Author's response to reviews

Title: Practical considerations for estimating clinical trial accrual periods: application to a multi-center effectiveness study

Authors:

Rickey E Carter (carterre@musc.edu)
Susan C Sonne (sonnesc@musc.edu)
Kathleen T Brady (bradyk@musc.edu)

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Author's response to reviews: see over
Response to reviewers:

Reviewer 1:
“The website reference given by the authors took me only to the 1st author’s home-page.”

The manuscript has been updated to reflect the necessary link (<homepage>/manuscripts) and the files have been listed under this manuscript.

Reviewer 2:
Major compulsory revisions-
The “simulation” study conducted by the reviewer uncovered some incorrect information in the manuscript. The original rate of 2 participants per month was multiplied by a random uniform number (0-1), so the rate after adjustment is actually 0 – 2 with a mean of 1. This is consistent with the reviewer’s intuition. However, upon additional review of the simulation program and manuscript, a design specification of the simulation was not incorporated into the manuscript. Enrollment was determined to occur only on “week days”, and thus for 2 days of a week, no participants would be accrued into the study. The manuscript has been updated to reflect this model specification.

Minor essential revisions-
“…motivation for looking at the distribution of required recruitment periods could be expanded”

The reviewer’s suggestion has been incorporated into the introduction of the Poisson process.

“…a brief discussion of how data could be brought to bear on this methodology”

A new paragraph has been added to the background section to address this need.

Discretionary revisions-
“…the graph of estimated recruitment rates …if there would be discrete jumps at the time a site comes into the trial…”

While we agree with the reviewers the functional form of the accrual pattern is a step-function, we have elected to keep the figure as is. Since the manuscript is accompanied by the Excel spreadsheet that performs the calculations, keeping the figure the same as the spreadsheet seems most beneficial. We too are not sure if Excel offers additional graphics (in the default installation) that would produce the step function.