Reviewer's report

Title: Approaches to interim analysis of cancer randomised clinical trials with time to event endpoints: a survey from the Italian National Monitoring Centre for Clinical Trials.

Version: 7 Date: 27 June 2008

Reviewer: Heinz Schmidli

Reviewer's report:

Major Compulsory Revisions

Abstract: “The decision of stopping systematically overestimate treatment effects, generating seriously inflated estimates of treatment effect violates the ethical research requirement of scientific validity. Subsequent use of inflated estimates to inform clinical decision making and practice guidelines violates the ethical requirements of social value and a favourable risk-benefit ratio. Researchers and Ethical Committees, who give consent to the study activation, should better balance the risk and benefit of implementation of interim analysis and carefully evaluate protocols from this point of view.”

These concluding sentences are completely unrelated to the research presented in the main body of the manuscript, and should be deleted.

Minor Essential Revisions

1. Results section, 3rd paragraph. What are the number in brackets? For example 520 (300-820)? Is this the range? Please mention this, e.g. 520 (range 300-820).

2. Results section, typo “Overall neither form of monitoring was took place in 30 out of 150 protocols (20.0%).”

3. Results section, typo “and 10 (11.6) more then 3 analyses.”

4. Conclusion section, typo “on the contribute of the results of such analyses on the final decision to be taken.”

3. Table 3, typo “Same of primary analysis”

Discretionary Revisions

NA

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable

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