Lessons Learned (so far)

The NIH Clinical Trials adventure

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NIH had a problem

“fewer than half of trials funded by NIH are published in a peer reviewed biomedical journal indexed by Medline within 30 months of trial completion. Moreover, after a median of 51 months after trial completion, a third of trials remained unpublished.”

Ross et al (2012) Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis

BMJ 344

What is a clinical trial? *(We all know....right?)*

My molecule worked in a mouse

Let’s see if it is safe and effective in humans

Yay!

https://www.cbinsights.com/research/clinical-trials-ai-tech-disruption/
NIH decides to round up the wandering sheep
The Four Questions

1. Does the study involve human participants? ✔

2. Are the participants prospectively assigned to an intervention? ✔

3. Is the study designed to evaluate the effect of the intervention on the participants? ✔

4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ✔
A couple of us get the word

Now what do we do?
We got the word from Bill Riley, Director of the NIH Office of Behavioral and Social Sciences Research (OBSSR).

"An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints."

*Uh...yeah....we call that an experiment*
Find allies
Make some noise

not your parent's NIH clinical trial

Jeremy M. Wolfe & Nancy G. Kanwisher

Do not assume evil intent
NIH et al. are not the opposition party

In dialogue with the NIH on clinical trials policy

In his capacity as immediate past president of the Federation of Associations of Behavioral and Brain Sciences, Jeremy Wolfe interviews Mike Lauer about the new NIH clinical trials policy. Mike Lauer is NIH’s deputy director for extramural research, serving as the principal scientific leader and advisor to the NIH director on the extramural research programme.

Thank you for taking the time to answer a few of the questions that have been worrying scientists in the basic human behavioural and brain sciences about the implementation of the new clinical trials policy. Perhaps you could start by telling us what the National Institutes of Health (NIH) goals are for this policy?

Thank you for the opportunity to talk. When we announced our clinical trial policies, we were addressing two major concerns: first, the main results for perhaps as many as half of NIH-funded trials are not publicized within a reasonable timeframe (for example, within 2.5 years of completion). Many results are never reported. Second, as the Government Accounting Office pointed out, the NIH as an agency wasn’t collecting a minimum amount of data to enable it to function as effective stewards. Our goals are transparency and stewardship.

A way forward?

Basic Experimental Studies with Humans

Clinical Trial

Other

BESH
We are not out of the woods yet