



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Collaboration & risk-sharing programs experience longer development times

Interrupted development programs take 14.8 months longer than uninterrupted

- About half of all new therapeutic drugs approved in 2000-11 involved a risk-sharing approach to clinical development.
- The share of new drugs developed clinically under the auspices of a single developer declined from 47% of 2000-03 approvals to 41% of 2008-11 approvals.
- The share of co-developed drugs rose from 12% in 2000-03 to 22% in 2008-11.
- The extent of risk-sharing and collaborative clinical development relationships among firms varied by therapeutic class; 25% of AIDS antiviral approvals involved risk-sharing, compared to 65% of central nervous system drug approvals.
- Mean clinical phase time was 8.9 months longer for new drugs in multi-firm, risk-sharing clinical development relationships, and total phase time was 9.5 months longer, compared to new drugs that did not involve these relationships.