Reviewer's report

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

Version: 3 Date: 24 April 2015

Reviewer: Ian Tannock

Reviewer's report:

This manuscript records the extent to which industry sponsored trials are undertaken, wholly or in part in less developed countries. It therefore provides a useful reference, although it is a pity that it does not go further to discuss issues of quality and ethics, mentioned in the paper, relating to trials performed in different parts of the world.

Please put page numbers on future submissions

Major compulsory revisions:

In a survey like this it is important to provide information about the types of trial - that needs statements in the text and a table. You need to break them down into trials for cancer, CV disease, pulmonary disease etc, by adult vs. pediatric populations (last row in Table 2 is an oddball in a table responding to other properites), by drug, device or nutritional supplement etc.

Minor essential revisions:

p2, Abstract: Add total trials reviewed (22,511) on line 14.
On lines 15/16: Here and elsewhere you separate Central and Eastern Europe but on your map (Fig 1) you do not separate these areas and you do not describe this separation in the text.
On line 8 you define this study as limited to RCTs, yet on line 20 (and elsewhere in the text of the paper) you indicate phase 3 and 4 trials. Phase 4 indicates post-marketing surveillance and I am not aware of any such "trials" as being randomized.

p4 line 11: "First" not "Firstly"
Lines 16/17: Is it really true that trials are more expensive in Western Europe than USA. Only one ref is given - I would have expected the reverse to be true.
Lines 17-19: Yes but other work has shown that Pharma concentrates its research on common diseases in Western countries rather than those common in lower income countries (see for example Seruga et al, Ann Oncol: 2010;21:895).
Line 21: Suggest delete "however".
p5, line 16: I think I know what you mean by "correspondence with disease burden" but please rephrase to make this clearer.

p6, Lines 11,12: You define here only "Eastern Europe" (which apparently includes Siberia on the map in Fig 1, but elsewhere you break the survey down to Eastern and Central Europe. You need to define these two regions if you keep that classification.

p9, line 9: Again"phase 4 trials"

p10, line 4: Rarely appropriate to claim to be first - and you have only addressed rather trivial "trial differences" in this paper. You have merely classified the trials by region - this is a first step, but evaluating differences in quality, ethics etc will be more important for the future.

**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:**

No COI