Reviewer's report

Title: Screened Selection Design for Randomised Phase II Oncology Trials: An Example in Chronic Lymphocytic Leukaemia

Version: 1 Date: 2 May 2013

Reviewer: Christopher J Weir

Reviewer's report:

This study is well motivated, with a clearly stated objective to improve the design of drug screening trials in cancer. The appeal of the proposed method is its simplicity supported by the accompanying R code. The Methods are appropriate and generally well described. I have suggested some additions in the revision recommendations. The Discussion is well balanced and considers a range of possible design alternatives.

Major Compulsory Revisions

1. On p11, “sections 2 and 3” are referred to but it is unclear what this means. Initially it seemed to be referring to parts of the R code cited in the previous sentence but on inspection of the R file this did not seem to be the case. This section needs to be restructured to improve clarity.

2. P14, paragraph 2 – can the sample size required by the Jung & George approach described be stated?

Minor Essential Revisions

3. p8 “...is a high probability...” change to “...should be a higher...”

4. It would be helpful if the notation in equation 1 were introduced directly rather than via a reference.

5. 1 million replications were used in the simulations. How was this number determined?

6. It would improve the clarity if the scenarios considered in the simulations were briefly introduced in the methods section.

7. The Discussion point about introducing more flexible stopping boundaries for futility in the SSD merits being expanded.

Discretionary Revisions

8. It would be helpful for some indicative numerical results to be included in the results section of the abstract.

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests’