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16 October 2018

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Negative versus nil in regard to results from trials

When you are up to your ass in alligators it is hard to remember you were trying to drain the swamp. The swamp I was in with my note of 11 October was of pundits lumping trials that produce results in the opposite direction of what was expected with those producing nil results.

Steve Piantadosi wrote:

I agree that "negative" is not a good term for trial results that do not meet prior expectation. It might be appropriate for trials where the new treatment was significantly worse than control. Unfortunately "nil" is not a great improvement because it means zero (noun) or nonexistent (adj). "Null" is slightly better, but also means something close to nil, except in its statistical use. "Null" seems like a good word when the findings are nearly equal in the compared groups.

A problem that the word "positive" seems to avoid is whether we refer to the trial or to its findings. We should probably refer to good trials as "conclusive" or something similar. For the results, we need a word that conveys a non-negative, non-zero finding which is short of what we expected. Some candidates might be: ineffective, worthless, inefficacious, or useless. So a trial result would be "conclusively ineffective" for example.

One other idea: we could repurpose some word like the archaic "naught" or "nought", or the Latin "nihil", although these have meant nothing or zero in the past. We would need a writer of clinical trials dictionaries to tackle this sort of definitional transformation.

Comment

You can call nil results inconclusive, ineffective, worthless, inefficacious, or useless, but you doesn't hasta to call them negative.

John Breitner wrote:

Do you use "null" to describe trial results that do not permit exclusion of-either the stated hypothesis or its opposite? What is the distinction with "nil"? I don't remember your ever speaking of "nil" trial results.

Comment

Nil and null are largely interchangeable. I prefer nil in regard to results over null because of use of null in "null hypothesis". For the record, nil (adj) in my dictionary (2012; Wiley and Sons) indicates my preference for nil when results are inconclusive.

Bob Wise wrote:

Just yesterday, I had a pharma person tell me that their trial was positive because it showed non-inferiority with the comparison product. What about that?

Comment

Your pharma person wondered off the ranch. Non-inferiority trials are done to determine whether the test product is not unacceptably less efficacious than an active control treatment. Too many double negatives for a farmer from Sleepy Eye.

Tom Louis wrote:

Positive is in the eye (or business model) of the beholder.

Comment

Cynical.

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