Reviewer’s report

Title: Specific barriers to the conduct of randomised clinical trials on medical devices

Version: 0 Date: 07 Jun 2017

Reviewer: Rakesh Aggarwal

Reviewer’s report:

The manuscript is a systematic review of barriers for randomized clinical trials on medical device. In addition to published literature on the subject, internal communications of an organization (ECRIN) were also considered. The listing of various barriers and description of each barrier should be useful to those interested in the field of medical device research.

The review is primarily descriptive with no quantitative input (no meta-analysis) - this is unclear from the title. It would help to state this upfront in the title.

The discussion on 'acceptability' is unclear and can be improved. In particular, the distinction from 'operator experience (learning curve)' is not fully clear. It would help to state this better.

It may be useful to refer to 'Trial registration' and 'making trial data available' in the manuscript. Trial registration is a standard requirement in the field of pharmacological trials and should be useful for device trials too. Similarly, the need to make trial data available for secondary analysis is being adopted by medical journals and should be alluded to in relation to medical devices too.

Level of interest
Please indicate how interesting you found the manuscript:

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Needs some language corrections before being published

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Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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