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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Posted results

A trial ends when: (1) enrollment is finished, (2) treatment under the study protocol ends, and (3) data collection is finished.

But to provide a lasting record finished results should be published for repose in libraries, but, in reality only a small fraction of results are published because trialists do not write them up and because editors are picky.

The alternative is posting results to ClinicalTrials.gov. Posting became a requirement for FDA regulated trials with passage of the 2007 Food and Drug Administration Amendments Act (FDAAA). The act requires posting within one year of completion with provisions for hefty fines for failure to post.

Now, with the inevitable creep of regulations, the requirement extends to all trials whether or not under the control of the FDA and regardless of where registered.

To be sure posting results without written comments is a poor substitute for publication, but it is better than nothing. So how are trialist doing?

Not very well. As seen in the tables below, postings are all less than 50% except for phase 3 drug trials started 2009 (51.02%).

Table 1: Trials by year started, completed, results posted

Year started	Completed	Results posted	% posted
2000	1,561	131	8.39%
2001	2,026	205	10.12%
2002	2,982	343	11.50%
2003	4,039	619	15.33%
2004	5,243	959	18.29%
2005	6,206	1,454	23.43%
2006	7,165	2,208	30.82%
2007	7,808	2,712	34.73%
2008	8,806	3,005	34.12%
2009	9,452	3,123	33.04%
2010	9,339	2,933	31.41%
2011	10,039	2,880	28.69%
2012	10,226	2,725	26.65%
2013	10,383	2,747	26.46%
2014	10,863	2,536	23.35%
2015	10,529	2,300	21.84%
2016	9,698	1,716	17.69%
2017	8,280	1,146	13.84%
2018	6,282	555	8.83%

Table 2: Drug trials by phase and year started, completed, results posted

Year started	Phase	Completed	Results posted	% posted
2000	0-2	823	52	6.32%
	3	385	47	12.21%
	4	135	9	6.67%
2004	0-2	2,293	494	21.54%
	3	1,299	239	18.40%
	4	757	135	17.83%
2009	0-2	4,068	1,309	32.18%
	3	1,414	724	51.20%
	4	1,152	458	39.76%
2014	0-2	3,426	856	24.99%
	3	1,173	533	45.44%
	4	1,054	322	30.55%

Table 3: Trials by year started by funder, completed, results posted

Year started	Funder	Completed	Results posted	% posted
2000	Fed govt	702	56	7.98%
	Industry	501	55	10.98%
	Other	398	27	6.78%
2004	Fed govt	1,074	293	27.28%
	Industry	2,659	529	19.89%
	Other	1,569	156	9.94%
2009	Fed govt	1,080	531	49.17%
	Industry	4,430	1,983	44.76%
	Other	4,023	657	16.33%
2014	Fed govt	790	322	40.76%
	Industry	4,019	1,493	37.15%
	Other	6,133	766	12.49%