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Majority of Clinical Trial Protocols Are Amended, But One-Third of Those Changes Are Avoidable, According to Tufts Center for the Study of Drug Development

BOSTON – Sept. 13, 2011 – Nearly 60 percent of all protocols used in clinical trials for new drugs are amended during the trial. Moreover, one-third of those changes could have been avoided, according to the first-ever analysis, conducted by the Tufts Center for the Study of Drug Development, quantifying the impact of protocol changes on clinical trials.

Completed protocols across all clinical trials incur an average of 2.3 amendments, with each requiring an average of 6.9 changes to the protocol, leading to significant unplanned expense and delay, according to Tufts CSDD.

Until now the incidence, causes, and impact of protocol amendments have never been systematically quantified across the pharmaceutical and biotechnology industry. A protocol is a plan detailing the methodology of a clinical trial.

“Although amendments to protocols of clinical trials are sometimes necessary to optimize study results and ensure patient safety and ethical treatment, study sponsors can minimize the number of protocols through better initial study design and improved recruitment of study volunteers,” said Ken Getz, Tufts CSDD senior research fellow and assistant professor at Tufts University, who conducted the study.

He noted that a high incidence of protocol amendments will likely continue, as the analysis found that the mean number of amendments was positively and significantly correlated with the rising number of procedures per protocol, study length, and number of investigative sites participating in each clinical trial.

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

- * Across all phases of clinical trials, 43% of protocol amendments occur before first patients are enrolled, with amendments more likely to occur in Phase I studies.
- * More than half of all protocols require one or more amendments, with Phase III studies requiring the highest number of changes per amendment at 8.5.
- * One-third of all amendments relate to protocol description and patient eligibility criteria.
- * Median total cycle time to identify and resolve a protocol problem is 61 days.

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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