Reviewer's report

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

Version: 2 Date: 13 Jun 2017

Reviewer: Johanna van der Lee

Reviewer's report:

The manuscript has indeed improved considerably. Only a number of minor remarks:

The p-value of 0.41 on page 3, line 12 must be incorrect.

Page 3, line 21. Please remove "the" before "sample sizes".

Page 4, line 3. Please change "an Investigation Pediatric Plan" into "a Paediatric Investigation Plan".

Page 5, line 12. Please change "submitted and approved protocols" into "submitted versions of ultimately approved protocols". Line 18: change "group parallel" into "parallel groups".

Page 7, line 19. Please change "the medical intervention" into "a drug intervention". Lines 21-22: change "blind level" into "level of blinding".

Thank you for changing the sentence on Page 11, lines 21-23. However, it is not entirely correct as it is now. I recommend: "Public access to trial protocols should not be limited to regulatory agency submissions that have led to positive decisions for market authorization, as many .....".

Page 12, line 3. I suppose you mean "generation" instead of "generalization"?

Page 13, line 7. Please change "checklist SPIRIT" into "SPIRIT checklist".

The reference list contains superfluous information in French.

Table 1 has a column headed p-values, but there are no p-values in the column, only asterixes when p-values are below 0.05. I object to this.

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?
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Yes

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

Yes

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I am able to assess the statistics

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Needs some language corrections before being published

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