Reviewer’s report

Title: Trends in the number and the quality of trial protocols involving children submitted to a French Institutional Review Board

Version: 1 Date: 24 Apr 2017

Reviewer: Lucie Biard

Reviewer's report:

The authors have addressed most of my comments. Please find below my review of their responses (numbered after their response document numbering for my initial comments) and some few other remarks.

1. P5L16: « read each protocols » -> « protocol »

2. P7L23: "filter:year" : please clarify the specified filter exactly, for reproducibility.

5. The added part is unclear and suggests regulation 536/2014 is French. I would rephrase, for instance: "The new EU regulation 536/2014 on clinical trials entered into force in France in the second semester of 2016 after it had been harmonized with the new French law on research involving humans. This EU regulation aims to…"

P12 L 15: CPP, please homogenize with the rest of the paper (French IRB) or define the acronym

8. The first sentence was intended to follow the first part of my initial major comment#1 rather than the sentence about the comparison of time periods of the same duration. Does the quality of trials differ starting from 2008 (decrease? If fading effect of the Pediatric regulation over time)?

The last sentence "are results consistent if similar …" have been addressed, I think (response #2 reviewer2)

Table 1 : The title can be misleading : since observational studies were included, why not use the word "studies" or "protocols" instead of trials (table title and title of first variable "Type of clinical trial")

"iterim analysis" -> "interim analysis"

Homogenize "sample size calculation" and "calculate the number of subjects"
Figures 1 and 2: please remove the accent on "median" in the legend.

Also, why use a "barplot"-type graph for the Jadad score, which is in parallel analyzed as quantitative (median, min-max reported) on the same figure? Why not boxplots? What does the "length" of the bars represent exactly for a quantitative variable (why represent a colored bar below the average estimate and not above?)? It makes it confusing to see some of the median estimates high above the top of bars. Box plots might be more adequate.

References: please check the formatting of references in the text: they sometimes appears both in Arabic and Roman numbers concomitantly

P3L22 : RTCs -> RCTs

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

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