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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Clinical trials essentials

The WHO has called for help in strengthening clinical trials. (Public consultation related to the WHA 75.8: Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination)

One of the key problems in trials is failure of investigators to publish.

Trials are undertaken to generate new information concerning the merits and safety of treatments. There is no lasting information absent publication.

An inducement for enrolling in trials is the promise of contributing to the collective knowledge base regarding treatment. The failure to publish constitute breaches of that promise.

But editors are picky. Not all papers get published, even after repeated tries. But the overriding reason for not publishing is authors not trying.

Experience teaches that trials most likely to publish have features akin to those listed below. The WHO would do well to pay attention to these features in its drive to strengthen trials.

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