Reviewer's report

Title: Safety and Efficacy of Anti-PCSK9 Antibodies: A Meta-analysis of 25 Randomized, Controlled Trials

Version: 1 Date: 5 March 2015

Reviewer: Yoon Kong Loke

Reviewer's report:

Thanks for giving me the opportunity to review this submission.

Minor Essential Revisions

Quality assessment - it is not clear to me how you detected selective reporting of adverse events. Also, did you collect information on what the trialists said they were going to do in monitoring adverse events?

Statistical analysis - you should state that continuity correction was added to zero cells? What was the correction, and was it added to both cells?

Results, study selection and characteristics - should state the duration of most of the RCTs - majority seem to be less than 12 weeks, and there are very few long-term trials?

Discussion - there is too much emphasis on absence of statistically significant safety issues. You should point out major Limitations in safety data:
- broad 95% CI in some estimates, making it impossible to rule in or rule out problems
- lumping of broad categories into TEAE, SAE, so no ability to detect increased risk of specific events
- small, short-term trials cannot detect serious, rare problems

You make a statement at the end about 0.5 correction added to zero cells. Your statement is incorrect. The 0.5 added is purely for calculation purposes of RR/OR in the meta-analysis. It should not be used to affect the raw numbers (totals of events/patients. Also, the continuity correction does not necessarily lead to over-estimate, it could work in either direction depending where the continuity was. Usually, it biases towards the null.

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