Pharmaceutical Clinical Trial Planning under Uncertainty

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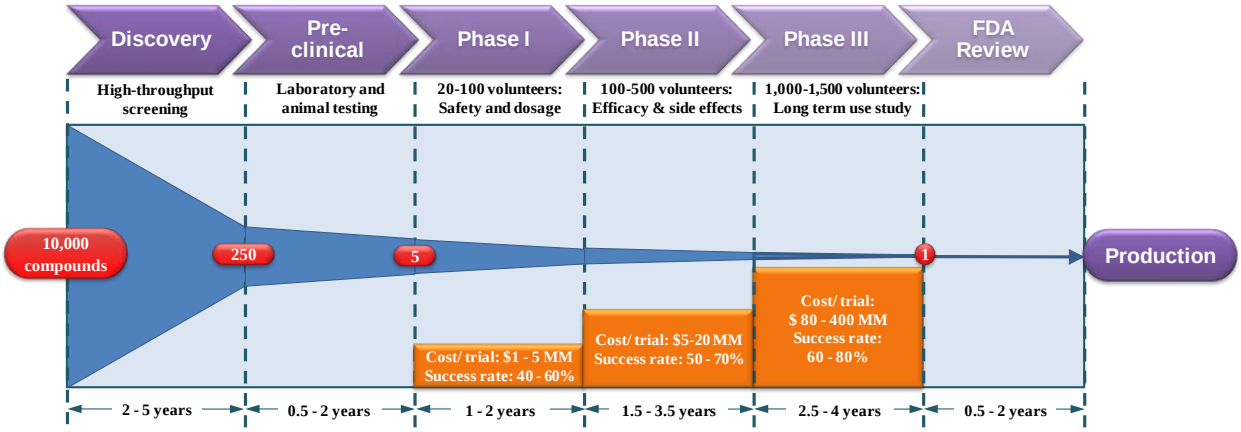
The development of new pharmaceuticals is a long and expensive process. It takes an average of 15 years for a new drug to move from the discovery into the marketplace, and the average cost for the development of a new drug is more than $900 million. Out of 5,000 compounds that emerge from discovery, only five perform well enough to move into human testing, and only one of these five compounds is approved by the Food and Drug Administration (FDA). At the same time, due to changing circumstances in the managed-health-care environment, the profit margins of US pharmaceutical companies and the productivity of their Research and Development (R&D) pipelines (in terms of new entities registered per dollar of investment) have started to decline; effective patent lives have been shortened, and patents provide lower barriers to entry even while active. Therefore, it is imperative for pharmaceutical companies to manage their R&D pipelines more effectively to reduce the cost of developing new drugs. This is a challenging task due to the highly stochastic nature of the R&D process: if a drug fails a clinical trial, its development stops and all prior investment is lost; if it passes all trials, it enters the marketplace and profits are typically significantly larger than development costs.



To address this problem, we will develop a multi-stage stochastic programming strategy that accounts simultaneously for the selection of drugs, the scheduling of clinical trials, and the resource planning and out-licensing decisions. We will also develop new theoretical results and solution methods to solve large-scale instances. The planning of R&D activities falls into a broader class of less-studied optimization problems, namely, stochastic optimization problems under endogenous observation of uncertainty. The challenge in addressing these problems is due to the fact that the decision-maker alters the underlying stochastic process by changing the timing of uncertainty observation. We study this class of problems and generalize the results and solution methods we developed for R&D pipeline planning.