HLM comments on regulation (EU) no 536/2014 on clinical trials on medicinal products for human use

We are submitting these comments on the behalf of HLM, a public health nonprofit.
Contact: Megan Rooney

General comments

First, HLM would like to thank the EMA for allowing the public this opportunity to comment and for recognizing the need for trial summaries to be accessible to the general public. Many of the recommendations in the guidelines document are health literate principles that we practice daily in our work to improve shared understanding and decision making for patients. We are glad to see them being put to use in this regulation. Below, we offer up a set of recommendations to further improve and clarify these summaries.

Scope comments

- We believe it would be helpful for summaries to have an at-a-glance key facts section at the beginning of the document. This would include a 1-2 sentence summary of the research method, population studied, and results.
- We agree with the intent of the inclusion and exclusion section and agree that too many details here will take away from the important information patients need. We have a concern about how researchers will identify the most important information, so we suggest more guidance on how to limit these lists. Consider limiting the list to no more than 10 items.
- The breakdown of number of participants by country seems out of scope for these documents, as it may not add information that would aid in health decisions. Consider removing it or offering sponsors flexibility in how this information is presented. As written, this has the potential to add unnecessary length to the document and distract from more important information, such as results and side effects.
- Consider removing any secondary endpoints that are not clinically significant, so that the focus is only on the endpoints that could be used for medical decisions. Exploratory secondary endpoints could be excluded to avoid confusing patients.

Plain language comments

- The required headings are not in plain language, which may make them difficult for some readers to access. We recommend this language be flexible so that the document can be as clear as possible. In Annex 1, you say both that “the wording cannot be changed” and that “the use of suggested wording is not mandatory.” Please consider clarifying that sponsors may use plain language wording in the headings. HLM is working

on a template that we would be happy to share with the EMA on completion for further suggestions about wording and structure of the headings.

- Similarly, you allow for “side effects” to be used instead of “adverse reactions,” but then require the use of “adverse reactions” later in the document. “Adverse reactions” is a jargon term that will likely be unfamiliar for many readers and may cause confusion. Consider allowing the more common term (side effects) to replace it entirely in the document.
- From research, we know that a conversational tone aids in patient understanding and comprehension. To that end, consider changing the use of “lay” (terms such as lay, laypersons, lay summaries, lay language, lay title, and lay audience) to more common terms, such as general public and simple language. Also, consider changing the term “subject” to person, patient, or volunteer. These changes will help to make both the regulation and the final documents more accessible.
- There were references to Levels 2-3 in Europe and 6th grade level in the US (through Microsoft Word) that don’t seem compatible. It was mentioned that Level 2 is approximately high school level, which is grade 9-12 in the US. Please clarify.

Numeracy and visuals comment

- We appreciate you mentioning the importance of graphics, but we think the language could be stronger. Research says that visuals make numbers easier to understand and use in decision making. Consider asking for all numeric data to be visualized in simple, clear tables or other health literate visualizations, such as graphics or images.

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