



[Pediatric versus adult drug trials for conditions with high pediatric disease burden.](#)

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Abstract:

Optimal treatment decisions in children require sufficient evidence on the safety and efficacy of pharmaceuticals in pediatric patients. However, there is concern that not enough trials are conducted in children and that pediatric trials differ from those performed in adults. Our objective was to measure the prevalence of pediatric studies among clinical drug trials and compare trial characteristics and quality indicators between pediatric and adult drug trials.

For conditions representing a high burden of pediatric disease, we identified all drug trials registered in ClinicalTrials.gov with start dates between 2006 and 2011 and tracked the resulting publications. We measured the proportion of pediatric trials and subjects for each condition and compared pediatric and adult trial characteristics and quality indicators.

For the conditions selected, 59.9% of the disease burden was attributable to children, but only 12.0% (292/2440) of trials were pediatric (P

Notes:

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