

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

25 August 2021

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Things learned doing trials

You spend your entire professional life doing trials, you will come away with sayings and observations. Some of mine are below, in no particular order.

Pigs is pigs, data is data; my way of reminding people *data* is plural

Too many pigs under a blanket and they all get away; my way of telling writers they have too much crammed in what they have written

Trialists are like squirrels, they both collect more than they need

Publish first, present later

That was the policy for the first trial I was involved in – the University Group Diabetes Program (UGDP) – but investigators thought results for its first publication would be published before a scheduled presentation. They were wrong! (see <u>https://www.jameslindlibrary.org/articles/the-trials-and-tribulations-of-the-university-group-diab</u> <u>etes-program-lessons-and-reflections/</u>)

Learn from your mistakes

All investigator groups I worked with after the first publication in the UGDP, held firmly to "publish first, present later" policies

The phases of a trial:

- 1 Euphoric phase (fleeting; prompted by news that the trial will be funded)
- 2 Holy shit phase (brought on by realization that now you must do the trial; normally ends when meaningful work begins)
- 3 Anxiety and emotion stage (marked by bickering, sniping, and squabbles; generally starts with screening for enrollment and may last well into enrollment period)
- 4 Max Q phase (space age term for maximum dynamic pressure; in trials generally occurs when investigators realize that they will fall far short of their sample size goal)
- 5 Doldrums phase (marked by tedium and boredom; usually starts after enrollment and may last for years in long-term trials)
- 6 Accolade phase (transitory; unlikely except where published results are what the world wants to hear)
- 7 Bunker phase (may begin with primary publication if results are unpopular; may persist well beyond the completion of the trial)

Get into a pissing match with an editor, you lose

Collect no more than 10 times the data needed to answer the question

## Things learned doing trials

The way to cure a disease is to start a trial

Definitive is a label affixed 30 years after the fact

The difference between a good and bad paper is 15 iterations

Save a nickel, spend a dollar

Counting is hard

Two moves equals one fire

Leave too soon and you will be late arriving

A meeting ends three hours before the first plane departure

You can't roller skate in a buffalo herd (Roger Miller)

This whistle ain't made of gold (Boxcar Willie)

If it ain't broke, don't fix it

- For actual number of people to be enrolled in a trial: divide number promised by four and multiply time given for enrollment by two
- When you are up to your ass in alligators, it's hard to remember you started out to drain the swamp (sign over mechanic's bench)
- The hypothesis is unencumbered by any supporting evidence. The budget is the only part of the application which seems to have any substance whatsoever (anonymous NIH study section member)
- Just as the Sphinx winks if you look at it too long, so, if you perform enough significance tests, you are sure to find significance even when none exists. (Jerome Cornfield)
- On being asked to talk on the principles of research, my first thought was to arise after the chairman's introduction, to say, "Be careful," and sit down (Jerome Cornfield)

The way to improve a paper is to reduce its length

I am just a farmer from Sleepy Eye: A go to statement when confronted with scientific questions I cannot answer

\Blog\ThingsLearned.WPD