Research and Development Costs for New Drugs by Therapeutic Category
A Study of the US Pharmaceutical Industry

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Summary

The clinical period (i.e. clinical trial and long term animal testing) development costs of a random sample of new chemical entities (NCEs) were examined for differences in average cost. All of the NCEs studied were first tested in humans between 1970 and 1982, and were classified for the purposes of the study by therapeutic class. The costs of unsuccessful projects were included with those of projects that resulted in US marketing approval.

Including income forgone from expending funds before returns are earned ('time costs'), the capitalised (i.e. out-of-pocket plus time) clinical period costs per approved NCE were $US70, $US98, $US103 and $US163 million (1993 dollars) for anti-infective, cardiovascular, neuropharmacological and nonsteroidal anti-inflammatory drugs, respectively. Combining the data for all therapeutic categories, the mean clinical period cost per approved NCE was $US93 million.

Omitting costs associated with unsuccessful projects, the mean capitalised clinical period costs for approved NCEs ranged from $US7.1 million (for topical steroids) to $US66.7 million (for cardiovascular agents) [1993 dollars].

The estimates of total clinical period costs per approved NCE depend on average out-of-pocket clinical phase costs, attrition rates across phases (i.e. the rates at which compounds drop out of active testing), the probability of marketing approval, and development and regulatory review times. Phase attrition and approval rates are the most important sources of variability in total clinical period costs between therapeutic categories.

Development cost estimates by therapeutic category did not correlate strongly with US sales in the fifth year of marketing. Cardiovascular NCEs had much higher than average sales revenues, but clinical development costs for these drugs were only slightly above average. Conversely, nonsteroidal anti-inflammatory drugs attained average sales revenues, but had much higher than average development costs.

Growing concern over escalating pharmacy budgets of national healthcare authorities and managed care providers has led to pressures on pharmaceutical firms to offer cost-effective therapies. Regardless of whether or how healthcare reform in the US develops, the pharmaceutical industry will continue to face a marketplace where cost containment is a critical element. As a result of these de-
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developments and of rapidly rising research and development (R&D) costs for new drugs,[1] pharmaceutical firms have paid increasing attention in recent years to improving the drug development process.

Although a given firm can examine its own development costs, it cannot know how its experience compares with that of the industry as a whole unless a third party provides that information. Elsewhere,[1] we have estimated the average cost of getting a new drug approved in the US and compared the results with those of another study that covered an earlier time period.[2] The development costs for individual drugs were, however, found to be highly variable. Part of that variability may be associated with the therapeutic category to which the drugs belong. In this study, we examine that issue in detail by providing estimates of the clinical costs of developing drugs in several therapeutic classes.

In addition to providing development cost benchmarks, the results of our study can serve as inputs for analyses of the profitability of drug development in various therapeutic programmes. These analyses, in turn, could be useful in developing insights into the R&D budget process for individual firms and for the pharmaceutical industry as a whole. Specifically, they may help us to learn more about how sensitive budgetary allocation decisions are to economic factors.

Methods

In estimating new drug development costs, we treated drug development as an investment with potential future returns. We also fully recognised the substantial risks in new drug development by including the costs of research failures along with the costs of the successes (drugs that eventually reach the marketplace). With the exception of anti-infective drugs, no data on preclinical period (time from drug synthesis to first testing in humans) expenditures were available, so most of our analysis was restricted to development that occurs after clinical testing has begun.

The basic methodology that we used to calculate clinical period costs (that is, the costs of clinical trial and long term animal testing) is described in detail elsewhere.[1] An overview of the data, how component cost estimates are derived and how these estimates are used to construct full development cost estimates is presented here.

Data

We obtained data on the cost and timing of development for a stratified (according to time in testing and regulatory fate) random sample of 93 new chemical entities (NCEs) first tested in humans in any country sometime between 1970 and 1982. The NCEs belonged to 3 broad and 1 very specific therapeutic categories: anti-infectives, cardiovascular agents, neuropharmacological and nonsteroidal anti-inflammatory drugs (NSAIDs). The data were taken from a confidential survey of 12 US-owned pharmaceutical firms. The sample includes NCEs that the firms abandoned without obtaining US marketing approval as well as NCEs that were approved. The full R&D costs for licensed or acquired NCEs are not reflected in the R&D budgets of the firms that acquired them, making it difficult to track those costs. Therefore, we restricted our analysis to self-originated NCEs (i.e. NCEs discovered and developed by one of the survey firms).

The sample was selected from a Tufts Center for the Study of Drug Development (CSDD) database on NCEs tested clinically in any country by US pharmaceutical firms. The CSDD obtains its information from a triennial survey of US pharmaceutical firms. Using this database, we were able to select a random sample of NCEs that met our inclusion criteria (i.e. self-originated and first tested in humans between 1970 and 1982) and were developed by firms that agreed to participate in our cost survey. Thus, no firm could pre-select drugs on which to report costs.

The surveyed firms provided clinical testing phase start and finish dates, clinical phase costs by year, animal testing costs incurred during the clinical testing period by year, and the date that testing