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Memorandum

To: Trialists
 Fr: Curtis Meinert
 Re: Industry versus NIH drug trials: Sample sizes and times to completion

The previous memo, distributed 14 November, gave mix of trials done by industry and NIH. This memo is focused on completed trials; size and time to completion for industry and NIH-funded drug trials logged in ClinicalTrials.gov from 2000 through 2015. Time to completion is the elapsed time from start of enrollment to the end of data collection.

Industry-funded completed drug trials..... 34,958
 Mdn sample size..... 71
 IQ (75%) sample size range..... 31-226
 Mdn time to completion..... 488 days
 IQ time to completion range. 213-972 days

NIH-funded completed drug trials..... 5,886
 Mdn sample size..... 65
 IQ sample size range. 30-193
 Mdn time to completion..... 1,369 days
 IQ time to completion range. 822-1,979 days

Results by phase of trials are below. Median (Mdn) times to completion in days.

		Industry-funded			NIH-funded		
Phase		No.	Mdn SS	Mdn time	No.	Mdn SS	Mdn time
	0	116	27	426	69	33	1,095
	1	11,034	32	212	1,876	34	1,218
	2	9,481	81	610	2,690	58	1,523
	3	9,393	311	610	836	293	1,704
	4	4,934	110	638	415	100	1,430

Median sample sizes of 100 for phase 4 trials are pitifully small given that they are to provide information on safety and efficacy of approved drugs. If randomized and involving two treatment groups that means there are just 50 people per treatment group. Fairly powerless for detecting differences for most outcomes.

Whatever the reasons, it is obvious that industry is more efficient at doing trials than the NIH. Times for NIH-funded trials range from twice to almost six times those for like industry-funded trials.

Why?

Your thoughts?