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Clinical Success Rates for New Cancer Drugs Doubled from the Mid-1990s to Early-2000s, According to the Tufts Center for the Study of Drug Development

BOSTON – May 7, 2013 – Clinical success rates for new cancer drugs doubled between the mid-1990s to the early 2000s, while the number of new cancer drugs entering clinical testing increased 50 percent during the same time, according to an analysis recently completed by the Tufts Center for the Study of Drug Development.

Clinical success rates—which reflect the share of investigational new compounds entering clinical testing that eventually obtain marketing approval from the U.S. Food and Drug Administration—rose from 9.9 percent in the mid-1990s to 19.8 percent in the early-2000s, the study found.

The clinical success rate for new cancer drugs entering clinical testing over the entire study period was 13 percent.

"That success rates increased during the 12 years we examined suggests, while drug development remains highly complex, drug companies are making headway in improving the development process," said Joseph A. DiMasi, Tufts CSDD director of economic analysis, who served as principal investigator on the study.

He added, "Lower transition rates between Phase I and Phase II studies, and between Phase II and Phase III studies, suggest that early termination of less promising candidates early on helps improve later transition rates."

DiMasi said a similar study he previously conducted found that, for the top 50 drug companies, clinical approval success rates for self-originated compounds across all therapeutic areas that entered clinical study during the same period ranged from 14 percent to 18 percent.

Study results, reported in the May/June Tufts CSDD Impact Report released today, also found that:

- The total number of new cancer compounds that first entered clinical testing increased from 250 in 1993-98 to 375 in 1999-04.
- The number of new biologics entering clinical testing grew by 59% between 1993-98 and 1999-04, compared to 47% for small molecule drugs during the same period.
- Transition rates differed most for Phase II. Only one-third of the biologics tested in Phase II transitioned to Phase III, compared to 45% for small molecule drugs.

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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