



Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Pediatric study costs increased 8-fold since 2000 as complexity level grew

Despite rising costs, drug sponsors respond to pediatric exclusivity incentive

- The cumulative number of completed pediatric studies, subsequently accepted by the U.S. Food and Drug Administration (FDA), rose from 58 in 2000 to 568 in 2006.
 - Efficacy/safety studies, the most resource-intensive and expensive type of study, now account for 40% of all pediatric studies conducted, up from 25% in 2000.
 - The mean number of patients required for studies in response to an FDA request was up 178% between 2000 and 2006; the mean number of studies per request rose 60%.
 - Time required to complete a study and submit a final report nearly doubled since 2000.
 - The average cost to respond to a written request grew from \$3.93 million in 2000 to \$30.82 million in 2006 (in nominal dollars), an 8-fold increase.
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