Case Study

Portfolio Prioritization

Project Objective

The project objective was to identify which candidate drug, among six in the customer's clinical development pipeline, would offer the greatest long-term health outcomes and costs benefits.

Introduction

Selection of a pre-clinical drug candidate for advancement to clinical trials is a critical decision. Large clinical trials often require years of observation and cost millions of dollars. When a clinical trial runs over schedule, drug developers can lose over $600,000 a day in sales for smaller niche products and over $8,000,000 a day for blockbuster drugs. Adding to this problem, the average cost of running clinical trials has increased substantially. The cost of a typical 400 person clinical trial can easily run over $10,000,000.

Thus, when a company has several candidate treatments for a given disease in its pipeline, choosing the correct one to advance to clinical trials must be done with vision and care. Which drug(s) are most worthy of the expense and time involved with performing the clinical trials needed to successfully pave the way to approval? Which drug will lead to improved patient outcomes, reduced costs of disease treatment and greatest return on investment?

Not only is selecting the right drug candidate crucial, but also selecting the optimal recipient population can be equally important. Determining if there is a sub-population in which efficacy is enhanced can lead to substantial savings in time and money and considerable improvements in outcomes.

With the success or failure of a single drug intricately connected to entire clinical development programs, predicting the best pipeline candidate and selecting the optimal population is a dual-pronged approach that enhances the rates of success while mitigating the risks of failure. Preclinical studies can give part of the predictive picture; the Archimedes Model can provide the rest.

Project Approach/Methodology

Archimedes created a simulated population of 50,000 people representative of the U.S. population, and explored the effectiveness of each of 6 candidate compounds with 3 control arms over the course of 10 simulated years. The efficacy of each candidate compound was specified according to its effect on several cardiovascular and metabolic biomarkers such as LDL, HDL, fasting plasma glucose, and a variety of others. Sub-populations, including patients with different metabolic syndrome phenotypes, those with diabetes, cardiovascular disease, and those already taking a variety of interventions, as well as those that had failed other interventions were explored as candidates for the compounds. The long-term effects of treatment on biomarker changes, health outcomes (myocardial infarction, stroke, diabetes, and diabetes complications), and cost-effectiveness were evaluated.

"This gave us more information in the drug development process to estimate which profile might provide the best patient outcomes.

The Archimedes Model allowed us to compare the relative merits of several different target product profiles prior to performing expensive clinical trials."

Principal Research Scientist
Project Sponsor