Author's response to reviews

Title: Factors associated with compliance and non-compliance by physicians in a large-scale randomized clinical trial

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Author’s response to reviews:

Thank you for your valuable comments. We revised our paper, and we highlighted all changes in red color in the manuscript. Here are our responses to the referees.

To Referee 1 (Dr. Wright)

About major revision,

Thank you for your meaningful opinion to my article. As you say, I also think that there are not obvious causal relationships between these factors and the physician's compliance. These factors are the just candidate for the factor to affect the physician's compliance. And also there are unclear how intervene to the factors at now. Our conclusion was relatively strong. We changed the title and conclusion, and integrated the expression not to mention strongly.

About Discretionary Revision,

The theme of cost is minor issue and we de-emphasize these part. We stated to the doctors that this questionnaire is to improve the future clinical study protocols and our management systems in our consent document when we sent the questionnaire. So we could get the consent their personal data for the purpose of the current report.

To Referee 2 (Dr. Tenhave)

Thank you for your detailed suggestions. We respond to your opinions one by one.

>1) The analysis is done separately for patients and physicians, but should be combined >using hierarchical logistic or linear models. This will adjustment for patient and >physician factors with compliance as suggested in the Background Section on p. 6, but >not implemented.

In this article, we focused on whether the collaborating doctors report their periodical CRF or not. This compliance is mainly related to the physicians, not to patients, because physicians only report the state if patients didn't come to the centers. The physician's compliance of this article doesn't relate to the patient's compliance. So, we consider that the adjustment for patient's factor is not needed. However, this concept is difficult to get the point across the readers from our old manuscript. Therefore, we changed the sentences, mainly the background part. Would you check the revised manuscript?

>2) Adjustments for clustering by clinical center also need to be included as they could >confound results for physicians and patients. The number and type of clinical centers >needs to reported as well.

There are 390 institutions where the 512 collaborative physicians belonged and the number of physicians is almost same as the number of institutions. Therefore, we think that we don't need to consider the institutions as a cluster in this study. The number and type of clinical centers are listed in Table 1 (Please see the row about "Working Site"). In Japan, doctors who belonged in own private clinic have seldom collaborated to clinical trials differently from doctors in university, national or private hospital. Therefore, we divided the place of work to "own private clinic" and "university, national or private hospital" in Table 1. That information is also listed in the related papers of CASE-J (Please see the reference 9, 10, and 11).

>3) On p. 17, the sensitivity analysis by varying the cut-off for adherence is appreciated. >However, the authors need to indicate specifically the maximum change in odds ratios >and p-values.

We added the result of sensitivity analysis. Please see p.16 in the results.

>4) As another aspect of the sensitivity analysis, the authors need to move "additional >assistance group" into the complier group to see how the results change.

In this article, we want to identify the physicians' factors associated with the need for special visits and in future we want to examine how to intervene those factors. We consider that the assistant group is as same problem as the incomplete dataset group. We don't need to conduct your suggested sensitivity analysis in...
this article.