Author's response to reviews

Title: Facilitating Accrual to Cancer Control and Supportive Care Trials The Clinical Research Associate Perspective

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Author's response to reviews: see over
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Dr. Irene Pala, Executive Editor
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Dear Dr. Pala,

We wish to thank you and the reviewers for the thoughtful review of our manuscript entitled “Facilitating Accrual to Cancer Control and Supportive Care Trials: The Clinical Research Associate Perspective”.

The comments were very helpful and we believe that the manuscript has been improved by the modifications. Please find below an itemized list of the comments and how they have been addressed in the manuscript. We hope that you will find these modifications satisfactory.

We look forward to further correspondence with your office.

Yours sincerely,

Lillian Sung MD, PhD
All changes in the revised manuscript are highlighted.

Referee #1:

1. *The information in this manuscript would be of interest to all those involved in development and conduct of cancer control studies.*

**Response:** Thank you very much

2. *Would include n for total number of COG centers. Would it not be as important to survey those centers who do not participate as to reasons for non-participation?*

**Response:** We have included this information in the Methods as follows:

> “There are approximately 200 institutions that participate in COG clinical trials.”

We agree that it is important to survey centers who do not participate in CCL trials and this is a component of our future work. We have addressed this comment in the Discussion as follows:

> “Future research should focus on surveying institutions who do not participate in CCL trials as these responses will be particularly informative. The ideal format for surveying these sites may differ and more specifically, telephone contact may yield better response rates since non-participation may reflect lack of interest in CCL studies.”

3. *As the survivorship population continues to increase, late effects of treatment are becoming an important issue in health care. I would suggest the addition of a statement stressing the importance of CC studies in preventing or minimizing potential late effects.*

**Response:** We agree and have added the following to the Background:

> “CCL studies are also important in terms of the prevention or minimization of potential late effects of therapy.”

4. *As a descriptive study based on opinion only, strength of evidence is limited.*

**Response:** We agree and have added the following to the Limitations section to address this comment:

> “Finally, as a descriptive study based on opinion only, the strength of evidence is limited in our report.”

5. *May want to discuss authors recommendations as to most important changes that could be implemented which might result in increased accrual.*

**Response:** We agree and have added the following to the Discussion to address this comment:
“We believe that identification of institutional CCL champions is a particularly important step toward enhancing accrual rates.”

6. Additional impact of quotations in table 1 is limited and may consider removing

Response: We thank the reviewer for this comment. We would prefer to maintain the quotes since they add richness and insight into the themes and sub-themes. However, we would be happy to remove them if requested by the Editor.

Referee #2:

7. The authors addressed the accrual issue from the perspective of clinical research associate (CRA). A survey was conducted and analyzed. No major flaws in the manuscript.

Response: Thank you.

Associate Editor:

8. Would have recommended that the authors consider expanding to either a mixed method design or include additional qualitative assessment protocols to explore further the issue of non-participation.

Response: We agree that a mixed method design would have been useful although this was not the approach used in this study. We have addressed this comment by adding the following to the Discussion:

“Future studies may also consider a mixed method design or include additional qualitative assessment protocols to explore further the issue of non-participation.”

9. I would recommend that the authors be more clear as to the strengths and limitations of their study design.

Response: Please see response to Comment # 4 above.

10. I would recommend that the authors incorporate quotes into their text/narrative to better illustrate the themes discussed (as opposed to listing in Table 1).

Response: We believe that the quotations do provide insight into the themes and sub-themes and thus, we would prefer to maintain the quotations in Table 1. However, we would be happy to remove if you believe that they are not useful. We have added example quotations into the text as suggested.

11. I agree with the reviewer who suggested that the authors consider recommendations as to changes that might be implemented to increase accrual.
Response: We agree. Please see response to Comment # 5.

12. It is not clear why you have declared that the study does not need oversight by Institutional Review Board. Could you kindly clarify why the study does not need ethical approval?

Response: Institutional Review Board approval was not required as this project was focused on quality improvement. We have addressed this comment by adding the following to the Methods:

“Because this survey was developed to improve CCL accrual among COG institutions (in other words, this project was considered a quality improvement project), Institutional Review Board oversight was not required.”

In addition, we added to the Background the following, which highlights the performance improvement aspect of this project:

“Given the importance of timely accrual and the potential for challenges with the activation of, and accrual to CCL trials,[8] we sought to identify modifiable barriers to CCL enrollments in order to develop strategies to improve accrual.”