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Drug Developers Actively Improving Efficiency of Clinical Trials, According to Tufts Center for the Study of Drug Development

BOSTON – April 26, 2011 – Looking to improve the operational efficiency of clinical trials, drug developers are actively pursuing new strategies that include collaborating with investigative sites in developing protocols and educating patients about trials before they agree to participate, according to a panel of leaders from the research-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

“The pharmaceutical and biotech industry is facing a crisis in that it needs to develop new drugs more quickly and control expenses,” said Tufts CSDD Senior Research Fellow Ken Getz. “Developers understand that substantial operational improvements will more likely flow from new approaches that increase the probability of success, rather than from actions which merely seek to reduce or prevent failures.”

According to Tufts CSDD, two-thirds of investigative sites fail to meet the patient enrollment requirements for a given clinical trial. And, whereas in 2001 nearly half of all patients screened for clinical trials completed them, in 2010 less than one in four screened patients were retained for the duration of the clinical trial.

Once enrolled, patients are subjected to an ever increasing number of procedures. For example, between 2000-03 and 2004-07, the median number of procedures per clinical trial increased by 49%. Improving patient enrollment and controlling the number of procedures could provide substantial benefits, Getz said.

The executives, who met as part of the Tufts CSDD Executive Forum Roundtable, also agreed that:

* Communication between developers and investigative sites—before, during, and after trials end—is critical to developing good relations.

* Having a medical advisor engage with sites helps sites better understand the goals and requirements of a study.

* Testing trial protocols with potential patients is often critical as to whether those patients will enroll in clinical trials.

* Electronic medical records help define and manage the data flow, including letting project managers understand where patients originate.

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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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