



8 September 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Wish list for ClinicalTrials.gov

ClinicalTrials.gov came into being as a result of the 1997 FDA Modernization Act. The act required registration of clinical trials done under INDs. Registration received a push in 2004 when the International Committee of Medical Journal Editors (ICMJE) announced requirements for registration before initiation of enrollment for trials starting after 1 July 2005 as a condition for publication.

Registration provides a resource for persons interested in finding trials suitable to their condition and also provides a research tool for persons interested in characterizing the state and nature of trials. This wish list is from the perspective of a researcher interested in tracking the state of trials over time.

Wish # 1: *That designers would have called a spade a spade*

The main study type on ClinicalTrials.gov is interventional study. Why designers opted for that rather than clinical trial on a website with clinical trials in its name is a mystery. One can only surmise the choice was driven by a desire for a softer term than trial.

Trial means to try. Intervene means to come between. Which term do you think better describes the focus of the registration effort?

Wish # 2: *Better editing of the dataset*

ClinicalTrials.gov datasets can be downloaded as CSV (Comma Separated Values) or XML (Extensible Markup Language) datasets. Rogue commas in CSV files and special characters in XML text like \geq or \leq create problems when converting data to SAS files.

One can only imagine the problems managers of the website have maintaining a database with thousands of people registering, but experience downloading datasets causes one to wonder about the editing process done to keep files "clean".

Wish # 3: *Refinement of the "All Others" funder category*

The ClinicalTrials.gov website has four funder categories: NIH, Other U.S. Federal Agencies, Industry, and All Others (individuals, universities, and organizations). One wishes for a breakdown of the All Others category because it accounts for over 50% of the trials registered.

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Wish # 4: *A field to indicate if results have been published*

A major reason for the action of the ICMJE was concern regarding publication bias but ClinicalTrials.gov is ill-suited for identifying publications of study results.

The advanced search feature on ClinicalTrials.gov allows users to get counts by phase of trial, by funder type, and several other variables, but not by whether results have been published. Addition of that feature would be useful in comparing publication records by phase of trial and by funding source.

As it stands now, the only way to get such counts is by analysis of XML downloads - a headache. But even then, without looking at publications, there is no way to know if they are from the trial in question. Even looking at publications may leave one uncertain as to whether they contain data from the trial in question if the publications do not contain registration numbers. Only 20% of the 2014 PubMed publications of randomized controlled trials had registration numbers.

Wish # 5: *Identification of publications containing primary outcome data*

Registrants are required to specify the primary outcome measure of trials; defined as "the planned outcome measure in the protocol that is the most important for evaluating the effect of an intervention".

As presently constructed, there is no easy way of identifying those publications.

Wish # 6: *Identification of publications containing the registration number of the trial in question*

The website contains a field to allow registrants to list relevant publications. That list is supplemented by ClinicalTrials.gov with MEDLINE publications, not listed by the registrant, but containing the registration number for the trial in question.

There can be dozens of publications listed with all, some, or none being from the trial in question. For example, the registration for the PeriOcular INTravitreal Corticosteroids of Uveitic Macular Edema Trial (POINT; NCT02374060) lists 95 publications (31 August 2015) but none are from POINT.

Registrants should be required to differentiate publications from the trial from other listed publications.