



30 September 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: My ClinicalTrials.gov wish list

I distributed 8 September 2015 a document listing wishes for ClinicalTrials.gov:

- 1: That trials would be called trials on the website
- 2: Better editing of the ClinicalTrials.gov dataset
- 3: Refinement of the "All Others" funder category
- 4 A field to indicate if results have been published
- 5: Identification of publications containing primary outcome data
- 6: Identification of publications containing the registration number of the trial in question

Alas, I fear my list irritated Dr. Zarin (Director of the website). My apologies. She has a formidable job, made worse by wishes.

Dr. Zarin points out that I was not among respondents to a Notice of Proposed Rulemaking (NPRM) describing an expansion of the site under FDAAA (the Food and Drug Administration Amendments Act of 2007) and an NIH proposal to require registration and results reporting for all-NIH funded clinical trials.

But wishes do not come on schedules. Mine arose from use of ClinicalTrials.gov in the last few months to characterize the nature of NIH-funded trials.

Dr. Zarin takes issue with Wish #1 that trials be called trials instead of interventional studies on the website. I suppose a trial is a trial by whatever we call it. So what difference does it make? Maybe none — unless you are a dictionary writer concerned with word clutter.

Wish #3 was for refinement of the "All Others" funding category. That category accounts for over 50% of the trials registered.

One can be sure the other three funder categories (NIH, Other Federal Agencies, and Industry) involve real money flows. One does not have that assurance with "All Others". It would be useful if the category distinguished sponsors providing real money versus other forms of support.

Leastwise Dr. Zarin think otherwise, I rejoice in the existence of ClinicalTrials.gov. It is a giant leap forward in helping to understand the art and science of trials.

Until registration, there was no reliable way of knowing how many trials were undertaken, how many were carried to completion, sample sizes, or anything about publication.

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One of the overriding motivations for registration was to provide a tool to address issues of publication bias. The unfortunate reality is that the website is ill-suited for addressing that question. My last three wishes related to "fixes" regarding that concern.

Dr. Zarin points out that it is easy to identify studies with results by using the advanced search option on the website. Indeed it is, but the more relevant issue is publication. Given a choice, I would rather be looking at results published in peer-reviewed journals than "tabular results" listed on ClinicalTrials.gov, but finding results publications among publications listed is problematic.

There were 1,062 NIH-funded trials logged as completed from 2008 through 2014. Of those there were 233 with tabular results only, 371 with publications only, and 202 with both. The issue is identifying publications containing results of the trials. At present the only way to do that is by looking at all 371 + 202 publications.

Dr. Zarin points out that my last three wishes would add to the burden of registration if granted. Yes, but there is already misery in registration. Would a little more really matter?