Author’s response to reviews

Title: Thematic series: The future of pragmatic trials Building Internal Capacity in Pragmatic Trials: A Workshop for Program Scientists at the U.S. National Cancer Institute

Authors:

Wynne Norton (wynne.norton@nih.gov)

Merrick Zwarenstein (Merrick.Zwarenstein@ices.on.ca)

Susan Czajkowski (Susan.Czajkowski@nih.gov)

Elisabeth Kato (Elisabeth.Kato@ahrq.hhs.gov)

Ann O’Mara (omaraa@mail.nih.gov)

Nonniekaye Shelburne (nonniekaye.shelburne@nih.gov)

David Chambers (dchamber@mail.nih.gov)

Kirsty Loudon (kirsty.loudon1@btinternet.com)

Version: 1 Date: 26 Jul 2019

Author’s response to reviews:
Reviewer #1

This paper is very clearly written and provides a summary of how a workshop was conducted for NIH researchers. It is somewhat unusual to see the write up of a workshop published. However, as demonstrated in this paper there is much to be learnt to run workshops well.

1. Would it be useful to publish any of the workshop tools you describe? Or provide a link to where they can be obtained?

Some of the materials that were used for the workshop are not available in the public domain and we do not have the capacity to host some of the other materials on the federal government website. As an alternative, we now include an expanded agenda of the workshop as Appendix A, which provides a brief description and format of each component of the workshop. Note that the tools, worksheets, and guides used as part of the interactive sessions were adapted from materials and examples provided on the PRECIS-2 website, all of which is available in the public domain. We note this in text, as well.

2. Some of the terminology will not be familiar to those outside the NIH / UA. You describe what program scientists etc. are nicely in the introduction, but on reading the abstract it was unclear to me who your target audience was.
To the first point: We agree that the terminology used throughout the manuscript is too variable and U.S.-centric. In response, we have changed text to be consistent throughout (e.g., changed health science administrators to program scientists).

To the second point: We have added more text about the target audience of the workshop in the abstract (i.e., program scientists at the NCI).

3. You use the term extramural investigators and I am not sure what you mean by this.

The terms ‘extramural investigator/researcher’ or ‘extramural research’ refer to researchers or studies that are not part of internal research programs at NIH. An example of an extramural investigator would be an academic researcher. However, since this term is rather unique to NIH, we have removed it throughout the manuscript and replaced it with investigator, researcher, or research, as applicable.

4. Could you add a table describing the participants (just simple summary stats) and their responses?

After much consideration and discussion, we ultimately feel that it is best not to provide more detailed information about participants (aside from number of attendees, professional title, cancer program areas, and division affiliation) in order to protect their confidentiality. We think this is particularly important since participants are U.S. federal employees and because this was a workshop internal to NCI staff, rather than an external expert meeting or conference. We have retained the descriptive information about participants in text.

5. There is a lot of focus on the PRECIS tool. To the extent that the paper even feels a little like an advertisement. You have a very nice opening introduction where you describe pragmatic trials, could you consider adding how the PRECIS fits into all this? So, when exactly should a researcher be using this tool? At the design stage, reporting? Specifically, one of the reviews is criticized for not including the PRECIS tool, but to me it is unclear exactly when and why it should be used. (I apologies if this is obvious to the authors, but I don’t think it will be to your intended readership)

We thank the reviewer for bringing this to our attention, as we certainly do not want the paper to be perceived as endorsing the PRECIS-2 tool. To this end, we have now added text to clarify why, when, and how the PRECIS-2 tool should be used and by whom. We also note that while there are other general resources available on pragmatic trials, the PRECIS-2 tool is the gold standard in the field and the only tool that has been validated to date. We hope that the additional description provided in text helps readers better understand why the PRECIS-2 tool was used, rather than it being perceived as explicit (or implicit) advertising for PRECIS-2.

Reviewer #2

In this paper, Norton and colleagues describe an interactive one-day workshop on pragmatic trials designed to support program scientists—specifically, health science administrators and program directors employed at the U.S. National Cancer Institute—in their roles as researchers
and stewards of research funds. Overall, the authors provide an effective template for other research funding agencies who may wish to conduct similar workshops for their research staff.

1. The article could be improved by removing unnecessary acronyms that make the manuscript difficult to follow; in particular, PD, HSA, FOA, DCP, and DCCPS. Presumably the workshop used the PRECIS-2 tool, so reference to PRECIS version 1 may be removed. RCT is a commonly used acronym, but since it appears only twice (page 7) in the paper this can be removed as well.

We have removed unnecessary acronyms in the manuscript, which we agree are particularly distracting and difficult to follow for readers who are unfamiliar with these U.S.-centric terms. We removed the acronyms from the list of abbreviations, as well, and removed reference to the PRECIS version 1 tool, as suggested. We have retained a few of the more common acronyms (i.e., NCI, NIH, PRECIS-2, RCT, and U.S.); hopefully they are not too distracting, but we are happy to remove them pending reviewer or editor request.

2. The number of participants could be included in the background section on page 6, last full paragraph.

We now include the number of workshop participants (n = 29) on page 7.