Reviewer's report

Title: Comparison of anticipated and actual control group outcome in randomised trials in paediatric oncology provides evidence that historically controlled studies are biased in favour of the novel treatment.

Version: 1 Date: 30 July 2014

Reviewer: Nicolas Rasmussen

Reviewer's report:

This paper is brilliant. It is well conceived, soundly executed, and well analysed and reported. Its subject matter -- bias in the clinical trails literature -- and findings are both important. And while the findings come as no enormous surprise, it adds a valuable and convincing piece of evidence to the literature showing historically controlled clinical trials to be unreliable and positively biased for new therapies.

It requires no changes in my view. As a discretionary revision, I would suggest just one or two sentences, probably in the introduction, rehearsing how sample size calculations are typically carried out. This would make the paper more accessible to those who themselves have never conducted such studies.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I have no competing interests of any type described here (or any other type I can think of)