

Clinical Trial Site Selection and Maximizing Patient Enrollment

Vertical

Manufacturing **Pharmaceutical** Healthcare Portfolio Logistics Financial Government Business

Genre

Case Study **Project Review** White Paper Technology Overview

Client

Large Pharmaceutical Firm

Situation

Over the past several years a Large Pharmaceutical Company's Clinical Research Department was facing unacceptable increases in costs and delays in conducting their Clinical Trials.

- More than 70% of their clinical trials were late.
- Delays were attributed to difficulty in predicting and recruiting patients.
- Delays were costing greater than \$30,000 per day.

To help better plan for the future, Clinical Research needed an improved methodology for projecting the required number of sites, start up timing, and patient randomization to reach trial milestones. Without an accurate predictive solution, the company was more vulnerable to:

- Hard to fill shortages in patient recruiting after the trial began.
- Exorbitant costs of adding sites to increase recruitment beyond the original plan.
- Unacceptable delays in LSLV, Study Close Out, or Completion.

Objectives

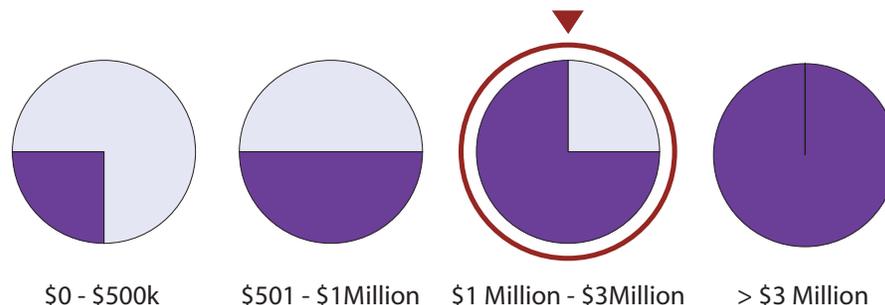
Develop a predictive solution to:

- Accurately forecast the optimal number of sites, their locations, and the timing that would be required in order to plan a study which meets all milestone requirements and closes out on schedule.
- Rapidly model different scenarios after the trial was underway, including the ability to analyze the impact and cost of adding sites beyond the original planned protocol.

Results

- For the first time, the client had the ability to accurately forecast Site and Patient recruitment for several very difficult trials in their portfolio.
- Aided in preemptively redesigning the protocol recruitment plan to reset and then meet their milestone goals.
- Client confidence improved as the changes were tested and results showed no projected delays due to a shortage of patients.
- Created a better understanding of the differences in patient recruitment profiles by Therapeutic Area (TA).
- Avoided a large unnecessary expenditure attempting to follow an unachievable plan.

Cost Avoidance

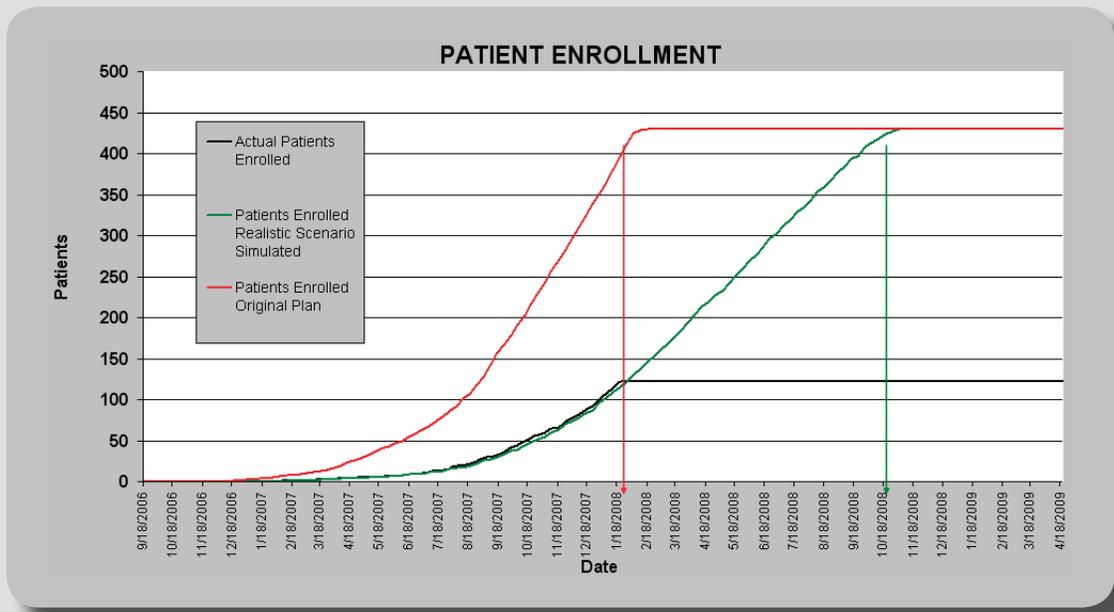


Solution

The client's project team, working with ProModel, used ProModel's Clinical Trials Simulator solution to help achieve the results stated above.

- First, they captured all the variability and resource interdependencies in their process and protocol.
- Next, they used Clinical Trials Simulator to robustly simulate the site and patient recruitment under base protocol conditions and then subsequently simulated many alternative plans.
- Finally, they identified and selected the parameters which allowed them to mitigate their risk in setting and meeting their Trial Milestones.

The solution was validated to be 90% accurate when compared to actual historical recruitment performance.



Sample Patient Enrollment Clinical Trials Simulator Output Report

The results of the simulation solution can be displayed in a variety of visual and meaningful ways. The above chart, just one of many possible output display selections from this solution, shows dynamic patient recruitment of the simulated original protocol plan versus the actual and simulated realistic recruitment plan.

As can be seen, if the solution had been used in the beginning, the company would not have been under the impression that they could achieve the unrealistic recruitment in RED.

Since they began using the Clinical Trials Simulation solution after the start of this trial, the best thing that could be done was to realistically project the real outcome from that point forward and adjust the plan accordingly.