

Results Mixed on Postmarketing Studies of New Drugs, According to the Tufts Center for the Study of Drug Development

BOSTON – May 15, 2007 – While drug developers over the past six years have stepped up the number of postmarketing studies they conduct on newly approved medicines, sponsors feel that those studies have contributed little to their understanding of safety, efficacy, or quality, a recently completed assessment by the Tufts Center for the Study of Drug Development shows.

According to a Tufts CSDD survey, 68% of clinical study sponsors and 79% of non-clinical study sponsors said results contributed either marginally or not at all to their understanding of the safety, efficacy, or quality of their product.

However, 32% said clinical studies significantly or very significantly increased their understanding of their products.

“A lot of progress has been made in the area of postapproval studies since 2001, when the U.S. Food and Drug Administration regulation requiring sponsors to provide annual reports on the status of postmarketing studies went into effect,” said Tufts CSDD Associate Director Christopher-Paul Milne. “But a major challenge drug sponsors face is completing the studies on time.”

More than half of all postmarketing studies, for which final study reports were submitted, were finished by their projected completion date, Tufts CSDD found, but 45% were delayed due to enrollment problems, technical difficulties, additional FDA requirements, or sponsors expanding the scope of their own studies.

The *Prescription Drug User Fee Act* (PDUFA), which authorizes the FDA to request postmarketing study reports, is due for renewal in Congress later this year.

The analysis, reported in the May/June *Tufts CSDD Impact Report*, released today, also found that:

- * Clinical studies, on average, took 10 months longer to complete and cost nearly nine times as much as non-clinical studies.
- * Postmarketing studies are typically the responsibility of applicable R&D departments, e.g., clinical development, preclinical, toxicology, laboratory, not marketing departments, as some PDUFA critics claim.
- * Between 1998 and 2005 sponsors spent, on average, \$5.3 million per clinical postmarketing study, compared to \$610,000 per non-clinical study.

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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