Reviewer’s report

Title: Health-related quality of life as an endpoint in oncology phase I trials: a systematic review

Version: 1 Date: 03 Apr 2018

Reviewer: Everardo Saad

Reviewer's report:

In this manuscript, authors report the results of a systematic review of the literature pertaining to the assessment of health-related quality of life (HRQOL) in phase I trials in solid tumors among adult patients. Not surprisingly, HRQOL has been reportedly used very rarely. I personally do not see this as a problem and do not believe HRQOL assessment really adds value to phase I trials. Most phase I trials assess patients for a short period of time and at doses below the MTD or RP2D, thus providing little role for HRQOL assessment. Despite my personal views, I believe the manuscript has merit and is well written. A discretionary point is the fact that reference 7 does not correspond to the citation to Paoletti's work in the text. More importantly, unless I missed it, the authors have not pointed to limitations of their work. They could perhaps say explicitly why hematological malignancies were left aside, and how they have dealt with papers that included patients with both solid tumors and hematological malignancies. Arguably, the period of analysis is short, so authors could build the case for why they chose to restrict the period.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics
Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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