Dear Madame or Sir,

I am responding as an individual, interested citizen and am OK with publication of my name, together with the paragraphs below.

My comments/contribution to this consultation revolve around the specific templates and language guidance you present in the annex. Since you mention several software tools in the main body of the document, I wonder whether you have considered to also implement your recommendations in software?

I would like to suggest that you (EMA, HRA, EC or the expert group on clinical trials) fund such a development project. It should publish both a [permissively licensed][2], free/open-source library and a reference implementation. Software code in my opinion can have a larger impact than the letter of the law (see Lawrence Lessig's [Code is Law][1], referenced below), because it can be injected more conveniently into the workflows of your target audience, than for example printing out or memorising a document.

The library should be usable by others in their own tools, while the implementation should be immediately useful for your target audience. The latter could be an add-in for Microsoft Word, or an extension for Open/LibreOffice, or a stand-alone program. Such implementations could assist the writers in real-time, like a grammar- or spell-checker. Existing examples for style improvement tools are [Grammarly][3] or [Cleartext][4].

Such an approach would in my opinion increase compliance with your recommendations, because it would make following them easier. Moreover, a free/open-source software project can take root in the interested public and in relevant companies more than a mere document can.

Thanks for your work on this topic, and kind regards,

Katrin Leinweber

PS: References

[1]: https://en.wikipedia.org/wiki/Code_and_Other_Laws_of_Cyberspace
[2]: https://www.fsf.org/licensing/
[3]: https://www.grammarly.com/
[4]: https://github.com/mortenjust/cleartext-mac#whats-this