FOR IMMEDIATE RELEASE

Extraneous Data Collected in Clinical Trials Cost Drug Developers $4 Billion to $6 Billion Annually, According to Tufts Center for the Study of Drug Development

BOSTON – Nov. 6, 2012 – One out of every five procedures performed during later stage clinical trials collects extraneous data and costs drug developers more than $1 million per trial, a newly completed study by the Tufts Center for the Study of Drug Development has found.

According to Tufts CSDD, 18 percent of a typical clinical trial budget, or $1.1 million, is spent on direct costs to administer procedures for supplementary secondary, tertiary, and exploratory endpoints.

"The impetus to collect these data is strong, and until now there has been no systematic assessment of this practice," said Ken Getz, assistant professor at Tufts CSDD. "We believe our findings offer a framework that pharmaceutical and biotechnology companies can use to streamline protocol designs, improve clinical research performance, and reduce development costs."

Based on the total number of active Phase II and III clinical trials regulated by the U.S. Food and Drug Administration, Tufts CSDD conservatively estimates that the pharmaceutical industry spends between $4 billion and $6 billion each year on procedures that generate extraneous clinical trial data.

The study, reported in the November/December *Tufts CSDD Impact Report*, released today, also found that:

- An average 22.3% of all clinical trial procedures are considered to be non-core, including 17.7% of Phase II procedures and 24.7% of Phase III procedures.
- Half of all procedures—54.3% of Phase II procedures and 47.9% of Phase III—support primary and key secondary endpoints.
- The typical clinical trial protocol has an average of 13 endpoints, with the number of less essential endpoints per protocol nearly doubling the average level observed 10 years ago.

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 Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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