Reviewer's report

**Title:** Making clinical trials more relevant: improving and validating the PRECIS tool for matching trial design decisions to trial purpose

**Version:** 1 **Date:** 22 March 2013

**Reviewer:** Janice Pogue

**Reviewer's report:**

Authors have taken on an important task and addressing validity and reliability of the PRECIS-2 tool will represent an important advance. The authors should consider that they are not really demonstrating improvement between PRECIS-2 and the original PRECIS, but rather perceived improvement. To demonstrate improvement would involve the same trials being rated using the old and new tool, and compared.

There are a few minor omissions. Although I am sure the authors intend to use the matching of the pragmatic and exploratory trials in the analyses planned in phase 4, the statistics section do not mention this pairing. It would be useful to know what is the specific hypothesis that will be tested using the Cochrane risk of bias score? Is it that pragmatic trials should have greater risk of bias? This should be stated within the protocol. Also what is the purpose of the prognostic model to be built through multivariate regression?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests'