Reviewer’s report

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

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Reviewer: Jue Wang

Reviewer's report:

The author proposed a Bayesian method to monitor rare safety events for non-inferiority trials incorporating experts' opinions on margins. The article is well written and the topic is of clinical interest. I have few comments below.

1. In practice, for a randomized phase-III trial, this type of analyses and safety monitoring would be most likely conducted by an independent data monitoring committee, is the proposed method easy to be pre-specified without reviewing the unblinded data and the detailed process easy to be followed and conducted by the independent committee?

2. From Figure 2, it seems the majority of experts' margin are 0. Does the proposed mixture Beta distribution on the range of (0, 1) fit the zero-inflated data well? Also, the possible values for experts' response seem very sparse, 0.01, 0.02, ... 0.05, and with a couple of outliers at 0.1 and 0.2? I'm not sure if the proposed distribution fit this data?

3. In addition, if the majority of experts had the same acceptable difference of 0, why not simply use 0 as the cutoff, instead of the rather complex mixture distribution, which might not fit the data?

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.

Yes
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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