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## New Protocol Design Approaches Will Improve Clinical Trial Performance and Efficiency, According to Tufts Center for the Study of Drug Development

BOSTON – April 9, 2013 – Growing protocol complexity—responsible for longer clinical study times, greater difficulty in recruiting volunteers, and rising drug development costs—is spurring new approaches to optimizing protocol design, according to leaders from the research-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

A key challenge for drug developers is to design protocols—plans detailing the methodology of a clinical study—that address increasing scientific, regulatory, and operating demands while maintaining patient safety and study feasibility, the panel agreed. Failing to do so, they said, could seriously threaten future clinical success.

Tufts CSDD studies conducted over the past decade have demonstrated that greater protocol complexity correlates with longer study cycle times, poorer patient recruitment and retention rates, and a higher number of protocol amendments.

"The good news is that drug developers are not sitting still. They're making headway in changing and streamlining protocol design that will have a major downstream impact on clinical trials performance and success," said Ken Getz, associate professor and director of sponsored research at Tufts CSDD.

New approaches to protocol designs are already yielding positive results, he said, including the establishment of internal governance mechanisms that promote cross functional collaboration and ensure higher levels of clinical trial efficiency and feasibility.

The panel discussion, key points of which are summarized in the April *Tufts CSDD R&D Management Report*, released today, included the following:

- Improving protocol design requires changes in organizational culture that emphasize compound probability of business, not just scientific, success.
- Computer-aided design tools that enable drug developers to model and assess alternative development scenarios will play an increasingly decisive role.
- Reviewing key design elements and collecting new measures that tie protocol procedures to major study endpoints and objectives should be included in the feasibility assessment process.

### SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

Upcoming Tufts CSDD Executive Forum Roundtable meetings:

May 16, 2013 — Partnerships, Alliances, Consortia, and Other Risk-Sharing Collaborations
Sept. 12, 2013 — Outsourcing to Maximize Operating Efficiency

### 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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