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31 October 2017

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Follow-on to my 26 October memo on gender composition of trials

The table below is from my memo of 26 October 2017.

Gender composition of trials registered in <u>ClinicalTrials.gov</u> by year of completion

		Gender mix (% of completed trials)		
Con	Completed trials		M-only	F-only
NIH trials				<u>.</u>
2000-04	3,134	83.66	4.12	12.03
2005-09	4,533	84.51	4.17	11.32
2010-14	1,747	84.83	3.72	11.45
Sum	9,414	84.29	4.07	11.58
Industry trials				
2000-04	1,721	88.79	3.83	7.38
2005-09	22,834	87.40	5.60	6.99
2010-14	17,233	83.75	11.30	4.95
Sum	41,178	85.95	7.88	6.16

Follow-on

First, to Taddy Dickersin's question as to whether I looked to see if female-only and male-only trials were concerned with female-only and male-only conditions.

No, I did not. I would expect that to be predominantly so, especially for male-only trials, because of the nature of NIH review processes and general reluctance of NIH review groups to approve male-only trials if there is no medical reason for them being male-only.

The single gender differential for NIH trials is not new. It probably existed prior to the NIH-Revitalization act.

What is interesting in what I distributed is that the female-only to male-only excess in NIH-funded trials of 3:1 is gone in industry-funded trials, but overall there are more females enrolled in industry-funded trials than in NIH-funded trials, laying waste to the notion that most industry-funded trials are done on males.

The other reality, based on numbers in <u>ClinicalTrials.gov</u>, is that NIH-funded trials are less than half the size of industry-funded trials.

Follow-on to 26 Oct memo on gender composition of trials

NIH

Females 436,976

Males 479,746

Total 915,722

No. trials 9,414

Mean/trial 97

Industry

Females 4,339,824

Males 3,913,462

Total 8,253,286

No. trials 41,178

Mean/trial 200

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