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Clinical Study Failures Vary Widely by Phase of Study and Therapeutic Class, According to the Tufts Center for the Study of Drug Development

BOSTON – Sept. 10, 2013 – While lack of commercial viability is the leading cause of Phase I failures for new drug candidates, efficacy issues dominate as the reason for Phase II failures, according to a new analysis from the Tufts Center for the Study of Drug Development.

Based on a study of products that entered clinical development from 2000 through 2009, Tufts CSDD found that commercial reasons accounted for 40.9% of all Phase I failures, but only 27.3% of Phase II failures. Efficacy issues explained 50.9% of Phase II failures.

Clinical study failures also vary widely by therapeutic class of drugs being investigated, the analysis showed.

“It is in the interest of drug developers to have new products fail earlier, rather than later, in development, as earlier terminations avoid the costs of larger, more complex studies,” said Joseph A. DiMasi, Tufts CSDD director of economic analysis, the principal investigator on the study.

He added, “While there is natural resistance to give up on a compound too early, the need to reduce costs and boost productivity is leading developers to establish new approaches to R&D, including the increased use of biomarkers and novel clinical trial designs, with the goal of terminating candidates as early as possible.”

The analysis, reported in the September/October Tufts CSDD Impact Report, released today, also found that:

- Safety issues accounted for nearly twice as many Phase III failures as did commercial reasons: 29.5% vs. 15.9%.
- Efficacy issues accounted for 54.3% of respiratory drug failures and 48.3% of drug candidates to treat central nervous system diseases.
- Cardiovascular drugs experienced the highest prevalence of commercial failures (46.7%) among all classes of compounds analyzed.

The study, based on investigational drugs in the pipelines of the top 50 firms in terms of pharmaceutical sales, examined the development histories of 812 compounds, which had 1,369 failed indications, and established reasons for failure by clinical phase for 410 of these compounds and 659 indications.

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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