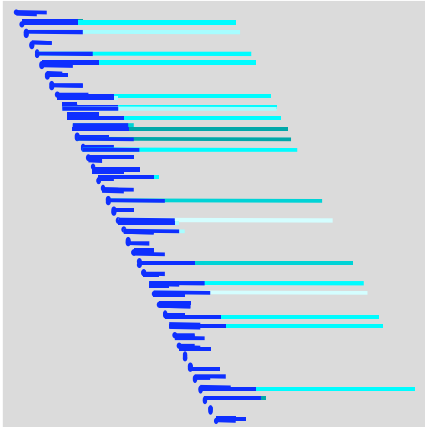


A Life-Cycle Financial Model of Pharmaceutical R&D

Synterein works with MIT Sloan School of Management to revise and validate a model of new drug development profitability



Drug companies develop new drugs. That much is obvious. What may not be obvious, however, is which drug candidates are worth funding their development. Even less obvious, even to the pharmaceutical companies, is which drugs will be a commercial success. This makes the determination of drug development cost and profitability uncertain and difficult. In order to shed light on this problem, Sloan School of Management faculty and researchers developed a stochastic model of drug development costs and revenue as part of the Program on the Pharmaceutical Industry at MIT. The model sought to illustrate how investors required rates of return varied over the life-cycle and to explore the validity of various measure of profitability for the pharmaceutical industry¹. This model was subsequently used at Harvard to investigate the affect of various accounting practices on these measures of profitability².

¹ Myers, S. C. and C. D. Howe, 1997, A life-cycle financial model of pharmaceutical R&D, *Program on the Pharmaceutical Industry* (MIT).

² Healy, P. M., S. C. Myers and C. D. Howe, 2002, R&D accounting and the tradeoff between relevance and objectivity, *Journal of Accounting Research*.

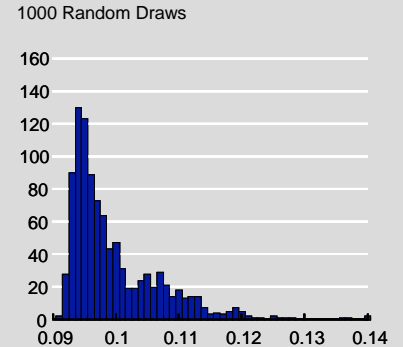
MIT Sloan School of Management engaged Synterein to revise and validate the model to incorporate new drug development cost figures³.

The model begins with setup and ongoing costs of a research program. The program discovers zero, one or more candidates each year. Candidates may survive pre-clinical, phase I, II and III clinical trials, and FDA filing and lead to the launch of a new drug. The resulting drug falls randomly into one of five drug commercial success categories, suffers randomly from competition, and rapidly fails to produce revenue once its patent expires.

The model is implemented by randomly drawing four drug candidates for each of 40 program years to provide one realization of the program. The process is repeated over many draws to generate distributions of cost of capital, financial accounting entries, and profitability measures.

Validation of the model implementation and structural changes to accommodate a reduced FDA filing period occupied the majority of the 136 hour project. Results of the simulation, planned for publication by Sloan, will guide researcher and regulators when considering the pharmaceutical industry.

Cost of Capital Distribution



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Pre-Launch Model Structure

	Year: 1	2	5	6	8	11
Original Model	Discovery Research	Pre-Clinical Testing	Phase I Clinical Trials	Phase II Clinical Trials	Phase III Clinical Trials	FDA Filing
Revised Model	Discovery Research	Pre-Clinical Testing	Phase I Clinical Trials	Phase II Clinical Trials	Phase III Clinical Trials	FDA Filing
Duration	1 year	3 years	1 year	2 years	3 years	3 years 2 years
Success probability	60%*	90%*	75% 71%	50% 44%	85%	75% 80%
Total expenditures per drug	2.2 M\$ 3.6 M\$	13.8 M\$ 22.4 M\$	2.8 M\$ 15.2 M\$	6.4 M\$ 23.5 M\$	18.1 M\$ 81.8 M\$	3.3 M\$

*Increased to offset corresponding decrease in number of drug candidates simulated

³ DiMasi, J. A., R. W. Hansen and H. G. Grabowski, 2002, The price of innovation: New estimates of drug development costs, *Center for the Study of Drug Development* (Tufts).