Reviewer's report

Title: Industry-Sponsored Clinical Research in Less-Developed Regions: An Empirical Analysis of Registered Clinical Trials from 2006-2013

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Reviewer: Dimitrios N. Lathyris

Reviewer's report:

Dear HARPS editors,

The authors of the study "Industry-Sponsored Clinical Research in Less-Developed Regions: An Empirical Analysis of Registered Clinical Trials from 2006-2013" addressed an interesting topic and tried to describe the current patterns of industry sponsored clinical trials in more or less financially developed countries and classified them into 21 regions and five major geographic groups. However, I consider, not only this classification should be re-evaluated, but also the distinction of countries according to their development should be based in three categories-more, middle and less developed, instead of two-more and less. For example, Eastern European group includes countries that entered the EU recently (Poland, Latvia etc.) or long time ago (Greece) and consequently not only follow strict rules regarding industry sponsored studies, but their financial status is not similar to Sub Saharian countries, for example. Furthermore, China, a country with a fast growing economy in the recent years is neither a "more developed" country, nor a "less developed" one.

Additionally, included studies should be classified according to their subject and the relationship between study subject and country of patients’ recruitment (e.g. a trial that studies malaria will naturally recruit patients from countries where malaria is endemic).

Finally, I think that characteristics of industry-sponsored clinical trials should be presented per industry, at least for the 10 larger pharmaceutical industries reported in the manuscript, since it is important to see if any of them recruits more patients than the others from less developed countries.

Discretionary Revisions

Countries included in the high income Asia Pacific group should be reported.

To my consideration, the manuscript needs major revisions before decision for acceptance or not is taken.

Kind regards

Reviewer

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.