Author’s response to reviews

Title: Review of the registration of clinical trials in UMIN-CTR from 2 June 2005 to 1 June 2010 - focus on Japan domestic, academic clinical trials

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Author’s response to reviews: see over
Dear Editors,

On behalf of my coauthors, I am submitting the covering letter for the manuscript entitled “Review of the registration of clinical trials in UMIN-CTR from 2 June 2005 to 1 June 2010 – focus on Japan domestic, academic clinical trials”. We have also uploaded the revised manuscript (all changes tracked and highlighted) to the online submission system of Trials.

According to the editors’ following opinion (received on 2 Sep 2013) on the manuscript:

"I would encourage the authors to consider creating a table that compares and contrasts the Japan registration policy with that of, say, FDAAA or WHO. I noticed the Japan registry does not require registration of trials for nonlicensed drugs- which was very surprising. I think a table like that could be very helpful for readers trying to get their bearings on practices in Japan- and will provide some context for this article."

we have made a table to compare the Japan registration policy with that of FDAAA in a chronological order (Table 1. Regulations on clinical trial information in Japan and USA) and added necessary context in the Background section. Please check them.

Finally, we really appreciate the precious opinions about our manuscript from the editors of Trials and two peer reviewers. We have tried our best to improve the quality of the submitted manuscript as you expected. Hope to hear from you soon.

Best regards.

Yours sincerely,

Tang Wentao