

INDUSTRY VALUE CHAIN STRATEGIES

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Case Study: Visualizing Clinical Trial Demand

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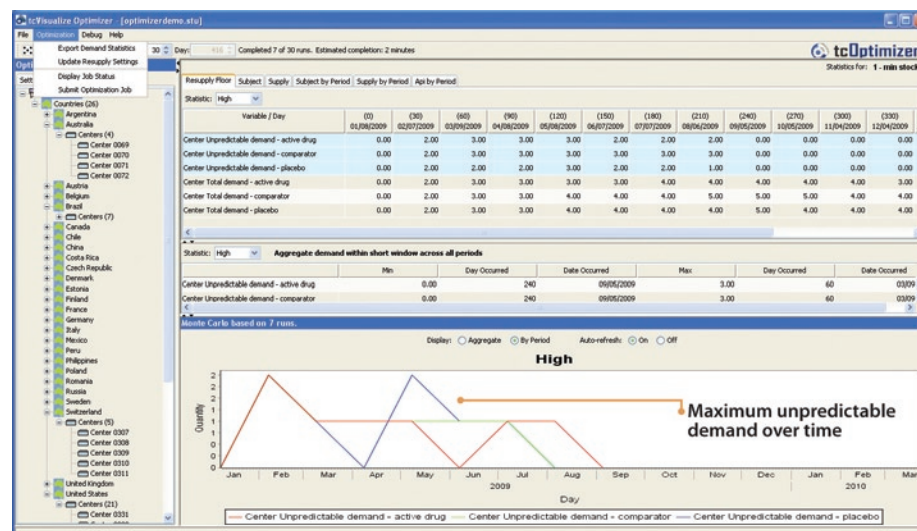
Demand-planning practices for clinical supply chains aren't healthy. Only 34% of the 107 pharmaceutical and biotech companies AMR Research studied recently forecast demand on more than a monthly basis, with most companies refreshing forecasts on a semi-annual or annual basis.

Regardless of frequency, most of these manufacturers still forecast demand using baseline, deterministic estimates of investigator site enrollment. It's therefore no surprise that the same companies reported demand forecast errors of 40% to 50% for their Phase II and Phase III clinical trials. To compensate for this poor accuracy, clinical trial managers add multiples of the baseline estimate to the forecast, with overages ranging from one to three times. These less-than-robust demand-forecasting capabilities often result in stockouts, higher prices for expedited remediation activities, increased inventories and safety stocks, and increased costs driven by excess waste in clinical trial supply over time.

Visualizing clinical trial demand

Despite the prevalence of such basic demand-planning practices, there are some companies that have developed more sophisticated, stochastic demand-modeling and simulation capabilities. This is where **Tourtellotte Solutions'** tcVisualize and its companion tcOptimizer applications shine. tcVisualize provides users the capability to simulate and model demand at individual investigator sites for a specific protocol over an extended period of time. tcOptimizer complements the demand simulator by modeling and recommending inventory and safety stock at both the country-depot and investigator-site level (see Figure 1).

Figure 1: tcOptimizer screenshot



Source: Tourtellotte Solutions, 2009

These applications feature the following capabilities:

- Monte Carlo statistical simulations of all patient and supply chain details, with advanced reporting to the subject, kit, or kit-component level
- Support for complex visit schedules and variable dosing designs, as well as fine-grained enrollment and site startup rates
- Predictive algorithms and a site buffer stock optimizer for establishment of depot and site inventory levels by country and site, including pooled drug supply across protocols
- Ability to import and replay actual data, compare and contrast to scenario assumptions, simulate forward from any point in a study, and simulate study changes, such as adding countries, sites, depots, or drug lots

Benefits of better demand forecasting

Better demand forecasting yields significant benefits in several areas, including supply chain visibility, fine-tuning inventory at the country and site level, minimizing the impact of supply crises, managing expiry and obsolescence costs, and reducing drug waste.

Consider these highlights we have drawn from over a dozen case studies we've reviewed:

- **Visibility**—A large pharmaceutical company's zero-tolerance policy for stockouts at investigator sites created significant drug and kit overages at all nodes of the supply chain. Through the use of tcVisualize, the company's analyses revealed that zero risk of stockouts was not realistic, and that it could manage inventory levels to ensure a very low stockout risk (however, not zero) at more than 95% confidence levels. Its mean savings from reduced inventory with this new risk tolerance was between 10% and 25% per trial.

- **Reducing drug waste**—A small biotech company was planning a relatively straightforward trial in terms of the number of countries and investigator sites. However, the drug substance was very expensive and the company had limited capacity to produce it, with the product having a relatively short expiry period. Using Monte Carlo simulations over high and midsize enrollment scenarios, tcVisualize identified a significant amount of drug product planned for manufacture that, because of enrollment rates over investigator sites, would never have shipped from the primary depot. The reduction in projected waste alone was over \$1M, not including the opportunity costs associated with allocating precious drug substance to a trial that would not use the material.
- **Fine-tuning supply to manage expiry**—A midsize pharmaceutical company planned for a single trial with straight-line enrollment, using three lots of drug product of equivalent size. The company recognized that if enrollment was lower than expected, it would require a fourth lot of product because of lot expiry. To avoid this, it used tcVisualize to simulate various enrollment scenarios and model the corresponding drug product lots required to support enrollment over time. With this fine-tuning of drug product lot sizes, the company saved nearly \$1M, or 15% of the originally estimated cost of product supply.

Robust simulation and modeling of clinical trial site enrollment, coupled with efficient manufacturing of clinical supplies and execution of protocols, can save life sciences companies millions of dollars in new product development costs. However, achieving these benefits is not as simple as installing a software application. Companies must identify and develop the talent required to change clinical trial forecasting and management processes and instill the requisite change across the clinical trial supply chain.