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14 November 2017

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Industry versus NIH trials: Mix of trials

This is the first of three memos aimed at comparing NIH and industry-funded trials using ClinicalTrials.gov.

This memo is focused on the mix of trials done by industry and NIH. The second and third memos will focus on completed drug trials. The second memo will compare sample sizes and time to completion for industry versus NIH-funded drug trials. The third memo will deal with publication records for the two classes of trials.

ClinicalTrials.gov is a registry of trials run by the U.S. National Library of Medicine. It was launched in 2000 and has now over 200,000 trials registered, about half of which are done by industry or the NIH (counts below).

Industry	79,000
NIH	21,150
Other U.S. Federal funding	4,700
Other (foundations, universities, persons)	104,000

Trials in ClinicalTrials.gov are logged as "drug" or "other" (not "drug"). "Drug" trials are registered by phase.

- **Phase 0 (early phase 1)**: Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies)
- **Phase 1**: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- **Phase 2**: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
- **Phase 3**: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- **Phase 4**: Studies occurring after FDA has approved a drug for marketing. These including postmarket requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

The numbers of trials that are "Drug" or "Other" are below. Counts are from 2000 through 2015. The category "Registered" includes trials that have not started enrollment, trials that have started and are ongoing, trials that have been completed, as well as trials withdrawn, terminated, or suspended (W, T, or S) .

"Completed" means registrations have dates for when trials are completed.

	"Drug"	"Other"	Total	% "Drug"	% "Other"
Industry					
Registered	52,406	7,666	60,072	87.24	12.76
Completed	34,958	4,251	39,209	89.16	10.84
% Completed	66.71	55.45	65.27		
W, T, or S	5,275	664	5,939	88.82	11.18
% W, T, or S	10.07	8.66	9.89		
NIH					
Registered	9,105	3,797	12,902	70.57	29.43
Completed	5,886	2,157	8,043	73.18	26.82
% Completed	64.65	56.81	62.34		
W, T, or S	974	156	1,130	86.19	13.81
% W, T, or S	10.70	4.11	8.76		

Eighty-seven percent of industry-funded trials and seventy-one percent of NIH-funded trials are drug trials. The bust rate (W, T, or S) is about the same for drug trials (10% for industry and 11% for NIH) but is about twice that for NIH for "Other" trials (9% for industry and 4% for NIH). The mix by phase is given in the table below.

		Total "Drug"	% Phase 0	% Phase 1	% Phase 2	% Phase 3	% Phase 4
Industry							
	Registered	52,406	0.43	29.96	29.37	26.01	14.24
	Completed	34,958	0.33	31.56	27.12	26.87	14.11
	W, T, or S	5,275	0.38	22.41	38.98	23.26	14.98
NIH							
	Registered	9,105	1.74	31.92	45.50	13.93	6.92
	Completed	5,886	1.17	31.87	45.70	14.20	7.05
	W, T, or S	974	1.43	30.80	51.03	13.14	3.59

The NIH, as a percentage of total "Drug" trials, funds about three times as many phase 0 trials as industry and about half as many phase 3 and 4 trials as industry. The "deficit" in phase 3 and 4 trials is surprising because of their importance in establishing the merits of drugs approved for use.

The two sets of trials differ in percentage that are randomized and multicenter. A higher percentage of industry-funded drug trials are randomized and multicenter than NIH-funded trials.

Percentages of trials randomized (Rz) and multicenter (MC) by phase

		Total	Phase 0	Phase 1	Phase 2	Phase 3	Phase 4
Rz							
	Industry	65.8	42.9	53.6	64.1	81.4	68.4
	NIH	48.9	36.0	32.5	43.8	91.4	77.8
MC							
	Industry	58.5	16.8	38.2	68.3	77.4	49.2
	NIH	38.4	12.5	26.2	41.4	65.4	31.0