



Automating Clinical Trial Enrollment

How Web-Based Predictive Modeling & Clinical Enrollment
Automation Software Can Help Clinical Trials Finish On Time



Introduction

Today's life sciences development teams face increasing pressures to meet clinical trial enrollment goals. As complex protocols, increased regulatory requirements, and a global patient population make managing clinical trials increasingly difficult, study managers struggle to finish trials on time and on budget.

Statistics show most clinical trial delays happen during enrollment:¹

- 34% of sites fail to attract a single subject
- 27% of screened subjects fail to randomize
- 76% of all Phase II & III studies are more than 90 days late

The following key factors contribute to clinical trial delays:

- *Isolated, global teams have difficulty collaborating*
- *Study teams lack a standardized approach to clinical enrollment*
- *Study managers are unable to adjust plans when enrollment veers off course*
- *Global, disparate data is difficult to gather*

Life sciences companies are well aware of these difficulties. However, few have taken steps to improve their trial enrollment processes. For example, rather than automating the enrollment process, study managers still use spreadsheets to manually plan and track enrollment. Business intelligence tools provide some reporting, but can't anticipate problems or model solutions. As a result, most study managers rely on a reactive approach that increases costs and delays completion of study enrollment. Although multiple systems capture supporting trial data, they require manual data aggregation—a time-consuming process that inhibits global collaboration and timely decision-making.

The results of these challenges? Studies show it takes \$1.7 billion to get a new drug to market.² And approximately 96% of all compounds fail to make it through the R&D process.³

This white paper explores the reasons behind clinical trial enrollment delays, and shows how web-based *predictive modeling & clinical enrollment automation software* can help to prevent these problems.

Isolated, Global Teams Have Difficulty Collaborating

Many global study teams have difficulty collaborating because they lack timely data across numerous countries and centers. Because the prevailing tools lack a shared system for tracking and monitoring progress, global clinical trials can create enormous difficulty for study teams. A lack of transparency impedes communications across multiple time zones, delays decisions, and increases enrollment and data clean-up problems. It also allows study teams to repeat costly mistakes. When study teams can't track each site's historical performance, they also can't identify top performers or weed out underperformers for future trials.

¹ Thompson Medstat Report Using Data and Metrics for Clinical Trials 2004

² Bain & Company 2002 Pharmaceutical State of the Industry

³ Tufts CSDD 1998 Impact Report

Study Managers Lack a Standardized, Accurate Approach to Planning Clinical Enrollment

Few study teams have standardized or automated clinical trial enrollment. Because the tools and activities currently used for planning, predicting, and modeling enrollment scenarios are limited and disconnected, study teams often depend on intuition, good fortune, and budget overruns to meet subject and timeline targets. In addition, processes vary from study manager to study manager, making it difficult to share best practices. The lack of a standardized enrollment planning process supported by an enterprise-wide application inhibits the development of good enrollment plans, which ultimately delays clinical trials.

A good enrollment plan is critical to completing the patient enrollment process on time. In developing enrollment plans, study managers often miss valuable insights and fail to spot potential problems because they lack the tools to forecast effectively and to quickly identify clinical trial enrollment trends. Home-grown models built with Microsoft Excel® can plug in assumptions, but can't visualize and predict problems. For example, study teams that use Excel to generate enrollment forecasts usually estimate with a linear path of "X" patients per week for "Y" months. This method can produce forecast errors of up to 40%. In reality, enrollment follows more of an "S-Curve" to reflect the initial ramp-up and subsequent slow-down of patient enrollment by site investigators.

Without the ability to run simulations and plan scenarios, study managers are unable to validate their enrollment plans.

Study Managers Are Unable to Adjust Plans When Enrollment Veers Off Course

Even good plans need to be adjusted from time to time. Subject availability, study protocol complexity, and drug reactions can all delay enrollment.

When enrollment does veer off track, modeling interventions to meet enrollment objectives—such as adding sites or launching patient recruitment ads—becomes cumbersome with Excel or other business intelligence tools. Without a way to predict, simulate, and model different scenarios, study managers may not notice a center or a country is off course until the trial schedule has already slipped, and significant time and resources have been spent.

Over time, the very nature of a spreadsheet's flexibility becomes a challenge for a clinical operations group to maintain a standardized, best practice. Spreadsheets are difficult to version-control, and updated models may not circulate to the entire clinical operations team.



Global, Disparate Data Is Difficult to Gather

Although leading life sciences companies invest in data warehouses and multiple transactional systems—such as CTMS, IVRS, CDMS, and EDC—global study teams continue to manually update their spreadsheet models with actuals. These manual updates are further limited to comparing the plan with actuals. Spreadsheets and business intelligence tools don't allow global study teams to easily re-forecast the plan and share the results.

Using Web-Based Predictive Modeling & Clinical Enrollment Automation Software to Improve Clinical Trial Performance

Introducing StudyOptimizer™

Although clinical enrollment is complex, life sciences companies can improve clinical trial performance and predictability by using an automated, standardized enrollment process that brings data together to support real-time decision making—even across global teams.

Web-based predictive modeling and enrollment automation software provides a built-in solution to optimize clinical trial performance.

StudyOptimizer—the first web-based software solution developed specifically for clinical trial enrollment—allows clinical operations teams to plan, track, diagnose, and adjust clinical trial enrollment. With StudyOptimizer, teams visually identify possible problems before they happen so they can take corrective actions and finish trials on time.

By aggregating data from multiple sources and providing a wide range of analytics, scenario simulations and models, all in a visually meaningful format, StudyOptimizer results in faster enrollment cycle times and lower trial costs.

StudyOptimizer improves transparency between global study team members, resulting in better communication and collaboration. Automating and standardizing the end-to-end trial enrollment process further increases organizational efficiency and effectiveness.

How It Works

Standardized System Keeps Global Teams on the Same Page

StudyOptimizer establishes and measures all key performance indicators. A standardized approach keeps local and global teams on the same page, and web-based collaboration

A Gartner Group case study of a major global pharmaceutical company found that approximately twice as many of the trials that used StudyOptimizer completed on time⁴.

keeps everyone working efficiently. The result is improved transparency and better global collaboration.

Tapping into completed study data offers valuable insights into what worked best for each country. Study teams can use country screening rates and screen failure rates to plan new studies. They can also drill down into historical studies to identify top investigators and filter out under-performing sites for future trials.

Visualizations & Scenario Modeling Tools Keep Enrollment on Track

Once enrollment begins, StudyOptimizer's visualizations and scenario modeling tools improve the predictability of trial completion dates by identifying problems before they impact the trial schedule. By modeling the best course of action, these tools help study managers take corrective actions quickly. StudyOptimizer's visualizations go above and beyond what can be done manually or in spreadsheets. The result is study managers keep enrollment on track.

Automated Aggregation Enables Informed Decisions & Improves Efficiency

StudyOptimizer aggregates data from IVRS, CTMS, and EDC systems to help study managers make informed clinical trial enrollment decisions. When clinical enrollment is automated end-to-end, study teams become more efficient and effective.

Conclusion

Clinical enrollment is a complex and often manual process. Inefficiencies and inconsistent results delay clinical trial enrollment. Spreadsheets can store enrollment data, and business intelligence tools can provide reporting, but neither can anticipate problems or model solutions.

Fortunately, the right software can help companies bypass these enrollment pitfalls. By using a standardized practice and an enterprise-class system to plan, track, diagnose, and adjust clinical trial enrollment, study teams can meet their enrollment goals on time and on budget. StudyOptimizer aggregates data from multiple sources and provides a wide range of analytics, simulations, and scenario modeling, all in a visually meaningful format.

See how StudyOptimizer can improve your organization's clinical trial performance. Contact DecisionView (sales@decisionview.com) to schedule a live demo.

About DecisionView

DecisionView develops innovative web-based software solutions that enable life sciences organizations around the world to improve clinical trial performance. DecisionView helps organizations make informed decisions by aggregating data from multiple sources and providing analytics, simulations, and scenario modeling tools that reduce clinical trial costs and improve clinical trial predictability.

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