Author’s response to reviews

Title: Improving outcome reporting in clinical trial reports and protocols: study protocol for the Instrument for reporting Planned Endpoints in Clinical Trials (InsPECT)

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Dear Dr. Møller,

RE: Manuscript ID TRLS-D-18-00829 – Improving outcome reporting in clinical trial reports and protocols: study protocol for the Instrument for reporting Planned Endpoints in Clinical Trials (InsPECT)

Thank you very much for your response to the above manuscript. We have responded to the reviewers’ helpful suggestions, and revised the manuscript as follows.

Reviewer #1:

This is well written paper. The information provided by authors are clear and concise. I enjoyed reading this protocol on the development and improvement of reporting outcomes of clinical trial protocols and reports. I have only minor suggestions beow:

1) Background. Line 134. "... efficacy, safety, and effectiveness." Please also add "efficiency).

   -The word “efficiency” has been added (Background, Lines 134-135).

2) Line 298. "We will engage multi-national participants involved...". It is not clear for me what the authors consider as "multi-national participants".

   -We have changed the wording to “international participants” (line 298) and added a statement that there will be no geographical restrictions with respect to participant eligibility (line 323).

3) Line 303. Can the authors list the specific inclusion criteria of participants?
-We have clarified the specific inclusion criteria of the participants for the Delphi in lines 313 - 325).

4) Line 326. "…highest level of education…” What will be the highest level of education for a participant with a profile including MD and PhD? I would suggest to not consider only the highest degree of education.

-We have removed the word “highest” from level of education (line 331) as participants will be provided with multiple educational options and will be able to select all that apply (e.g., MD/PhD, MD, PhD, Master’s Degree, and Other with a free-text entry box to specify).

We have also updated references and made minor corrections to the text for clarity as appropriate.

Thank you for considering our revised manuscript. We look forward to your response in due course.

Yours sincerely,

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