

We have shared our exact assumptions, the reasoning behind them as the full analysis with the client.
This document is for illustrative purposes only

Highly sophisticated Monte Carlo simulation: aggressive pressure testing

The task

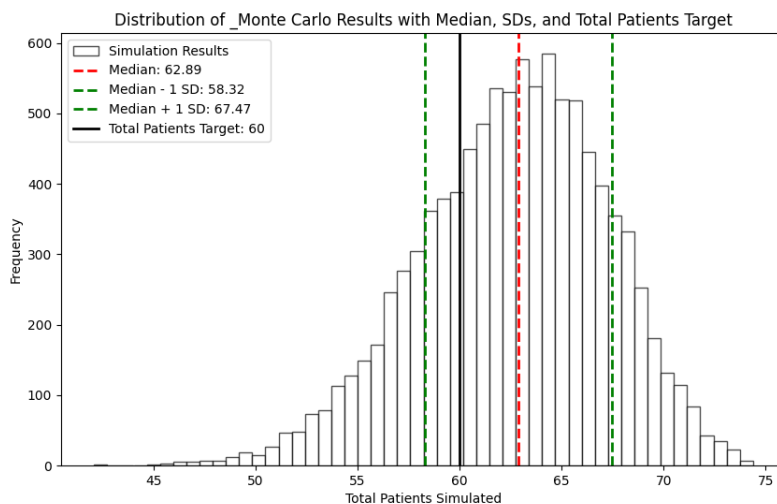
This goal of this analysis was to pressure-test conflicting assumptions submitted by vendors and provide clarity of which one submitted the most viable and realistic strategy. There are main factors that create bias when it comes to overoptimistic planning- CROs are highly incentivized overpromise, even if data shows reasons for concern; time and resources are limited considering the scale they work on; usually the structure creates a divide between the different teams and custom models are almost impossible to implement in the timeframe to proposal delivery.

Our goal for this project was to help the client navigate the complexities of 3 separate and very distinct proposals, and to choose the best one for their financial and operational situation

The presented version of Monte Carlo simulation is currently unparalleled in a market dominated by institutional inertia. On one hand each parameter is individually tailored and adjusted to reflect the protocol specifics by domain experts; on the other- the model itself includes factors that reflect real-life factors that influence trial execution and larger vendors fail to account for

In this specific case, the main difference between the proposals was the enrollment rate that could be achieved which of course affected the assumed enrollment duration. In addition, there were conflicting opinions whether the usage of a specific treatment (exclusion criteria under the current protocol) would present a significant risk to the success of the study. The client presented results from a blinded outreach. After reviewing the available data, protocol, competitive and regulatory landscape in the targeted geographies, as well as historical performance, we ran 10 000 simulations on all 3 strategies.

Below are presented the results of the simulation on the best performing strategy



- Target patients: 60
- Median simulated result: 62.89
- Performance delta: +2.89 patients (~ 4.8% above target)
- Median - 1 SD (58.32): High probability (~ 84%) of achieving core study objectives.
- Median + 1 SD (67.47): Represents the potential optimization when agile site management is executed perfectly.

The simulation confirms that the selected vendor's plan is the most realistic. The median result sitting just above the target indicates a model that respects the constraints of the current landscape and is a product of honest and realistic assessment rather than corporate optimism. Moreover, what we would reasonably expect based on the model is that, even if unforeseen factors delay the enrollment, it will be minor compared to the other proposed strategies- our calculations suggest up to 2.5 months, which corresponds to approximately 15% of the total timeline.