



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact R E P O R T

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

New mAbs entering clinical study rose steadily from 1997 through 2010

During the same time, 29 therapeutic mAbs received U.S. marketing approval

- The number of novel mAbs entering clinical study worldwide annually rose from 19 in 1997 to 53 in 2010, peaking at 54 in 2008.
- The U.S. Food and Drug Administration (FDA) approved 29 therapeutic mAbs in 1997-11.
- Clinical and FDA approval phases for mAb therapeutics averaged 7.2 and 1.0 years, respectively.
- The cumulative success rate was 17% for all humanized mAb candidates during 1997-11; anticancer mAb success rates were 13%, compared to 26% for immunological candidates.
- Nearly all (90%) mAbs currently in clinical trials are in Phase I or Phase II study.
- Antibody-drug conjugates comprise the largest share of new mAb formats that developers are exploring.