Reviewer’s report

Title: Data sharing in clinical research is a moral imperative

Version: 1 Date: 25 June 2011

Reviewer: Elina Hemminki

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Referee comments on the paper "Data sharing in clinical research is a moral imperative"

This is a polemic and stand taking selective review of debate over openness of drug trials data. I found the paper interesting to read: it had collected into one paper discussion and cases which otherwise one has to make a special effort to find. However, even though I enjoyed reading it, for a journal article it could be made more attractive, by changing it, e.g. according to the following guidelines:

1. The nature of the paper: it is not a usual results paper, protocol, review or editorial. It could be a debate paper, but it is too long and contains too much data for such. This is something the editors should look at.

2. The title refers to “clinical research”. However, the paper is almost totally on drug trials and drug research; I recommend narrowing the title.

3. The paper is very long and contains many different issues. It could be made into two papers, or alternatively concentrating on the main issues. Currently the paper deals with the following issues, among others: publishing results, publishing protocols, publishing raw data.

4. The text contains repetition, particularly in regard to recommendations and their argumentation. All that could be collected to the end.

5. The style is emotional and moralistic. I would abolish emotional expressions. The data are convincing enough without additional adjectives and sentences.

6. Likewise, I would separate the “should” sections (recommendations, condemnations) from the rest of the text. Following the traditional sections in a scientific paper (even though not with those subtitles) might help. A possibility is to structure the paper: 1. Introduction (the purpose of this paper and the issues to be covered), 2. Cases, 3. What are the problems and what has been made this far, 4. Future and recommendations.

7. The data on withdrawals because of adverse effects by the decision time and speed, is interesting. However, the text on dead-lines is formulated in a difficult way; please, clarify.

8. The problems of current secrecy and ownership rules are well presented. However, I would like to see thinking what are the unintended possible (negative) consequences if total openness to data will become mandatory, and what measures might be needed to correct such effects.
9. The chapters on “Necessary legislation” and “punitive measures” are weak. There are many different issues, and all suggestions are not well thought of. I would either leave these out (and say something general about that these measures are needed to amend the current situation) or make the chapters more well-thought.

10. References are many (needed); I did not check them but trusted they are OK.

Details
1. Both trade-names and generic names are used; trade-names are not identified with R.
2. Some of the sentences are long and complicated, e.g. p.6, 6th para, 1st sentence, p.7, 5th para both sentences (these are just examples, there are many more).
3. Citations on EU regulation is not needed (reference + summary), p 7.
4. The statements in italics on p.8-13; I would delete them. Not clear why they are given as separate text.
5. On p.12 last para before “Academic interests” the author recommend excluding from meta-analyses such trials in which authors are not willing to share their data. I wonder how many trials would be left. I wonder would happen to claim to include all trials and to the interest of doing meta-analyses if such clarification is needed. In long term it may be realistic.

Comment 5, some concrete sentences which particularly bothered me:

   p. 3, 2nd para, 2nd sentence.
   p. 6, 4th para

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests