Reviewer's report

Title: Sponsor's influence on conduct and reporting of industry trials: a comparison of protocols and published papers

Version: 1 Date: 13 March 2012

Reviewer: Dimitrios N. Lathyris

Reviewer's report:

Reviewer's report

Title: 'Sponsor's influence on conduct and reporting of industry trials: a comparison of protocols and published papers
Date: 13 March 2011
Reviewer: Dimitrios Lathyris

Reviewer's report: “Ghost management” has already been recognized as a serious threat that can distort the results and conclusions of published industry sponsored trials. In the current descriptive study, the authors describe industry participation in different phases of industry sponsored studies, focusing on the procedures of data management, data analysis and publication of results.

Comments and major compulsory revisions.

1) Is the question posed by the authors new and well defined?

The question is not new, but it is interesting that the authors tried to show the participation of industry to important phases of studies elaboration. Unfortunately, they don’t describe the participation of industry in the elaboration of studies' protocols.

Also, the authors insist on the comparison between protocols and published papers. With the exception of the data analysis part, no other comparison is clearly shown.

2) Are the methods appropriate?

Methodology is simple, acceptable but not new.

I don’t understand what the authors mean by “...were not part of the planned trials (e.g. secondary analyses).” (Methods, paragraph 1). They mean duplicated studies or studies that violated their original protocols?

3) Data control and deposition

Data are presented in a descriptive way and comparisons are not clearly shown. The result section should be extensively revised, if the authors want to
emphasize on comparisons. Otherwise, the words comparison, compared etc, should be replaced by the words describe, descriptive etc.

Moreover, the result section, which I really found difficult to follow, describes in exhaustive details the two tables provided by the authors plus additional data. Focusing on the most important points of the tables will help the reader better understand the manuscript.

4) Are the discussion and conclusions well balanced and adequately supported by the data?

The discussion is better written than the result section, in my opinion. Nevertheless, the authors didn’t avoid to arrive to hypotheses that may reflect their opinion, but are not justified by the results: (Result section, paragraph 6, “…This continuous access to accumulating data could potentially have led to premature stopping of the trial.”) and (Discussion section, paragraph 2, “…We find it likely that tasks not described were handled by the sponsor because the protocols were written by the sponsor. It was therefore implicit that what had been left out would be managed by the sponsor. The role of the sponsor may therefore be even more extensive than our results indicate.”). The above phrases should be rephrased, so that they better correspond to the results or even omitted.

5) Do the title and abstract convey what has been found?

I propose the title “‘Sponsor’s participation on conduct and reporting of industry trials: a descriptive study” that is closer to the message given to the reader by the result section.

In general, the abstract convey the authors’ ideas, but the result section of the abstract should be better written.

I couldn’t correspond the numbers of the following phrases from the result section of the abstract to the results reported on the tables or the manuscript: “One trial had independent data analysis and two reporting of results.”, and “In another 10 trials it was not possible to tell who analyzed the data based on the published paper alone.”

General comments

The authors’ main objective, that was to show that the sponsors’ ownership of studies’ data leads to manipulated studies, can only be hypothesized and is not explicitly shown.

Another disadvantage, also mentioned by the authors, is the fact that the trials were retrieved only by Lancet and the study focused only on industry sponsored trials. The paper could be considerably improved if the authors included clinical trials from other peer reviewed journals and non industry sponsored trials.

A reference list with the analysed studies is missing and should be added.

Minor essential revisions
Abstract

Methods: Last phrase “… on trial conduct and reporting and compared them.” One ‘and’ should be omitted.

Results: The phrase “In 11 of the trials there was a disagreement between the protocol and paper concerning who analyzed the data” should be better written

Conclusions: Last phrase “… statistical analysis and writing of the manuscript ….” The “and” should be omitted.

Manuscript

Background: Second paragraph:” Some journals therefore require that the involvement of the sponsor is stated in the published article.” References should be added.

Results-Data management: Second paragraph: “Thirty-one of the remaining 34 trials described processing of some efficacy and safety outcomes by adjudication committees” What do you mean by some?

Quality of written English: Acceptable, few improvements.

Level of interest: An article whose findings are important to those with closely related research interests

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'