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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Gender composition of trials: Myth versus reality

The majority of people studied in trials are males. True or false?

Odds are, if you did a survey, most people would say "True".

They would be wrong, but who cares about facts when it comes to perceptions?

The issue of women in trials came front and center in the late 1980s and early 1990s with the "women's liberation movement". A few high profile male-only trials like the Coronary Drug Project and the Multiple Risk Factor Intervention Trial fueled the perception that women were being purposefully excluded from trials. The perception ultimately gave rise to the requirement (NIH Revitalization Act of 1993) that the Director of the National Institutes of Health ensures (for conditions common to men and women) that trials be:

> *designed and carried out in a manner sufficient to provide a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.*

The clause has the effect of requiring trialists to look for treatment by gender interactions. Good luck, given the reality that most trials are too small to detect main effects, let alone treatment interactions.

Until registration of trials became a reality, there was no reliable way of addressing the gender mix of trials.

The counts and percentages in the table below are from ClinicalTrials.gov. Counts are by year of completion.

Gender composition of trials registered in ClinicalTrials.gov by year of completion

	Completed trials	Gender mix (% of completed trials) Both	M-only	F-only
NIH trials				
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**

Most trials, whether funded by NIH or industry, involve both gender groups. The difference is in the fractions of trials that are single gender. The ratio of female-only to male-only trials is 3 to 1 for NIH-funded trials, compared to 6 to 8 for industry-funded trials. The difference may be due to the types of trials done by NIH versus industry or due to the impact of the NIH revitalization act encouraging more female-only studies.

Counts of the numbers of females and males enrolled in completed trials can be obtained from data in ClinicalTrials.gov for trials ("baseline data" defined in ClinicalTrials.gov as "data collected at the beginning of a clinical study for all participants and for each arm or comparison group").

The female to male ratios of persons enrolled in NIH-funded trials for the time period covered in the table above is 0.91 (436,976/479,746) and 1.11 (4,339,824/3,913,462) for industry-funded trials.

The gender mix in trials is secondary to the primary question of whether a treatment works. Usually, treatments that work, work in both gender groups. That said, the focus should be on design rather than gender composition. The most prudent recruitment strategy is to take all comers and let the gender mix be driven by the mix of the disease or condition in the two gender groups.

Thanks to Jill Meinert for counts herein.