Reviewer’s report

Title: A Bayesian non-inferiority approach using experts’ margin elicitation – application to the monitoring of safety events.

Version: 0 Date: 08 Mar 2019

Reviewer: LiAn Lin

Reviewer's report:

This paper presented a novel NI sequential design to monitor rare safety events using experts' margin elicitation. The authors applied the proposed method to illustrative trial demonstrate its utility. The results are certainly interesting and are of great interest to personnel in safety monitoring and those who are making similar efforts in other fields. However, I do have a few comments/questions that might improve the quality of this paper a bit:

1. The title of this manuscript indicated that the method is designed for rare safety events. However, the authors didn't provide detail of statistical challenge in monitoring rare safety events and how the proposed method can solve the challenges.

2. At page 3, the authors model the maximal acceptable difference as mixture distribution. Why can’t use the weighted average of expert's elicitation? What's the difference between these two methods?

3. At page 4 line 43, what is the priors p? this notation (and also some other notations) didn’t pre-defined.

4. At page 6, what's the rational to define tau at first analysis as 0.95? why can’t use alpha spending function to control the multiplicity in sequential analysis?

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?
If not, please specify which controls are required in your comments to the authors.

Yes
Are the conclusions drawn adequately supported by the data shown? 
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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