REMARQUE SYSTEMS SM

Predicting Dropout Rates in DCTs

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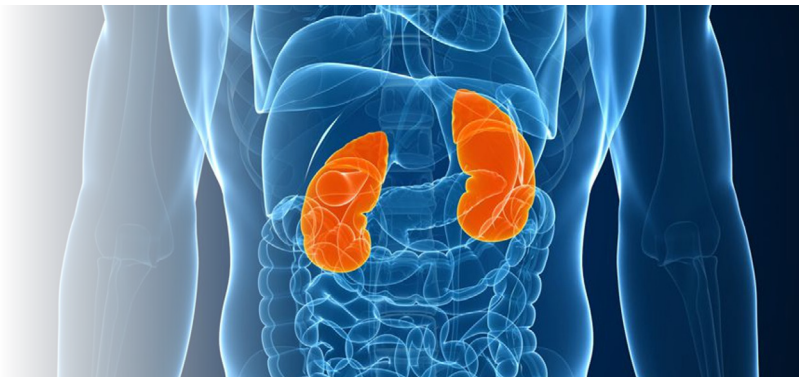
In phase 3 trials, the stakes are high. Not only do sponsors need to prove safety and efficacy, but they need to have a sufficiently robust study population for their outcomes to be statistically significant. Enrollment is important; retention is essential; decentralized trials (DCTs) may add complexity due to the lack of interaction between patient and trial personnel.

Our client was in the midst of a phase 3 trial for their lead drug, with 1350 patients at 250 sites across the United States. They came to us asking for help identifying those patients most in danger of discontinuing, so our client could take action to retain those at risk—attaining a high subject retention rate and reaping all the downstream benefits of low subject discontinuations.

CUSTOMER INTRODUCTION

Our client, an innovative clinical-stage biotherapeutic company, develops medicines for orphan diseases of the kidney.



THE CHALLENGE

The best way to bolster retention is to address patient concerns before they become real issues. Yet, that requires understanding exactly which patients are at risk for dropout and why. Asking them is unlikely to produce actionable information; patients who indicate they are considering discontinuation are likely to have already decided. The challenge is to have that critical insight soon enough to be actionable.

THE APPROACH

Our solution: Bring all the study data into a single platform, then apply predictive modeling to search the data based on pre-defined metrics and rank each patient on a range from 0% to 100% risk of discontinuation.

We began with a thorough literature review of two previous clinical trials studying similar therapeutic interventions in the same therapeutic area. Next, we identified key reasons for discontinuation, including adverse events (AEs) and disease progression, age, gender, and baseline renal function.

We then built machine learning algorithms to scan site- and subject-level data to:

- Flag any patient at risk based on specific factors
- Develop a scoring algorithm for risk of discontinuation based on those metrics, and calculate individual patient scores
- Develop a prediction model including site-specific demographics and subject-level data

The major hurdle in developing a prediction model is curating the data in a standard way. Because Remarque is source-agnostic, we could pull data from across all inputs—including the ePRO entries essential in DCTs—then run searches across the data against specific potential outcomes, such as the likelihood of discontinuation.

THE RESULTS

Our strategy enabled the client to identify specific patients at risk of discontinuation—and information on why each of those patients is at risk. Our client was then able to engage in targeted activities to optimize retention.