemented in medical writing. It is particularly valuable in clinical research, in which it can improve transparency for regulatory authorities and promote understanding and engagement for research participants. Given the increasing demand and potential benefits, medical writers may be tasked to write in plain language and should be familiar with its principles. Accordingly, Fey shared the following best practices for developing plain language documents:

- **Word choice**
 - o Aim for a sixth to eighth grade reading level
 - o Use the active voice
 - o Define complex terms with simple terms (“familiarizing”)
- **Organization**
 - o Order information from broad to narrow (inverted pyramid structure)

- o Break large blocks of text into smaller paragraphs (“chunking”)
- o Limit cross-referencing between sections

- **Design elements**

- o Use ample white space around elements
- o Use a large font size
- o Use visual aids, including graphics and icons

EU CTR 536/2014

Plain language makes a document more accessible but also usually makes it longer. White space, graphic elements, and additional definitions take up space, which can be a problem when trying to adhere to a page limit. Nowhere is this challenge more apparent than in the conditions of EU Clinical Trials Regulation (CTR) 536/2014, which, effective January 2022, (1) requires that clinical trial applications be accompanied by a 2-page protocol synopsis and (2) suggests that the synopsis be written in plain language. Applicable to all new clinical trials conducted in EU member states, the regulation further stipulates that the protocol synopsis must include the following 9 elements:

- Trial title
- Rationale
- All objectives
- All primary endpoints
- All secondary endpoints
- Population
- Trial design
- Interventions
- Ethical considerations

According to Fey, the target audience of the PLPS remains unclear and may vary by sponsor. Furthermore, because of the regulation's wording, there is some question as to whether the use of plain language is required, recommended, or merely suggested. Nonetheless, Fey noted that many of the sponsors who work with CISCRP have begun including a PLPS in their clinical trial applications, allowing Fey's team to develop and refine their strategies—along with a comprehensive template—for these documents.

BALANCING ACCESSIBILITY AND LENGTH

The PLPS poses a challenge for writers accountable to EU CTR 536/2014, but its difficulties are relatable for any writer who strives to balance clarity with conciseness. Nevertheless, skilled medical writers can adhere to principles of plain language while also limiting document length. Fey shared the following 5 tips for balancing these interests in a PLPS:

- **Use tables and other visual aids:** Tables and graphics are visually engaging and can break up otherwise large blocks of text, making a document more inviting to readers. Well-designed ones can also present a lot of information compactly, saving space.
- **Use bulleted lists where possible:** Bulleted lists are easier to navigate than lists in a body of text, making the information contained more accessible. They also allow for more brevity than full, grammatical sentences, which can reduce word count.
- **Condense similar secondary endpoints:** Secondary endpoints can be numerous and often have similarities. If this is the case, some may be able to be grouped together in a bulleted list or table. This approach consolidates related information, limits cross-referencing, and saves space.

- **Use color (and be consistent in its meaning):** Color coding makes text visually appealing and informative at a glance. When colors are used to convey meaning, they can also reduce explanatory text.
- **Add a third-page glossary:** If definitions are taking up too much space in a PLPS, they can be housed in an optional third-page glossary. This approach preserves important definitions in an easily referenceable format while saving space in the core document.

CONCLUSION

Although writing in plain language often adds length, it can still be done when space is limited. As Fey explained, many principles of accessibility are applicable—and even conducive—to writing with a page limit. The key, Fey emphasized, is finding the right balance between accessibility and length.

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