



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Pace of CNS drug development and FDA approvals lags other drug classes

Clinical-plus-approval time for CNS drugs 35% longer vs. non-CNS drugs

- The clinical approval success rate for central nervous system (CNS) drugs from 1993 to 2004 was about one in 10, compared to one in six for all self-originated drugs.
- The Phase III-to-regulatory-submission transition rate for self-originated CNS drugs was 50% for drugs with clinical testing initiated during 2002-07.
- Clinical approval success rates for self-originated CNS drugs declined since the early 2000s.
- Since the mid-1990s, CNS drugs had relatively few priority approvals (18% vs. 46% for other drugs).
- During 1996-10, mean clinical phase time for CNS drugs, compared to non-CNS drugs, was 40% longer, while mean approval phase time was 13% longer.