



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## CNS drugs take longer to develop, have lower success rates, than other drugs

*U.S. approval rate for CNS compounds less than half that of all other compounds*

- Mean clinical development time for CNS drugs approved for marketing in the United States from 1999 through 2013 was 12.8 months, or 18%, longer than that for non-CNS compounds.
- The overall clinical approval success rate for CNS compounds first tested in human subjects from 1995 to 2007 was 6.2%, or less than half the 13.3% rate for non-CNS drugs.
- The overall approval success rate for CNS compounds first tested in human subjects during 1995-07 varied from a low of 3.7% for 1997-00, to a peak of 11.3% for 2001-04, and then to 4.7% for 2004-07.
- During 1999-13, mean approval phase time for CNS compounds approved for marketing in the U.S. was 19.3 months, or 31% longer than the 14.7 months for non-CNS approvals.
- From 1999 to 2013, about one in six CNS compounds received a priority review rating from the U.S. Food and Drug Administration (FDA), compared to nearly half of all non-CNS compounds.
- Despite longer clinical and approval phase times, and lower clinical success rates, CNS approvals have held steady, accounting for about one in 10 of all U.S. approvals since the 1980s.