



Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Tufts CSDD quantifies savings from boosting new drug R&D efficiency

Increasing success rates can reduce R&D outlays by up to \$242 million

- More productive discovery programs or better preclinical screens that boost clinical success rates from one in five to one in three would reduce capitalized total cost per approved drug \$221 million to \$242 million.
- Shifting 5% of all clinical failures from Phase III/regulatory review to Phase I would reduce out-of-pocket clinical costs by up to \$20 million.
- Cutting development and regulatory review times by 25% will lower total costs by \$129 million.
- Firms can achieve a \$200 million reduction in total development costs by reducing phase times by 41%, or by increasing clinical success rates from the current value of 21.5% to approximately 31%.

Faster development times, quicker decisions to terminate unsuccessful compounds, and higher success rates, would enable drug firms to reap substantial savings in the cost of new drug development. Tufts Center for the Study of Drug Development (CSDD) recently reported that it costs \$802 million, on average, to develop and win market approval for a new drug in the United States. A new Tufts CSDD analysis, summarized in this *Impact Report*, quantifies the savings that could be realized by improving the efficiency of the drug development process, and represents the most accurate assessment of potential savings currently available.

While overall industry clinical success rates have remained stable since the 1970s, the industry has made improvements in the timing of decisions to terminate research on drugs that will fail. But, clearly, there are greater gains to be made. Whether those savings ultimately derive from public policy initiatives, better management, or new technologies, the impact on R&D costs can be substantial. Ultimately the increased efficiency could result in more innovation and new therapies reaching patients sooner.

Faster development and regulatory review times reduce capitalized costs

Decreases in Capitalized Cost per Approved New Drug from Shorter Development and Review Times

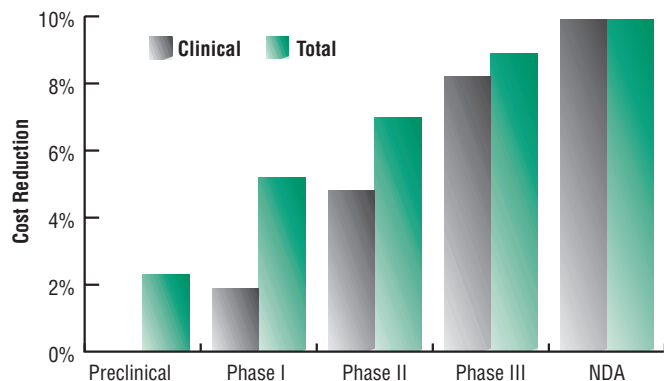
Reduction in phase length	REDUCTION IN COST				
	Pre-clinical	Phase I	Phase II	Phase III	Reg. Review
10%	1.0%	0.6%	1.6%	2.3%	1.6%
20%	2.0%	1.1%	3.1%	4.6%	3.1%
30%	2.9%	1.7%	4.6%	6.9%	4.6%
40%	3.8%	2.2%	6.1%	9.0%	6.1%
50%	4.7%	2.7%	7.5%	11.2%	7.6%

Source: Tufts Center for the Study of Drug Development

- Capitalized costs per approved new drug fall, with increasing percentage reductions in each phase, as phase lengths are reduced.
- A reduction in the length of one phase will reduce capitalized costs for earlier phases.
- At base case values, total capitalized costs decline in absolute terms from a low of \$2.4 million for a 5% reduction in Phase I time to a high of \$89.8 million for a 50% reduction in Phase III time.

Reducing the preclinical period by one year cuts capitalized costs by \$18.4 million

Clinical and Total Cost Reductions from a One-Year Reduction in Phase Time



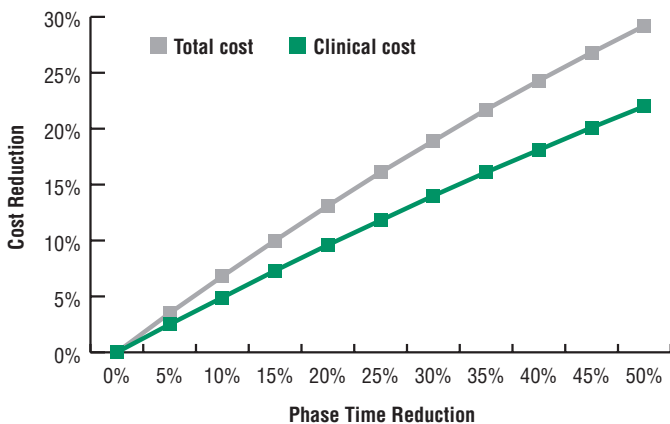
Note: Phase time counted as the time from the beginning of one phase to the start of the next phase.

Source: Tufts Center for the Study of Drug Development

- A one-year reduction in the preclinical period will result in a \$18.4 million decline in total capitalized cost per approved new drug.
- Cutting one year from Phase III will save an average of \$71.4 million from the total cost.
- Cost reductions increase with phase because a time reduction in one phase reduces time costs for that phase and all earlier phases.

Cutting development and regulatory review times by 25% will lower total costs by \$129 million

Capitalized Clinical and Total Cost Reductions from Simultaneous Reductions in all Phase Times

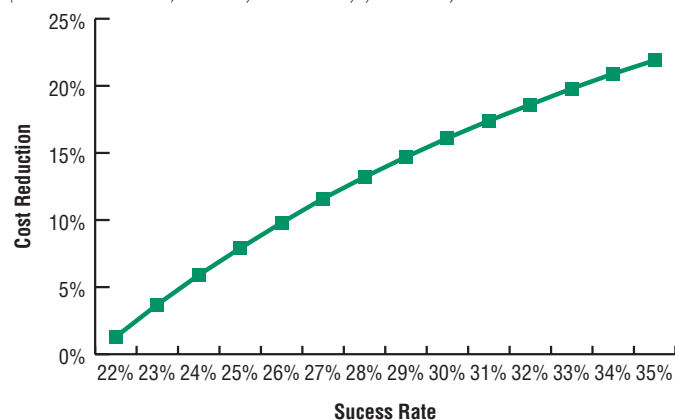


- The \$129 million savings in average capitalized cost per approved drug equals 16% of the approximately \$802 million in R&D costs to bring a new prescription drug to market.
- A 33% reduction in development and regulatory review time (four years) will decrease average capitalized cost per approved new drug \$167 million (21%).
- Reducing development and regulatory review time by 50% (six years) will lower total average capitalized cost per approved new drug \$235 million (29%).

Increasing success rates to 1 in 3 can reduce R&D expenditures by up to \$242 million

Out-of-Pocket Clinical Cost Reductions from Increases in the Clinical Success Rate

(Phase cost-adjusted for cost of failures)



Source: Tufts Center for the Study of Drug Development

- Improving discovery program productivity or using better preclinical screens to increase success rates from the current 21.5% to one in three, could reduce capitalized total cost per approved drug \$221 million to \$242 million.
- The same improved success rate reduces out-of-pocket clinical cost per approved drug \$57 million to \$71 million...
- ...and reduces capitalized clinical costs per approved drug \$103 million to \$123 million.

Earlier termination decisions can also significantly reduce clinical costs

Decreases in Out-of-Pocket and Capitalized Clinical Cost per Approved New Drug from Shifting Failures from Phase II to Phase I

% of investigational drugs shifted to earlier failure	REDUCTION IN CLINICAL COST			
	Out-of-pocket	Capitalized	Out-of-pocket (Adjusted for different costs for failures)	Capitalized
5%	1.5%	1.6%	0.9%	0.9%
10%	3.0%	3.2%	1.8%	1.9%
15%	4.6%	4.9%	2.6%	2.8%
20%	6.1%	6.5%	3.5%	3.8%
25%	7.6%	8.1%	4.4%	4.7%

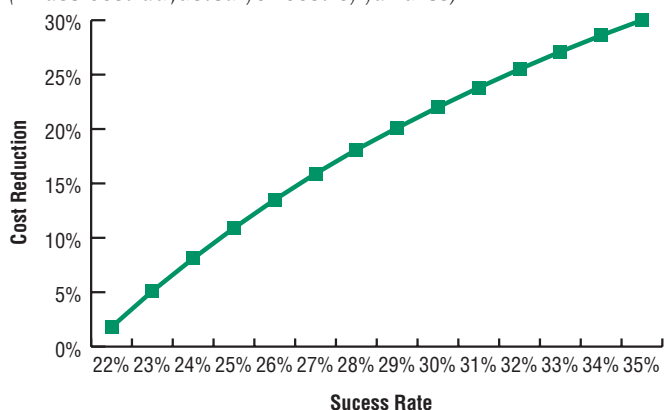
Source: Tufts Center for the Study of Drug Development

- Shifting 5% of all clinical failures from Phase III/regulatory review to Phase I:
 - Reduces out-of-pocket clinical costs by \$15.5 million to \$20.0 million.
 - Lowers capitalized clinical cost \$23.8 million to \$29.4 million.
- If one-quarter of all failures are shifted from Phase II to Phase I, then out-of-pocket clinical costs per approved drug will be reduced \$12.4 million to \$21.4 million.
 - On a capitalized basis, a one-quarter shift would lower costs \$21.9 million to \$37.8 million.

Study's data can help determine times and success rates needed to yield cost savings

Total Capitalized Cost Reductions from Increases in the Clinical Success Rate

(Phase cost-adjusted for cost of failures)



Source: Tufts Center for the Study of Drug Development

- The findings of the Tufts CSDD study reported here can be used to determine the reductions in time and increases in success rates that are needed to yield a given reduction in cost.
 - For example, a \$100 million reduction in total capitalized cost per approved drug can be achieved by either an 18.9% decrease in all phase lengths or an increase in the clinical success rate from 21.5% to between 25.2% and 25.6%.
 - Similarly, reducing phase times by 41.3% or increasing the clinical success rate to between 30.4% and 31.7% will yield a \$200 million cost reduction, about one-quarter of the total average cost of developing a new drug.

About the study

The study reported here, authored by Joseph A. DiMasi, Ph.D., Director of Economic Analysis at the Tufts Center for the Study of Drug Development, is scheduled to be published in *PharmacoEconomics* during the fall of 2002. It uses results from a recent Tufts Center for the Study of Drug Development study of R&D costs for new drugs as a benchmark against which improvements in the discovery and development processes are simulated.

The benchmark R&D cost study used project-level financial data on a randomly selected set of 68 new drugs that 10 pharmaceutical firms had first tested in humans anywhere in the world from 1983 to 1994 and aggregate annual expenditure data by development period to estimate the average R&D cost per approved new drug. The R&D expenditure information was obtained through a survey. The estimates were also dependent on development timelines, estimated phase attrition rates, and overall clinical approval success rates. Out-of-pocket costs were capitalized to the point of marketing approval according to a development timeline for a representative drug. Included in these estimates are the costs of failures (i.e., drugs that are tested but abandoned at some point in development or regulatory review). All costs were expressed in constant (2000) dollars, and a real discount rate of 11% was used to determine opportunity costs.

Definition of terms

IND — Investigational new drug application. Notification by a drug sponsor to the U.S. Food and Drug Administration (FDA) of its intent to conduct clinical studies on human subjects.

Clinical Phase I — Human studies typically done on a small number of healthy volunteers to determine the pharmacokinetic and pharmacodynamic properties of a drug and its safe dosage range.

Clinical Phase II — Controlled studies in a small number of patients to establish safety and effectiveness.

Clinical Phase III — Large, controlled human trials to confirm a drug's safety, efficacy, and optimal dosage range for treating the targeted indication.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

Tufts Center for the Study of Drug Development
Tufts University
192 South Street, Suite 550
Boston, MA 02111 USA

Tel 617-636-2170
Fax 617-636-2425
Email csdd@tufts.edu
Web <http://csdd.tufts.edu>

Impact Reports are published by the Tufts Center for the Study of Drug Development six times a year; Kenneth I. Kaitin, Ph.D., editor. An annual subscription is \$395 (\$445 outside USA), or \$195 (\$245 outside USA) for government, academic, and non-profit organizations. Subscriptions include the Tufts CSDD *Outlook Report*, mailed in January. ISSN 1535-2374

© 2002 Tufts Center for the Study of Drug Development. All rights reserved.