Tufts University

Tufts Center for the Study of Drug Development

PRESS RELEASE

Clinical Trial Design Holds Key to Improved Drug Development Efficiency, According to Tufts Center for the Study of Drug Development

BOSTON – Oct. 30, 2008 – Improved protocol design, perhaps more than any other drug development stratagem, holds the key to faster and more efficient development, according to the Tufts Center for the Study of Drug Development.

"Drug sponsors have been working hard to reduce development cycle times and costs by aggressively managing project timelines and investigative site performance, and by conducting trials in emerging global regions, but these strategies have a marginal impact on improving overall drug development efficiency," said Tufts CSDD Director Kenneth I Kaitin.

Speaking at a meeting of drug industry leaders to identify best practices in the development of protocols, recently convened by Tufts CSDD, Kaitin said, "Major advances in development efficiency comes from better clinical trial design."

Improved protocols, which provide step-by-step guidance for the conduct of clinical trials, have been shown to have a pronounced effect on reducing performance burdens and costs and accelerating development cycle time, according to Tufts CSDD research.

Average clinical development times for new drugs in the U.S. since 1993, when new regulations to speed drug development took effect, have hovered around 6.6 years. During the same period, time required for regulatory approval has trended downward from an average of 2 years in 1993-95 to 1.1 years in 2005-07, according to Tufts CSDD.

Participants at the meeting, part of Tufts CSDD's Executive Forum Roundtable Series, noted that good protocols:

* Include input early on from project managers, investigators, and study coordinators.

* Match protocol details with data collection tools.

* Provide enough information to justify core aspects of the protocol, e.g., design, dose, comparator, target criteria, patient population.

* Are simple in design, adhere to industry standards, and can be understood worldwide.

SCHEDULED R&D MANAGEMENT ROUNDTABLES

Upcoming Tufts CSDD Roundtable meetings will focus on the following:

* Nov. 6, 2008 – Assessing Change and Opportunity in the Phase I Landscape
* Feb. 26, 2009 – In-Licensing/Out-Licensing Strategies and Practice

To register, call 617-636-2170.

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. A core element of the center's educational efforts, the Tufts CSDD Institute for Professional Development, produces the Executive Forum Roundtable Series, along with postgraduate level courses, training workshops, symposia, and public forums.

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75 Kneeland Street, 11th Floor, Boston, MA 02111
TEL: 617.636.2170 | FAX: 617.636.2425 | EMAIL: csdd@tufts.edu | http://csdd.tufts.edu