Reviewer’s report

Title: True and False Positive Rates for Different Criteria of Evaluating Statistical Evidence from Clinical Trials

Version: 1 Date: 08 Oct 2019

Reviewer: David Colquhoun

Reviewer's report:

This is an impressive contribution to the literature on drug approval.

I have only two comments.

1. I'd welcome a brief comment about the relevance of clinically-meaningful effect sizes being expressed in normalised form. An individual patient isn't aware of the standard deviation. What matters to patients is the absolute effect size, not the normalised effect size.

2. No justification is given for use of the Cauchy prior. It might be worth mentioning that there are many ways (strictly an infinite number) of ways to calculate Bayes' factors. Held &amp; Ott (2018) would be a suitable reference.

I would have been interested to see results based on a point null prior. In this case the Bayes' factors become likelihood ratios and the math is greatly simplified, as is the comprehensibility to people who aren't familiar with Bayesian arguments e.g see http://fpr-calc.ucl.ac.uk/ ). However I'm not proposing that the authors should add this to their paper at this stage.

David Colquhoun

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

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