How to Write a Protocol Synopsis for Laypersons

GLOBAL

As part of the requirement to register new studies on the EU's Clinical Trials Information System (CTIS), sponsors now must provide both a protocol synopsis and a lay summary of the study's results. But what exactly does this requirement entail? This paper will explain the protocol synopsis and provide some tips for success.

Required Document Elements

As detailed in Regulation (EU) No 536/2014 Questions & Answers February 2023, the protocol synopsis is limited to 2 pages and has 9 required elements:

1. EU trial number and full trial title
2. Rationale
3. Objective
4. Main trial endpoints
5. Secondary trial endpoints
6. Trial design
7. Trial population
8. Interventions
9. Ethical considerations relating to the clinical trial, including the expected benefit to the individual subject or group of patients represented by the trial subjects, as well as the nature and extent of burden and risks.

While it is not required that the protocol synopsis be written in lay language, this is suggested. The February 2023 Q&A document states, "Sponsors should consider to make the synopsis understandable to a layperson." Providing a protocol synopsis that is accessible to a wide range of readers increases transparency and may boost enrollment. CTIS is a central repository of clinical trial information and could be a point of entry for potential study participants, so sponsors will benefit from having a well-written, lay-friendly document.

Writing for a lay audience requires a different tone and focus as compared to writing for regulatory bodies, and the writer should have a clear picture of the intended reader. The guidance on Good Lay Summary Practice recommends that a lay summary should be accessible to readers 12 years and older, but authors who imagine writing for a 12-year-old will likely end up with a document that sounds "dumbed down" and condescending. Instead, the writer should imagine that they are explaining the study to a stranger who is interested in the topic but lacks a strong understanding of science. (High school biology class was a long time ago for many readers.) With this mindset, the writer can better gauge what they need to explain, what details to omit, and how to best focus on the study's key messages.

Of course, a medical writer can also help to translate the protocol into a synopsis accessible to a wide audience. We're here to help, both with lay summaries and other clinical and regulatory documents. Contact us at info@globalrwc.com.