

PGx Tools Will Help Pharmas Mitigate Economic, Regulatory Challenges, Tufts Report Predicts

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By a GenomeWeb staff reporter

NEW YORK (GenomeWeb News) — Pharmaceutical companies this year will rely on pharmacogenomic technologies to offset rising drug-development costs, loss of patent exclusivity, and a tight reimbursement environment, according to the Tufts Center for the Study of Drug Development.

“Drug developers will work to validate safety and efficacy biomarkers, develop predictive preclinical toxicology screens, utilize micro-dosing studies, and expand pharmacogenomic programs to improve success rates,” according to an annual outlook report.

The report projects that “drug companies will strive to speed development and reduce failure rates” through “greater use of new technologies,” including pharmacogenomic tools.

“Despite a growing list of challenges facing drug developers ... there is reason for optimism,” according to the report.

The report, which can be found here, predicts that drug developers will be compelled “to improve the way they manage risk, especially as they seek to lower late-stage development attrition rates, and to increase their utilization of information technology.”

In another nod to pharmacogenomics, the outlook said that these challenges will “encourage sponsors to make greater use of innovative practices, such as clinical trial enhancement, to improve R&D performance and output.”

Pharmaceutical companies will also continue to “grapple with the complex economics” of developing drugs for subgroups, “including whether to internalize development of diagnostic markers that can be linked to therapeutics,” the study said.

Drug companies “are improving their management of risk, especially by actively lowering late-stage attrition rates through greater use of information technology and other development practices,” Tufts CSDD Director Ken Kaitin said in a statement accompanying the report.

Full Tufts Statement on report:

Despite Development Challenges, Drug Developers Have Reason to be Optimistic

January 3, 2007

BOSTON – Jan. 3, 2007 – Despite a growing list of development challenges — including rising R&D costs, increasing regulatory stringency, and mounting public hostility over safety and end-user costs — drug developers have cause for optimism, according to the Tufts Center for the Study of Drug Development.

Contributing to that optimism, Tufts CSDD said, is greater use of new technologies to reduce late-stage development failures and contain rising costs, increased reliance on global outsourcing to speed development and reduce costs, and more coordination between U.S. and European regulators.

The trends were cited in the Tufts Center’s Outlook 2007 report on pharmaceutical and biotech development, released today.

“While drug developers have understood that their long-term viability depends on improving R&D productivity — and have taken steps to address the issue — they’re about to see their efforts pay off in terms of improved success rates and greater numbers of new medicinal products reaching the marketplace,” said Tufts CSDD Director Kenneth I Kaitin.

Kaitin cited as evidence the fact that the number of new drugs entering clinical testing by the top 10 firms increased by 52% in the first part of this decade. Also, he said, new product development at small/mid-tier pharma and biotechnology companies is increasingly filling the product gap that large pharmaceutical firms have been experiencing.

“Most notably, drug companies are improving their management of risk, especially by actively lowering late-stage attrition rates through greater use of information technology and other development practices,” he said.

Other near-term trends cited in the Tufts CSDD’s Outlook 2007 report include the following:

- * Companies, acting alone and in consortia, will seek to improve drug discovery by examining pre-competitive data to identify and validate new targets.

- * The high cost and low success rates of human studies will lead small/mid-tier pharma companies to adopt outsourcing and other clinical practices that big pharma increasingly uses to control costs and manage risk.

- * Biotech firms will escalate biodefense and pandemic disease related R&D, emphasizing translational research and development of effective countermeasures.

- * Instead of directly addressing off-label uses of existing prescription drugs, the U.S. Food and Drug Administration (FDA) will evaluate current studies and likely request new ones before deciding whether to further regulate off-label uses.

- * Within two to three years, up to 65% of FDA-regulated clinical trials for top pharmaceutical companies will be conducted abroad.

* The European Medicines Agency (EMA) will focus on implementing new legislation and integrating drug regulatory agencies of new European Union members into a comprehensive pan-European system.

* U.S. third party payers will move away from a binary coverage model in which prescription drugs are either covered or not covered. Instead, more than 90% of prescription drugs will be covered with a variety of limits.

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 on related topics, and publishes the Tufts CSDD Impact Report, a bi-monthly newsletter providing analysis and insight into critical drug development issues.