Reviewer’s report

Title: Comparison of two data collection processes in clinical studies: Electronic and paper case report forms

Version: 1 Date: 22 July 2013

Reviewer: Kamala Thriemer

Reviewer’s report:

Major comments:

The main concern is that the comparison of the two methods include different studies and is therefore potentially biased. The authors describe this in the limitation section, however I would suggest to reduce the comparisons made through the paper as much as possible and stick to descriptive findings of both methods in the different studies included. E.g. the objective (last paragraph introduction) could be changed from “to compare” to “to describe”. And in the primary endpoints “to describe satisfaction among stakeholders”, “to calculate average cost for both methods” etc. Or e.g. in the results “the mean cost was higher than…” change “to the mean cost in group 1 was xy Euro and in group 2 xy euro.” In light of this I would also suggest to review the conclusion. I think the limitations of this data does not allow to state that “stakeholders support eCRF of paper”.

Minor comments:

Introduction:
At the end of the introduction it is stated that the objective was to evaluate the “efficiency” of the two CRF. However the definition of efficiency in this framework is not entirely clear. The primary endpoint is described with “satisfaction”. It would be good to streamline objectives and endpoints for consistency.

Methods:
For clarity I suggest to divide the paragraph “clinical studies” in two paragraphs: one “clinical studies” and one “cost estimation”.
It would also be good to add one paragraph on how the open ended questions were analyzed?

Results:
The authors included 27 studies. It would be good to show how representative those are for all studies ongoing in the sector.
The proportion of returned questionnaires is very low how can you exclude any bias due to this?
The cost estimate based on one software used in those trials. It might be good to
add cost estimates when using other software.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
'I declare that I have no competing interests'