Reviewer's report

Title: Legislation for trial registration and data transparency

Version: 2 Date: 29 March 2010

Reviewer: Lotty Hooft

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Major Compulsory Revisions

The topic of clinical trial registration and data transparency is important to every scientific clinical researcher. The rationale is sound, but with a better structured paper this key message could get more attention.

Some arguments are repeated and therefore the key message was sometimes difficult to follow. In the current manuscript two following paragraphs are “Why can previous efforts not ensure data transparency” and “Trial registration cannot automatically result in data transparency”, while trial registration is one of the earlier mentions efforts.

My suggestion would be to clearly divide the two initiatives: trial registration and data transparency. Also a more structured content, for example with the following items; the (historical) description, current state/'players in the field' and recommendation and implications for the future could be helpful and might improve the readability.

It is clear that trial registration alone does not automatically lead to data transparency. For me it would be interesting to include more discussion on 'side effects' of legislation of trial registration and data transparency (For example: What will be the effect on local research if country A has legislation on data transparency, but country B still has not. All research shift to B?). What is the opinion on this topic of other important stakeholders? Why is legislation the best option to provide data transparency? With the current version of the manuscript it is still difficult how we are we going to persuade our politicians to do this together. However, this article is definitely of importance in its field to raise awareness and provoke discussion.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Declaration of competing interests:

I declare that I have no competing interests.