



DecisionView: Taking Patient Enrollment Planning from Instinct to Insight

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IN THIS PERSPECTIVE

This Health Industry Insights Perspective examines the ongoing efforts at a global pharmaceutical company to optimize the planning and execution of patient enrollment during clinical trials. Faced with unpredictable recruitment cycle times and cost overruns resulting from inconsistent and rigid processes, the company engaged DecisionView Inc. to implement its StudyOptimizer application. Through the implementation of StudyOptimizer, the company experienced increased transparency of patient enrollment efforts, thereby empowering clinical trial study managers to better understand the underlying drivers impacting patient enrollment. StudyOptimizer's tools have helped to proactively identify problems during enrollment and determine workarounds, resulting in an increase in studies delivered on time from 33% to more than 66%. In addition, when presented with firm milestone dates early in development planning, study managers were able to objectively determine the likelihood that deadlines would be met and make adjustments to better ensure that project timelines were achievable.

This Perspective provides insights developed from direct discussions with a senior-level business process analytics manager at a major global pharmaceutical company and Gonzalo Castro, VP of product marketing at DecisionView.

Situation Overview

Gaining Control of Clinical Trial Patient Enrollment

Following an industrywide trend to improve operational efficiency and cut costs, life science companies are increasingly measuring and benchmarking processes and performance to better use both technical and operational data to improve decision making. As one of the most resource-intensive and time-consuming stages of drug development, clinical trials are coming under increased scrutiny while concurrently becoming larger, more complex, and increasingly global. As companies seek to efficiently drive clinical trials toward completion, they are looking for all opportunities to improve clinical trial processes and more effectively manage trial efforts.

As part of these efforts, a leading global pharmaceutical company examined DecisionView's StudyOptimizer solution in efforts to optimize the planning and execution of the patient enrollment process. While near-term goals focused on achieving more effective management of patient enrollment processes, the company also expected to improve trial efficiency, reduce trial execution time, and lower overall trial costs over the long term.

The Pitfalls of Patient Enrollment

Historically, the process of patient enrollment at the company has been highly subjective, with expectations for patient enrollment being largely based on prior experience and professional intuition of study managers. Insights such as how long to plan to run the trial, how many sites, how many countries, and who to select to serve as investigators to fulfill trial enrollment requirements were not thoroughly examined or validated. When fixed trial completion targets were presented, study managers did their best to attempt to meet these goals, often failing due to higher than expected screen failure rates, unforeseen delays in country or site initiation, too few sites, too few sites actually enrolling subjects, and so forth, leading to significant extensions of timelines and cost overruns.

Setting Goals and Expectations in Patient Enrollment

The core element needed to transform the planning and execution of patient enrollment was to enhance the experience of staff with the objective information and data available to them throughout the planning process. With an objective, evidence-based process in place, prior project and other organizational knowledge would be directly leveraged to better predict trial timelines and costs.

An added goal for an effective planning tool was the ability to demonstrate to senior management the basis of proposed timeline and cost expectations. With the aid of StudyOptimizer, and before the first patient is enrolled, it becomes possible to determine whether timelines and budgets are reasonable. If not, the use of the application enabled study managers to effectively push back on proposed dates and budgets and offer alternative scenarios to achieve project goals. As a result of using the StudyOptimizer product, the company has been able to double the number of clinical studies delivered to plan from 33% to 66%.

Moving Forward

The DecisionView solution continues to actively deliver value to the company today. As a result of the StudyOptimizer implementation, the number of studies recruiting to plan has doubled and overall cycle time variance has decreased. The application continues to change traditional

mindsets by providing study managers with defensible data, enabling more objective discussions of target dates and overall expectations. The company indicates that additional enhancements, such as increased automation and the ability to quickly identify fastest or lowest cost options, will increase the benefits realized from the application.

As is so often the case with ambitious initiatives, success depends upon true cultural change. While StudyOptimizer can help get the right information to the right people at the right time, if staff don't feel empowered to challenge assumptions, disagree with management, and/or offer alternative solutions, further improvement will remain elusive. That said, the StudyOptimizer solution has been a powerful catalyst for change and is helping the company to move forward toward more effective clinical trial planning and management.

Essential Guidance

With the alternative being principally an Excel spreadsheet, the DecisionView StudyOptimizer application has been an effective, paradigm-changing solution to begin to inject objectivity into the patient enrollment planning and optimization process. The tool has enabled clinical trial study managers to systematically assess patient enrollment requirements during trial planning and to better set expectations that are much more likely to be achieved during a clinical trial. When faced with hard deadlines or tight budgets, the solution enables study managers to better develop defensible trial approach options for senior management.

The StudyOptimizer approach is consistent with industrywide trends in the move toward the systematic objective approach to managing pharmaceutical development in the industry. It remains clear that this effort, as well as broader business intelligence efforts across the organization, is a core element of industry transformation and the move to operational excellence. The complexity of the clinical trial process and entrenched operational practices can be expected to slow adoption somewhat in this area; however, the change remains inevitable. It is important to build consensus and have early buy-in among stakeholders in study teams when implementing solutions that result in process changes. We expect to see continued growth of solutions in this area as well as additional solutions across both the clinical trial and the complete pharmaceutical R&D value chain.

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