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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: More on essentials to clinical trials

My list of 10 essentials was distributed 19 October 2022; as below.

1. Promise of funding through completion of the trial
2. Randomization
3. Masked treatment administration (when possible)
4. Multicenter
5. Multi-treatment (trials having several test treatments; platform trials)
6. Steering committee comprised of heads of study centers
7. Data coordinating and analysis center
8. Data and Safety Monitoring Board (DSMB)
9. Promise of funding for a minimum of two years following last data collection visit
10. Written policy committing study investigators to publishing

Point 1 is intended to keep the funding agency from “pulling the plug” if they do not like the results. If there is no guarantee of funding to completion of the trial, investigators should walk away.

Point 9 is there to remind the funding agency that the commitment to fund extends beyond the close of data collection; essential to provide time for close of data collection and to write up the results.

The existence of a DSMB (point 8) takes control as to stopping away from sponsors and investigators.

Point 10, having a written policy drafted early into the trial committing investigators to publish, is a prod to publish.

Both John Breitner and Paul Leaverton expressed concern about publication bias. John Breitner wrote:

But surely an equal or greater problem is "publication bias", particularly in industry sponsored trials. Sponsors have powerful incentives to keep null or negative results under the rug, attempts at mitigation of this issue notwithstanding.

Not publishing is a degenerate case of publication bias. Normal usage of the term is in reference to inclinations or tendencies to publish results supporting conclusions favoring a particular hypothesis or position.