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.

Looking to reduce the high risks, costs, and inefficiencies of drug development, pharmaceutical and biotechnology companies in recent years increasingly have engaged in innovative partnerships that include joint development, mergers and acquisitions (M&A), and in-licensing of drug candidates developed by others. While such collaborations can yield important advances, they also can interrupt the drug development process and affect program-level clinical and regulatory cycle times. Tufts CSDD sought to identify and quantify the impact of such interruptions. Highlights of that assessment are summarized in this report.

Most notably, the analysis showed that active drug development programs that experience a change in management structure, including a licensing, joint venture, co-development arrangement, or an M&A transaction—called interrupted development programs in this report—have longer clinical phase durations than uninterrupted development programs. This finding supports anecdotal reports from the front lines: adjusting to a new operating environment and new partners and uncertainty concerning resources most likely contributes to diminished development speed.