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Growing Complexity of Clinical Trials Increases Burden on Investigators and Volunteers, According to Tufts Center for the Study of Drug Development

BOSTON – Jan. 15, 2008 – More complex clinical trial protocols are demanding more of investigative site personnel and study volunteers, leading to longer clinical trials and increasing difficulty in recruiting and retaining patients, according to a new study recently completed by the Tufts Center for the Study of Drug Development.

"During the past decade, there has been a steady increase in the number and frequency of procedures per protocol, and a similar rise in the number of enrollment eligibility criteria and pages per case report form," said Ken Getz, a senior research fellow at the Tufts Center and lead investigator on the study. "These protocol design changes are largely due to the nature of diseases currently under investigation and intensifying competition among drug developers."

Getz noted that the increasing complexity of protocol designs is contributing to the growing time, cost, and risk of drug development. "The rise in protocol complexity represents a significant challenge for drug developers," he said.

The Tufts CSDD study is the first ever to quantify the impact of changes in protocol design on clinical trial performance. Results, reported in the January/February *Tufts CSDD Impact Report*, released today, specifically found that:

* The annual growth rate of unique procedures per protocol grew 6.5% between 1999 and 2005.

* Clinical trials are taking longer: between 1999-02 and 2003-06, total time from protocol design readiness to database lock rose from 460 to 780 days, or 69.6%.

* Volunteer enrollment rates dropped from 75% in 1999-02 to 59% in 2003-06, while volunteer retention rates declined from 69% to 48%.

* The work effort required of investigative site personnel to administer clinical study protocols is rising faster than the rate of growth of unique procedures or their frequency per protocol.

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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