

Tufts Center for the Study of Drug Development



Impact REPORT

TUFTS UNIVERSITY

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Despite more cancer drugs in R&D, overall U.S. approval rate is 8%

Tufts CSDD study suggests need for improved development efficiency

- The rate of clinical entry for cancer therapeutics developed by companies worldwide more than doubled, from 33 per year in the early 1990s to 73 per year in the mid-2000s.
 - Overall U.S. success rates were low for compounds that either have been abandoned or approved to date: 8% for all candidates, 10% for small molecule drugs, 9% for monoclonal antibodies (mAbs) of all types, and 14% for humanized mAbs.
 - Compared to all candidates and the small molecules, mAbs had the lowest Phase 1-to-2 and Phase 2-to-3 phase transitions, but the highest Phase 3-to-FDA review and review-to-approval transitions.
 - Total clinical and approval phases averaged seven years for the 32 therapeutics that entered clinical study in 1990-06 and have since gained U.S. marketing approval.
 - Synthetic drugs, including peptides and oligonucleotides, comprised half of the candidates entering study between 1990 and 2006.
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