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9 July 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Looks at pooled interim results

I wrote the following in a missive of 5 May 2015.

> *Some days back a colleague asked for my opinion on sharing interim pooled data with study investigators – pooled across treatment groups because investigators do not see results by treatment group while the trial is ongoing. The reason for the request was because investigators are concerned that the event rate is lower than planned and, hence, that something might have to be done to deal with the issue.*
>
> *My colleague was uneasy because he feared the information might lead to changes that could impinge on the integrity of the study.*
>
> *What would you advise? Yes or no and why?*

The answers to my question were about evenly split between yes and nos. I did not express an opinion, but now I will.

My advice would be "yes". After all, investigators are not potted plants. (Phrase from Brendan Sullivan, representing Oliver North in joint House-Senate Iran-Contra hearings. During the hearings Daniel Inouye suggested that North speak for himself, admonishing Sullivan for objecting to questions posed to North. Sullivan responded, "Well, sir, I'm not a potted plant. I'm here as the lawyer. That's my job.").

In my mind there is no compelling reason to deny the request and hence should be granted. It is difficult to argue that investigators seeing interim pooled results will jeopardize the integrity of the study. Designs are not that fragile.

The increasingly diminished role of investigators in the trials they do is concerning. Have we forgotten that it is they who are responsible for the trial? It is they, not sponsors and not DSMBs.

The diminishing role for investigators does not bode well for the future of trials. As it is now they are primarily data collectors without access to results until the trial is finished and then they are to analyze and write up results with all the experience in analysis and interpretation vested in a body (the DSMC) they are isolated from. Is that a good design?