Reviewer’s report

Title: Umbrella and basket trials in oncology: ethical challenges

Version: 1 Date: 11 Jun 2019

Reviewer: Rieke Van Der Graaf

Reviewer's report:

The authors have appropriately addressed my comments, apart from the response to comment 3.

Although the title now reads "ethical issues" and no longer aims at presenting both risks and benefits (which were absent in the previous version), the issues that are presented still primarily consist of challenges. Let me explain: the first issue (scientific validity) mentions "major challenges" (pg 9 line 69). This is ok, but the reader would also expect whether and to what extent these designs meet scientific validity as a requirement. Accordingly, page 12, line 38 sets out "benefits". I would merge benefits with risks and turn it into a second ethical issue, among others because the content only focuses on the positive aspects and secondly because benefits should always be offset against the risks. Finally, as regards informed consent on page 21ff also mere challenges are addressed (line 47). In other words, please provide an overview of the issues presenting arguments for and against meeting the ethical requirements of validity, favorable risk-benefit and informed consent. Alternatively, put challenges in the title.
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.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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