Reviewer’s report

Title: Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table

Version: 0 Date: 23 May 2019

Reviewer: Erik Cobo

Reviewer's report:

The authors report the process to update the CSRs by the CORE developers.

It is reported in a perfect and transparent manner, that deserves publication -- at least for me, a non-native English speaker.

I provide 4 minor comments for the consideration of the Authors.

Please consider adding a comment in your discussion about your plans to disseminate CSRs.

As I see them, the difference between the primary and the secondary endpoint is that the primary one(s) serves to arrive at a decision under the Neyman-Pearson paradigm (i.e. trial results recommend allowing public access to the intervention in a pivotal trial); and the secondary ones serve to learn more under the Fisher's evidence framework, adapted to CIs philosophy. So, I'm confused because you added a third class of end-points, exploratory. Please, consider, either to simplify, or justify this classification, or providing references.

Personalized Medicine may help to argue against evidence medicine. A student of mine recently advocates a clearer report for CT (Cortés et al). Please, consider commenting on the convenience, or not, to place the trial within the context of personalized medicine. I.e., to clearly state if the hypothesized effect was or not a constant; or if the report looked at this assumption.

Finally, I wonder if the part corresponding to estimands is as 'mature' as the rest of table 2. Unfortunately, I'm not an expert. So, I just suggest that authors double check the wording with experts.

Level of interest

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An exceptional article
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