Author’s response to reviews

Title: Legislation for trial registration and data transparency

Authors:

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Author’s response to reviews: see over
Dear Editor:

I have got the email dated 11 May 2010, and the comments attached about our manuscript titled with “Legislation for trial registration and data transparency” (Reference number: MS: 1489602353327790). We have revised the manuscript according the reviewers’ further comments. Now we submit it to the journal for further consideration.

Best wishes

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Reviewer 1:

1. The abstract is clearer now. The editors should be able to clarify the remaining small issues.
Response: Thanks. We have revised the abstract further.

2. The conclusion is now concise and clear.
Response: Thanks.

3. The grammar and flow are greatly improved. There are some moments of awkward wording still, but the editorial team should be able to solve the few issues. Example "...excluded drug Phase I trials..." should rather read "...excluded Phase I drug trials...". Also first paragraphs in subtopics "Legislation" and "Network" should be slightly re-worked for grammar and flow.
Response: Thanks. We have revised the manuscript accordingly.

4. The tone of the paper is much more positive – well done.
Response: Thanks.

5. This point has been clarified. Discussion is more inclusive with a wider view – follow-up articles with discussion of how local efforts can translate into a global system would be useful, but I understand that the authors are limited in word count.
Response: Thanks. We have added a point that local efforts are the basis for the global system.

6. Thank you. This has been dealt with accordingly.
Response: Thanks.

7. The general discussion of the need to register has improved, which deals with this without sensationalizing the issue in the context of US legislation – approach now seems more appropriate for the general theme of a global effort.
Response: Thanks.

8. Yes – the paper now reflects a slightly more global perspective, but a more in-depth discussion of this may be useful for a follow-up piece, as again, word limitation means focus is not centered on this discussion.
Response: Thanks. We have put more points about the global system for trial registration.
9. The authors have corrected areas where their information did not align with ICTRP.
The authors respond to this comment with the following "second step to establish a network involving all countries which has ability to conduct clinical trials" which is confusing – do they mean that they are calling for a global network to conduct clinical trials? Or to register clinical trials? The paper has more clearly outlined the key events in the development of the clinical trial registration effort globally.
Response: We revised the statement accordingly. The global network to conduct clinical trials is not our purpose, but to register the clinical trials.

10. The re-write of this paper has made what seemingly appeared to be a confusion between registration and ethical oversight more clear. Due to their response below, I am not sure the authors understood fully my comment, but the confusion is less of an issue in this version of the manuscript.
Response: Thanks. We understand your concerns about the ethical trial oversight and registration. And we further revised the manuscript accordingly.

Minor Essential Revisions
1. Yes. Thank you.
Response: Thanks.

2. Yes. The discussion is minimal but again I understand the authors are limited in word-count.
Response: Thanks for your understanding.

3. Yes thank you.
Response: Thanks.

4. Again due to limited word-count this issue could not be worked through as much as I think it should be. Ultimately the suggestion to create a global network has been made and is underway but a discussion of how to make this happen in depth has been lacking up to now.
Response: Thanks. We have added several points about the establishment of global network.

Discretionary Revisions
1. You are correct that Simes was the first to publish on this . . .I was just concerned by the statement as it leant itself to a reading that might allow a person to think that Simes was the first to come up with the concept of a registry and we cannot know that . . .all we
know is that he was the first to publish on it. But again, the statement is ultimately correct.

Response: Thanks for your understanding.

Quality of written English: Needs some language corrections before being Published.

Response: Thanks. We have revised the manuscript very carefully.
Reviewer's report

Title: Legislation for trial registration and data transparency

Reviewer's report:
The authors have revised the manuscript thoroughly and followed most suggestions of both reviewers. The readability has improved majorly and the key message gets more attention. The article can raise awareness and provoke discussion in its field.

Minor comments:
Page 4: only one explanation mark?
Response: Yes. Thanks.

Page 6: please be careful with the use of attention marks in an article.
Response: Thanks for your suggestion and reminders.

Discretionary Revisions:
Page 5: suggest adding information about relatively recent development. The new law in the US requires not only registration of trials but also that researchers enter results into the database. We can be cautiously optimistic that this law may be having an effect on publication bias. Reference: Tuma RS. "New law may be having some effect on publication bias". J Natl Cancer Inst. 2010 Mar 3;102(5):290-2. Epub 2010 Feb 19. Page 6: the authors’ plea for legislation can be sharpened, because unfortunately legislation is also not a solid solution. It depends on the consequences when you are entering the law. As mentioned on page 3, despite legislation (FDAMA 113) many drug trials were not registered in the US. What can we learn from this? What was the mean reason for the fact that registrations did not followed from this Act?
Response: Thanks for this question. We have added some points about the one point that the legislation is the only one step but not the last step for this trial registration. The more important one than legislation is the implementation and monitoring process of such law.