Tufts University

Tufts Center for the Study of Drug Development

PRESS RELEASE

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New Drug Development Still Takes Eight Years Despite Faster FDA Review, According to Tufts Center for the Study of Drug Development

BOSTON – Jan. 6, 2009 – While the U.S. Food and Drug Administration Drug has quickened review and approval of new medicines, the complex nature of diseases for which new therapeutics are being developed has resulted in longer clinical development times, according to the Tufts Center for the Study of Drug Development.

The average time for the FDA to approve new drugs declined to 1.1 years in the 2005-07 period, but longer average clinical phase time means combined clinical and approval time continues to hover around eight years, according to Tufts CSDD.

"Even though the total time to bring new drugs to market has remained essentially unchanged in recent years, drug developers are making progress," said Tufts CSDD Director Kenneth I Kaitin, who made his comments in connection with the release today of the Tufts Center's *Outlook 2009* report on pharmaceutical and biopharmaceutical trends.

"Many factors are leading to longer clinical times, including a focus on complex diseases and more complicated development design protocols," he added.

Drug companies have taken steps to speed clinical development, according to Kaitin, including improving project management, expanding use of partnerships and licensing arrangements, and increasing use of surrogate endpoints and adaptive clinical trials.

"Still, in drug development, the race—and rewards—go to the swiftest and most efficient drug sponsors, those that can deliver safe and effective new medicines in the shortest time," he said.

Among the near-term trends cited in the Tufts CSDD's *Outlook 2009* report are the following:

- Firms will continue globalization of their preclinical and clinical development activities to overcome local capacity constraints, increase speed-to-market, and expand their presence in emerging markets.

- Continued shortages of experienced personnel, especially among upper level managerial staff, will continue to hamper the FDA's ability to fulfill its mandate, as will advisory committees vacancies depleted by new conflict of interests and public disclosure rules.

- The recent trend of more candidates entering clinical study each year enhances prospects for new monoclonal antibody (mAb) approvals. Currently, 22 mAbs are available in the U.S. and more than 200 are in the pipeline worldwide.

- U.S. payers, including health insurance companies and managed care organizations, will increase their use of formulary management tools to contain costs, particularly with regard to specialty pharmaceuticals.

- Demand for services from contract research organizations (CROs) is expected to grow by more than 15% annually, as sponsors face capacity constraints and a rising volume of large, complex global clinical trials.

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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) 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 the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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