Reviewer's report

Title: Design of Phase II Cancer Trials Evaluating Survival Probabilities

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Reviewer: James Herndon

Level of interest: not specified

Advice on publication: Other (see below)

I do have a few suggestions that would make the manuscript more understandable to even the statistically inclined reader:

1. Upon first introduction, Table 1 was somewhat difficult to interpret until the authors went through an application. I wonder if the manuscript would be more understandable if the authors discussed the application before making general comments about what can be observed in Table 1?

2. Again, relative to Table 1, it would be nice if:

   a. A definition was provided within the table as to what "Interim Analysis" meant.
   b. The table clarified that columns EDA, DAmax, ETSL, and TSLmax were all computed under the null hypothesis.
   c. Given the large number of abbreviations within the manuscript, it might be useful to redefine the abbreviations within the table.....or have a separate table in the paper for reference defining all the abbreviations.
   d. It would be nice to elaborate in the text as to basis for the statement that "The maximum sample size remains relatively stable (approximately 15-16% greater than the fixed sample size)..." I eventually figured it out; however some explanation might make the interpretation easier.

3. Minor comment---At one point in the manuscript, a subscript was used to indicate that EDA was computed under the null hypothesis (i.e. EDA0). However, that notation is not used throughout the manuscript. It would be nice to be consistent.

4. In the discussion about simulations....

   a. What is the reference of Table 3.1?
   b. Please clarify why DAmax/DA is being multiplied by the fixed sample size. (I think this gets back to a lack of understanding of Table 1.)
5. In the background, the standard phase II hypothesis was structured as:

H0: pp0 versus H1: p>=p1

which is consistent with the notation used in Table 2. However, this hypothesis-testing notation is not consistent with that presented within the Application, nor within Table 4. In the latter cases, the structure does not reflect the alternative hypothesis. The manuscript should be consistent in terms of these notations/structure.

6. It would be nice to add to Table 4 the footnote about percentages included for Table 3.

7. In Table 5, please define ESS.

8. In Figure 1, please define what is meant by "Relative Efficiency".

Questions:

a) Level of interest. BMC Medical Research Methodology is willing to publish any scientifically sound paper. However, we would like to draw particular attention to the more interesting papers. Could you therefore indicate which of the four categories below best describes the paper:

XX UNCLEAR, the answer to this question is greatly dependent upon the journal's audience (see comments above)

b) What is your advice on publication?

- Accept after revisions ASSUMING the manuscript is appropriate for the journal

Competing interests:

None declared.