



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

28 March 2023

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Biostatistics versus trialists

Biostatistics, defined in Merriam-Webster:
statistics applied to the collection, analysis, and interpretation of biological data and especially data relating to human biology, health, and medicine.

I got my PhD in biostatistics years back from the University of Minnesota. When my daughters were young and asked in school what I did by their teachers, all three of them said I was a **badstatistician**. Maybe they had it correct.

A trialist is one skilled in the design and conduct of clinical trials. The truth is I learned very little about how trials were done until I joined the University Group Diabetes Program. Now various schools, including my own, have certificate programs in clinical trials.

Steve Piantadosi has one at Harvard. He wrote *Here's an idea that has been in my head for a number of years (kinda like writing a comprehensive textbook to help define the field of clinical trials). At the moment I am getting questions from the program managers at HMS about how to assess competency of students who finish a course or a program in clinical trials – let's say a master's degree. Is there a body of knowledge they should have and can be tested on? So I am wondering about a competency test in clinical trials and what it might look like. It can't be too highly structured or people could just memorize the answers and ChatGPT could regurgitate them. Would addressing this matter help push the field of trials in a positive direction? Could we convene some experts to discuss?*

The thing that sets PhDs apart from certificate programs is the oral exams at the end. A committee consisting of your advisor and three or four others picked by the school. The ritual is for each member of the committee to question you about whatever. Studying is pointless.

When done you are excused to pace the floor until called back to tell you the outcome.

In my case I passed, but by the time they were done with me I was not sure of my name. Even now the experience is indelibly etched in my mind.

An obvious starting point for Steve would be to compile a list of clinical trials certificate programs and persons responsible for them.