



7 January 2016

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Publication of trials

Registrants on ClinicalTrials.gov use the site to list publications relevant to and publications of results from registered trials. The listing is augmented by operators of ClinicalTrials.gov with publications attributed to registered trials, as identified via indexing in MEDLINE (done daily; personal communication with the director of the website).

The counts below are of publications in calendar years following the years of completion. The supposition is that the publications are of results, although there is no way of knowing without reading the publications.

A completed trial is one that ended normally (not suspended, terminated or withdrawn) and where participants are no longer being seen or treated.

Counts were generated using the ClinicalTrials.gov dataset, downloaded 30 June 2015 and the March 2015 AACT dataset (Aggregate Analysis of ClinicalTrials.gov; downloaded from the Clinical Trials Transformation Initiative website; <http://www.ctti-clinicaltrials.org/>). Counts are limited to trials funded by NIH or industry but not by both NIH and industry. Counts exclude abstracts and publications where date of publication is not reported.

NIH and industry-funded trials listing publications on ClinicalTrials.gov after completion

	NIH-funded			Industry-funded		
	Completed trials	≥ 1 pub after completion	% published	Completed trials	≥ 1 pub after completion	% published
All trials						
2006	544	77	14.2	2,077	212	10.2
2007	640	78	12.2	2,650	235	8.9
2008	574	80	13.9	3,475	315	9.1
2009	650	79	12.2	3,703	282	7.6
2010	674	91	13.5	3,619	202	5.6

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	NIH-funded			Industry-funded		
	Completed trials	≥ 1 pub after completion	% published	Completed trials	≥ 1 pub after completion	% published
Multicenter trials						
2006	197	41	20.8	873	86	9.9
2007	206	42	20.4	1,215	118	9.7
2008	153	35	22.9	1,671	187	11.2
2009	174	30	17.2	1,707	152	8.9
2010	208	41	19.7	1,719	106	6.2

The counts are upsetting to researchers who believe publication is the sine qua non of research.

The record is better for NIH-funded trials than for industry-funded trials and better for NIH-funded multicenter trials, but far from great.

To be fair, there is no way of knowing how many results papers were submitted and rejected. There is also no way of knowing how many results are published but not listed on ClinicalTrials.gov. As noted above, the operators of the website augment listings by adding publications identified to registration numbers in publications indexed in MEDLINE.

The utility of that practice is dependent on journals listing registration numbers so they can be indexed in MEDLINE. Unfortunately, only a fraction of journals list registration numbers. That being the case, the "good news" is that publication rate may be higher than indicated here. But even if the percentages are doubled that still means that less than one-third of NIH-funded completed trials and less than 20% of industry-funded completed trials are published. Not a record to be proud of.

Counting publications is tricky because of format variations in the way citations are listed and because counting involves two datasets; the ClinicalTrials.gov dataset and the AACT dataset. The old trick of having two people count independent of each other to see if they come up with the same count is not practical here because of variations in how counters choose to marry the two datasets. I had two people (Jill Meinert and Gillian Gresham) count independent of each other. The counts, using different methods, were close enough to give me confidence in what is reported.