Protocol Design Optimization Is Starting to Improve Clinical Study Performance

BOSTON – Sept. 9, 2014 – Efforts by drug companies to streamline and improve the execution of clinical study designs—to counter mounting costs and shorten development times associated with bringing new drugs to market—are yielding positive benefits, according to an assessment recently completed by the Tufts Center for the Study of Drug Development.

According to Tufts CSDD, greater emphasis by drug sponsors on upfront planning and governance to assess and challenge protocol feasibility and new approaches to development, including facilitated review mechanisms and greater use of adaptive trial designs, are helping to improve data quality and success rates, while cutting costs.

For example, the majority of large and mid-size pharmaceutical and biotech companies surveyed by Tufts CSDD reported implementing facilitated review processes and mechanisms within the past five years to challenge protocol design feasibility.

However, Tufts CSDD found, developers continue to collect a large amount of data that is not associated with primary or key secondary endpoints, regulatory compliance, or standard baseline assessments, with one-fifth of Phase II and one-third of Phase III protocol procedures, on average, collecting non-core data.

“Progress over the last decade has been very slow and it has been difficult for sponsor companies to streamline protocol design and improve feasibility despite the critical need to do so,” said Ken Getz, associate professor and director of sponsored research at Tufts CSDD. “Our research has shown that the push to collect more data and increase clinical trial complexity is associated with higher levels of drug development risk, cost, and inefficiency.”

Other findings from the analysis, reported in the September/October Tufts CSDD Impact Report, released today, include the following:

- On average, approximately one-quarter of a total study budget’s direct costs was dedicated to procedures that collect non-core data.
- Although non-core data do not support primary and key secondary endpoints, sponsor companies include the non-core data they collect in 92% of their clinical study reports and in 95% of the tables, listings, and figures included in their regulatory submissions.
- Sponsor companies use simple adaptive trial designs, including early terminations and sample size re-estimations, in 21% of active clinical trials to improve success rates and reduce operating costs.
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development 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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