Reviewer's report

Title: Analysis and design of randomised clinical trials involving competing risks endpoints

Version: 1 Date: 10 March 2011

Reviewer: Aurelien Latouche

Reviewer's report:

Major Compulsory Revisions

p8 line -2 the notation for exp(beta M1) must change, because even if estimate of subHR can be close to estimate of csHR, these are 2 different quantities.

p10 The pintile formula is used for its simplicity, but you mentionned that in the intro that the independence assumption is stringent, while Pintilie formula makes this assumption. The Schulgen method is well documented and is more appropriate here. For completeness i would compute the sample size also with this formula

Discretionary Revisions

p4 line 2. I would modify the sentence « Theoretically, the time respective events »
For some patients the full path from randomization to death can be recorded

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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