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.

Central nervous system, or CNS, drugs, which treat a wide array of psychiatric and neurodegenerative disorders, including depression, psychosis, epilepsy, and Alzheimer's Disease, are more challenging to develop than other medicines, because the conditions they aim to treat are typically chronic and complex, and the clinical endpoints are often difficult to measure. That’s why CNS drug development takes longer and has a lower likelihood of overall clinical success than non-CNS drug development. CNS drugs also experience longer regulatory approval times compared to non-CNS compounds.

To better understand the unique development challenges of CNS drugs, Tufts CSDD examined the development and approval histories of 274 CNS and 1,168 non-CNS investigational compounds that were first tested in human subjects from 1995 to 2007. Tufts CSDD also examined the development and approval phase times of 42 CNS and 345 non-CNS therapeutic compounds approved in the U.S. from 1999 to 2013.