ARCHIMEDES
Quantifying Healthcare

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**

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## Quick Facts

- **Number of drugs competing for pipeline slot: 6**
- **Number of diseases drugs were candidates for treating: 3 (MI, Stroke, DM)**
- **Percentage of people potentially affected: Up to 35% of all U.S. adults**
- **Number of virtual people simulated: 50,000**
- **Simulated Duration: 10 years with annual results**
- **Number of interventions used: 6 treatment arms and 3 control arms**

## Outcomes/Conclusions

The Archimedes Model predicted and differentiated between the candidate compound interventions in terms of health outcomes, costs, and quality of life over the 10 year simulation.

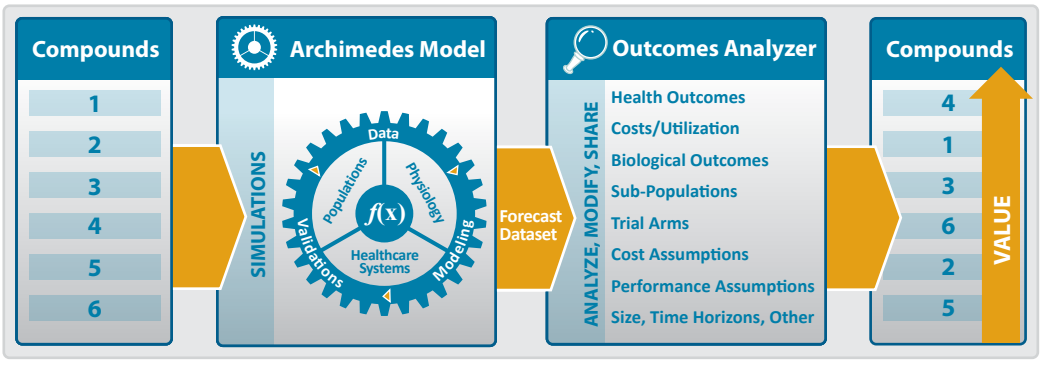
**Several notable predictions included:**

- The identification of two candidate compounds with the most significant effects on lipid biomarkers, and the identification of candidate compounds with the greatest reduction of diabetes incidence.
- The annual effects of each candidate compound on:
  - i. Myocardial infarction (MI)
  - ii. Stroke
  - iii. New diagnosis of diabetes mellitus (DM)
  - iv. Diabetes complications
- The overall effectiveness of each candidate compound on MI, diabetes and its complications.
- Price-point explorations and cost-effectiveness of each candidate compound in the general population and in sub-populations.

An interesting expansion of the work already done would be the identification of a target sub-population for which a significant new "window of opportunity" for treatment exists.

## Business improvements

- Clinical trials of 10 years duration involving 50,000 patients are prohibitively expensive. The Archimedes Model offers a way to anticipate outcomes that would otherwise be resource intensive, or simply impossible to perform in the real world.
- Predicting the long-term health and cost outcomes for each candidate from a pipeline of preclinical compounds is a high-value, low-cost means of choosing the right ones to advance to clinical trials.
- Simulated trials of this sort offer powerful means of exploring variations not only of candidate compounds, but of recipient populations and sub-populations in which the effects may be different.





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