



25 February 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: NIH vs industry trials

My memo of 19 February entitled "Clinical trials and the NIH" generated comments from several people. The comment from Dan Ford that

Interestingly when we bring this trend (the downward trend in NIH funded trials) up to NIH leaders one of the first comments is that maybe it is good they are no longer funding small clinical trials that do not provide useful information

set me wondering if the view expressed jibes with facts, as gleaned from ClinicalTrials.gov. The counts below are for "interventional studies" (clinical trials) registered in 2006, 2009, and 2012 and by NIH or industry funded. Trials classified as "Closed" in ClinicalTrials.gov include any of the following:

- Active, not recruiting
- Completed
- Enrolling by invitation
- Suspended
- Terminated
- Withdrawn
- Expanded access: No longer available
- Expanded access: Temporarily not available

"Completed" means the trial has ended normally and that participants are no longer being examined or treated (i.e., that the last visit has occurred).

Registered 2006				
	NIH funding	Industry funding	% total NIH	% total Ind
Open	65	120	4.7	2.6
Closed	1,312	4,461	95.3	97.4
Total	1,377	4,581	100.0	100.0
Completed	947	3,662	68.8	79.9
Multicenter	27	1,124	2.0	24.5
Randomized	592	2,593	43.0	56.6
Both	16	868	1.2	18.9
Registered 2009				
Open	203	362	17.4	5.7
Closed	964	6,030	82.6	94.3
Total	1,167	6,392	100.0	100.0
Completed	575	4,643	49.3	72.6
Multicenter	24	1,032	2.1	16.1
Randomized	405	3,231	34.7	50.5
Both	20	743	1.7	11.6
Registered 2012				
Open	535	1,451	53.1	25.3
Closed	473	4,276	46.9	74.7
Total	1,008	5,727	100.0	100.0
Completed	203	2,952	20.1	51.5
Multicenter	2	606	0.2	10.6
Randomized	156	2,100	15.5	36.7
Both	2	446	0.2	7.8

The counts suggest NIH funded trials are less likely to be multicenter and less likely to be randomized than their industry funded counterpart.

There is also evidence that custodians of industry funded trials are better at updating recruitment status than their NIH funded counterparts. The percentage of trials with unknown status (i.e., trials with status "not yet recruiting" or "active, not recruiting" and status has not been confirmed within the past 2 years) registered in 2006 and NIH funded is 8.4% compared to 4.4% for industry funded trials.

There is evidence that NIH funded trial take longer to complete than industry funded trials as seen by percentages of completed trials. One interpretation is that NIH funded trial are larger than industry funded trials and hence taking longer to recruit, but the difference could

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just as easily be due to the fact that investigators in NIH funded trials are slower at recruitment because many fewer NIH funded trials are multicenter than is the case for industry funded trials.

Explanatory notes

Counts for NIH and industry funded trials obtained by placing a check in funder type "NIH" or "Industry". Trials that are funded by NIH and Industry will be counted in both columns but the overlap is minimal. For example, the count for completed trials registered in 2006 with both NIH and Industry checked is 4,549 compared to the sum of counts for the two boxes checked separately of 4,609.

Counts for "multicenter", "randomized", and "both" ("multicenter" AND "randomized") were obtained by entering those terms in the "Search terms" box on the ClinicalTrials.gov website.