Reviewer’s report

Title: Item response models for the longitudinal analysis of health-related quality of life in cancer clinical trials

Version: 0 Date: 13 Apr 2017

Reviewer: Sangchoon Jeon

Reviewer's report:

#1. On Page 7, the equation (5) may show the probabilities based on reversed categorical order. Based on the function F defined on page 5 (i.e. r_m(pi)=F(eta_m)), the probabilities would be pi_0=F(eta_0), pi_m=F(eta_m)-F(eta_m-1), pi_M=1-F(eta_M-1). In the reversed categorical order, that is, r_m(pi) = 1 - F(eta_m+1), the probabilities in eq (3) might be correct. If it's correct, it needs to be stated that the eq(3) was calculated for reversed order because the CdF for the sequential model seems not being calculated for reversed order.

#2. On page 8, in the four components (r, F, Z_q, U_r), the index r, which is the number of random effect, is confused with the ratio of probabilities (r). I recommend to replace the index r with another character.

#3. Title of Table 4 and 5 state "Frequency (on N=500 datasets) of …". Seems Table 4 and 5 are presenting percentages of selecting M1 or M2 rather than frequency of the selections.

#4. On page 10, the authors state "This could be explained by the fact that the difficulty parameters were not uniformly separated around zero and also because they were too close." This statement does not explain why the other IRT model had good performance even compared to LMM. Additional explanations are recommended.

#5. On page 12, the authors stated "it referred to a difference between the two arms at day 15, day 30 (during treatment period) but no necessarily at baseline" for the significant group difference (i.e. |beta1|>0) on diarrhea at baseline. I am confused how group difference during treatment period can be referred from the significant beta1. Maybe more detail explanations about the data are necessary.

#6. Based on simulation study, the IRT models have greater powers to detect random slopes but it's compensated long with greater type I errors compared to LMM. More guidelines in application of IRT are recommended.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
Does the work include the necessary controls? 
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Yes

Are the conclusions drawn adequately supported by the data shown? 
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Yes

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