Risk-Sharing Drug Development Programs Experience Longer Development Times

BOSTON – May 8, 2014 – Drug development programs that involve several partners who share clinical development risks accounted for about half of all new therapeutic drug approvals in recent years and experienced longer clinical phase times, as well as longer overall time to approval, according to a study recently completed by the Tufts Center for the Study of Drug Development.

According to the study, mean clinical phase time was 8.9 months longer for new drugs in multi-firm, risk-sharing clinical development relationships, and total (clinical plus regulatory review) phase time was 9.5 months longer, compared to new drugs that did not involve these relationships.

A total of 143 new drugs that were approved in the United States between 2000 and 2011, about half of all new drugs approved during that time, were developed under a collaborative, risk-sharing arrangement, which included licensing, joint ventures, co-development, or M&A transactions, Tufts CSDD found. Of these 143 drugs, 57% involved licensing deals and another 29% involved co-development.

“The analysis shows that changing the management structure for active drug development programs brings with it operational challenges that most likely contribute to diminished development speed,” said Joseph A. DiMasi, Tufts CSDD Director of Economic Analysis.

Given the high risks, costs, and inefficiencies of drug development, developers have little choice but to engage in innovative approaches that span an array of partnerships with other drug companies, service providers, academic researchers, and patient groups, according to DiMasi.

“The more drug developers engage in innovative, risk-sharing arrangements, the better they will figure out how to collaborate more efficiently,” he said.

Other findings from the study, reported in the May/June Tufts CSDD Impact Report, which was released today, include the following:

- The share of new drugs developed clinically under the auspices of a single developer declined from 47% of 2000-03 approvals in the U.S. to 41% of 2008-11 approvals.
- The share for co-developed drugs rose from 12% in 2000-03 to 22% in 2008-11.
- Median clinical phase times were greatest for co-developed drugs (13.6 months longer than those from single firms), followed by drugs that were licensed (7.2 months longer than those from single firms).
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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