Reviewer's report

Title: What is the key issue in adherence evaluation of endocrine treatment of early breast cancer? - Methodological aspects of adherence evaluation

Version: 2 Date: 21 August 2012

Reviewer: Karin Ribi

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Major Compulsory revision:

1. Title: the first part of title is not adequate, as the question raised is not answered by the manuscript. Suggestion for change:

Adherence evaluation of endocrine treatment in breast cancer: methodological aspects.

2. I am still confused about how the SMAQ was composed. Is it a scale developed by the authors of the manuscript or is it an existing instrument (6 item questionnaire validated in a HIV population, Ref 18) that was amended by the authors? Probably the two references are misleading, but from the description is not clear why 3 items from the revised Morisky scale (Ref 19) were used, was it part of the SMAQ as used in HIV? Three questions were added by the authors. Do you mean by the authors of the manuscript? If yes, I understand that 3 items are ad hoc questions, developed for the purpose of this study and 3 questions are derived from the original SMAQ. Please identify in the text for the origin of each question.

3. Selection bias: If the subsample is part of a larger sample of the PRO-Beth study (N= 280 according to Ref 17) there is no description in the manuscript how this subsample (N=240) was selected. Did patients need to sign an additional informed consent for this substudy? If yes, a selection bias cannot be excluded. If not, what were the criteria to select patients for this subsample? Eligibility criteria seem to be the same as for the main study, but then you need to explain why the subsample is smaller than the original sample. This information is needed to convince the reader that selection bias is no limitation of this study. If selection bias can not be excluded, it has to be addressed as a limitation.

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 that I have no competing interests.