Author’s response to reviews

Title: Systemic and tumor-directed therapy for oligometastatic prostate cancer: study protocol for a phase II trial for Veterans with de novo oligometastatic disease

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Ana Donnelly
BMC Cancer

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RE: “Systemic and tumor-directed therapy for oligometastatic prostate cancer: study protocol for a phase II trial for Veterans with de novo oligometastatic disease”

Dear Ana,

Thanks for your correspondence, and for your assistance in granting an extension. Please find attached our amended documents, which we have also submitted online using the link you supplied in the email.

In addition to the revisions made to the manuscript, I also wanted to respond directly to your points below:

• You are correct - the study protocol was reviewed by the funding body as presented here, with the exception that we amended the trial to allow PSMA PET/CT staging (as this scan became available at our institution). Our trial is a single-arm study with all patients receiving treatment, thus making allocation/comparators/etc not applicable; we have reinforced this point in the revised manuscript. Specific objectives are explicitly stated on page 5 of manuscript, with hypotheses explicitly stated on page 4 (last paragraph of background) and page 7 (sample size) of manuscript. We have additionally gone through the SPIRIT checklist to ensure all points are met, and are accurately indexed to specific sections of our manuscript (also attached).

• Although the "study record detail" on clinicaltrials.gov (from 9/11/18) currently details our trial's primary endpoint alone, we have already submitted modifications to this record so that secondary endpoints are also shown. We are hopeful that this will be reflected on the website in coming weeks.

Thanks once again, and please reach out if we can be helpful with providing any additional information.

Sincerely,
Nicholas G. Nickols MD PhD

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