

Tufts Center for the Study of Drug Development



Impact REPORT

TUFTS UNIVERSITY

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Number of mAbs entering clinical study nearly tripled in last decade

Humanized monoclonal antibody products had an overall success rate of 17%

- The average number of all mAb candidates entering clinical study nearly tripled, from 12 in the mid-1990s to 34.5 in the mid-2000s.
 - The share of human mAbs entering clinical study grew from 11% in the 1990s to more than 40% in 2000-06.
 - Overall success rate was 17% for all humanized candidates, with a slightly lower rate (15%) for anticancer candidates and a slightly higher rate (21%) for immunological candidates.
 - Transition probabilities for humanized mAbs that entered clinical study during 1988-06 were 83%, 44%, and 81%, respectively, for the three phase transitions.
 - Clinical and approval phases for all 21 mAb products approved by the U.S. Food and Drug Administration (FDA) averaged 80.8 and 11.5 months, respectively.
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