Reviewer’s report

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

Version: 1 Date: 19 Apr 2019

Reviewer: LiAn Lin

Reviewer's report:

The authors has provided their response regarding my review comments regarding "maximal acceptable difference". I agree with authors that mixture distribution may be able to capture experts' opinion better in some scenarios. However, authors still need to provide theory or analytical evidence to prove it. A simulation study to compare both methods in extensive scenarios is needed.

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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