



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Cardiovascular drug approval rate in the U.S. fell as development time rose

But development time was less for cardiovascular vs. other drugs during 1999-16

- The overall clinical approval success rate for cardiovascular drugs first tested in human subjects from 1995 to 2007 was 3.7%, or less than one-third the 12.9% rate for non-cardiovascular drugs.
- Approval success rates for cardiovascular compounds first tested in human subjects in 2001-07 fell by 58% compared to those first tested in 1995-00 – from 5.2% in the earlier period to 2.2% in the later period.
- Fewer new cardiovascular drugs received a priority rating compared to other drugs approved during 1999-16 (38% vs. 50%).
- Clinical development time was 14% shorter and regulatory approval time was 22% longer for cardiovascular vs. non-cardiovascular drugs approved during 1999-16.
- The cardiovascular share of new drug approvals in the U.S. declined from 27% during the 1980s to 13% during 2011-16.