Reviewer’s report

Title: The case for doing first-in-human (phase 0 and phase I) clinical trials in developing countries.

Version: 1 Date: 28 March 2011

Reviewer: Sam K Newton

Reviewer’s report:

This paper addresses an important and topical issue of public health interest. The authors have made very good arguments which are logical and the reasoning is sound. The piece is well written and there are only minor essential corrections.

Page Three line 7 the word “trials” has been written as “trails”.

Page Three, second paragraph. Mention is made of the TGN1412 trial. It will be appropriate if something was said about what the trial was about.

Summary and Conclusion

The whole thrust of the argument by the authors is that the situation in developing countries have changed (page four, second paragraph). Even though they list well documented reasons why “First in human” trials have historically NOT been done in developing countries, they argue that the situation is now different. If that is what they mean then this should be reflected in the conclusion.

The authors should rather repeat what they have said all along in the manuscript that the situation has changed but after arguing forcefully that trials can and should be done in developing countries they conclude rather feebly that “all should work cooperatively to address those impediments that currently discourage FIH trials from being done in the developing world”.

I will prefer a more forceful conclusion that the situation has now changed and the well documented reasons why “First in human” trials have historically NOT been done in developing countries do not hold now and the situation is now different.

The paper should be accepted with these very minor revisions.

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 I have no competing interest