Author's response to reviews

Title: A Multicentric Observational Trial of Pegylated Liposomal Doxorubicin for Metastatic Breast Cancer

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Author's response to reviews: see over
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Dear Dr. Norton,

Thank you for sending the review comments on our manuscript (2159051022942625), "A Multicentric Observational Trial of Pegylated Liposomal Doxorubicin for Metastatic Breast Cancer." We have addressed the reviewer comments as follows below.

**Reviewer 1 Comments and Replies**
1. Are limitations of the work clearly stated? The major limitation of the study is its observational nature and it is not sufficiently stressed. It is the cause of heterogeneous schemes of treatment and different toxicity management. I believe that authors have to stress these limitations. This has been addressed in the Discussion section on page 9.
2. Is the writing acceptable? The writing could be improved (in particular the 4th paragraph of Background is not clear).
   Paragraph 4 of the Background has been revised for clarity (page 4).

**Reviewer 2 Comments**
   No revisions suggested.

Due to the observational character of this study, ethical approval was not required according to the German medicines law (Arzneimittelgesetz, AMG) at the time of the trial. In fact, ethics approval would not be required today according the new AMG. Today, ethical approval is often voluntarily secured but is not required by law.

Yours sincerely,
Jens Huober

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