Tufts University

Tufts Center for the Study of Drug Development

PRESS RELEASE

Drug Developers Looking to Learn as Much as Possible in Phase I Trials, According to Tufts Center for the Study of Drug Development

BOSTON – Jan. 27, 2009 – Under pressure to develop new medicines more quickly and at lower cost, drug sponsors are looking to answer as many questions as possible in Phase I, including those relating to efficacy as well as safety, according to the Tufts Center for the Study of Drug Development.

"The desire to learn more from Phase I studies has led to greater protocol complexity and larger trials, which, with growing regulatory oversight, has helped drive up costs and lengthen timelines, which is just the opposite of what the industry needs to achieve," said Tufts CSDD Director Kenneth I Kaitin.

In addition, developers are increasing their reliance on patient volunteers—now accounting for 38% of all human subjects in Phase I studies—who typically cost more to recruit and retain than healthy volunteers.

To help temper, if not reverse, the ever-growing cost of Phase I trials, the research-based drug industry as a whole will likely increase its use of outsourced services and make greater use of biomarkers and diagnostic tests, according Kaitin.

Kaitin made his remarks at a meeting of drug industry leaders recently convened by Tufts CSDD to discuss challenges and opportunities in the Phase I landscape.

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

* Integrated studies—those with multiple objectives—are likely to grow in popularity, partially in response to financial constraints, especially in smaller organizations.

* Pressure on drug developers to maximize the amount of information they obtain in Phase I studies will increase pressure on CROs to achieve proof of concept as soon as possible.

* Public concern over clinical trial safety is likely to keep pressure on sponsors to disclose information about ongoing studies.

SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

Tufts CSDD Executive Forum Roundtable meetings in 2009 will focus on the following:

* Feb. 26 – In-Licensing/Out-Licensing Strategies and Practice
* May 14 – Outsourcing: Economic and Operational Assessments
* Sept. 10 – Best R&D Practices of Top Pharma/Biotech Performers
* Nov. 12 – Comparative Approaches to Capacity Forecasting

To learn more, 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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