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Effective Drug Development Outsourcing Requires a Plan, According to Tufts Center for the Study of Drug Development

BOSTON – April 2, 2008 – While the trend to outsource key elements of drug development to service providers could slow down due in part to rising operating costs worldwide, drug developers need to adopt an outsourcing strategy that optimizes their skill sets, according to the Tufts Center for the Study of Drug Development.

The advisory was presented to a meeting of industry leaders recently convened by Tufts CSDD to discuss strategic outsourcing and global drug development issues.

“Rising operating costs, particularly in China and India, and growing regulatory scrutiny in the wake of recent high-profile safety incidents may lead some developers to consider slowing, or even reversing, their global outsourcing activities, but doing so could cost them more in the long run,” said Tufts CSDD Director Kenneth I Kaitin.

Instead, Kaitin added, “Developers should develop an overall outsourcing strategy, and the place to start is with an honest appraisal of what they can best contribute to the drug development value chain.”

The meeting, part of the Tufts CSDD R&D Management Roundtable Series, was organized to identify outsourcing strategies and tactics that can improve R&D productivity.

Among key steps discussed to achieve an effectively outsource in drug development were the following:

- * Decide what to outsource based on an in-depth assessment of core competencies.
- * Achieve consensus across the organization on a standardized approach to outsourcing.
- * Be prepared to commit management time to administer external service providers. Short changing that effort will likely lead to an unsatisfactory experience.
- * Annually review your forecast of planned studies and internal resources.

“Most importantly,” Kaitin said, “companies need to keep in mind that one approach may not be appropriate for all development programs. Some may require a tactical approach, which is more ad hoc and project oriented, while others may benefit from a more formalized and portfolio oriented strategic approach.”

SCHEDULED R&D MANAGEMENT ROUNDTABLES

Upcoming Tufts CSDD R&D Roundtable meetings in 2008 will focus on the following:

- * May 1 – Leveraging Metrics and Market Factors for Portfolio Decision Making
- * Sept. 11 – Optimizing Protocol Design--Strategies to Improve Clinical Research Performance
- * Nov. 6 – Assessing Change and Opportunity in the Phase I Landscape

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 R&D Management Roundtable series, along with postgraduate level courses, training workshops, symposia, and public forums.

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