# Companion Diagnostics, Key to Development of Personalized Medicines, Face Hurdles, According to Tufts Center for the Study of Drug Development

The Associated Press

Companion diagnostics, which are central to the creation of personalized medicines, have captured the interest of many drug companies, but face a number of hurdles that could impede development, according to a panel of leaders from the research-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

Still mostly in the early stages of development, companion diagnostics -- tests linked to a therapeutic medicine that help identify a population of patients who are likely to respond to the drug -- face a number of critical challenges, the panel said. They include reluctance on the part of investors to fund research, uncertainty regarding reimbursement from insurers, and questions about clinical and cost effectiveness due to insufficient data on the value that companion diagnostics deliver to patients.

"Despite these difficulties, interest in developing companion diagnostics remains strong," said Christopher-Paul Milne, director of research at Tufts CSDD. "That's because drug companies recognize that companion diagnostics co-developed with a therapeutic can increase the probability of winning regulatory approval for the drug.

"Also, companion diagnostics can enhance the use of targeted medicines, increasing their value and making them more cost-effective in the long run for health insurers, who are confronting the challenge of a growing proportion of aging members and a diminishing proportion of young healthy workers paying into the system."

Other key points made at the panel discussion, summarized in the January Tufts CSDD R&D Management Report, released today, included the following:
Meeting high standards for regulatory approval of companion diagnostics in the United States will help position developers for regulatory success outside the country, but the diversity of diagnostics regulations, as well as lack of precedent for co-development elsewhere, remain challenging. Drug developers that partner with a companion diagnostic company to co-develop and commercialize a diagnostic need to account for the fact that the two partners will have different business models based on different development platforms that employ different technologies.
SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

Upcoming Tufts CSDD Executive Forum Roundtable meetings:

Feb. 21, 2013 - Managing Protocol Design to Improve Clinical Study Efficiency May 16, 2013 - Partnerships, Alliances, Consortia, and Other Risk-Sharing Collaborations

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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