

Are women really under-represented in clinical trials?

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Several studies have reported a lack of gender diversity in clinical trials, with trials including mostly adult males; however, a recent review of publicly available registration data of clinical trials at the US Food and Drug Administration for the most frequently prescribed drug classes found no evidence of any systemic significant under-representation of



women.

The findings are published in the *British Journal of Clinical Pharmacology*.

The analysis entailed 38 drugs with a total inclusion of 185,479 trial participants and revealed that through the clinical development phase, the proportion of women participating in trials gradually increases from 22% in phase 1 to over 48% for phase 2/3 trials.

"The results of this investigation show that drug trials are appropriately designed regarding inclusion of men and women. Furthermore, the underrepresentation of women in trials as observed in the 1980s and before seems to be resolved for most <u>drug trials</u> that we investigated," said co-author Dr. Robert Rissmann, of the Centre for Human Drug Research, in The Netherlands. "Although some earlier studies had reported an underrepresentation of women, our results are fully in line with recent results of a Cochrane meta-analysis, which underlines the robustness of our findings."

More information: G. Labots et al, Gender differences in clinical registration trials; is there a real problem?, *British Journal of Clinical Pharmacology* (2018). DOI: 10.1111/bcp.13497

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