Extracting business value from clinical trial operations data

By collecting and analyzing clinical trial operations data, pharmaceutical companies can plan studies more effectively, minimize uncertainty, and reduce study cost and time.

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INTRODUCTION

While solid science is critical to successfully developing a new drug and getting it to market, clinical trial management also plays an important role. Most clinical trials are plagued by similar management challenges: under- and over- enrollment, lack of site accountability, and disparate data collection—all of which can increase costs and lengthen timelines.

Nearly 80% of all clinical trials fail to meet their patient enrollment targets on time, and each day a drug is delayed from reaching the market can result in billions of lost dollars across the global pharmaceutical industry.[1] According to the Tufts Center for the Study of Drug Development, it now takes an average of $2.5 billion to get a new prescription drug from concept to approval.[2] And while the bulk of that cost is due to more complicated R&D and the need for greater evidence generation, development delays increase costs as well.

Most pharmaceutical companies already have the data they need to optimize clinical trial management. Unfortunately, that data is often inaccessible and inconsistent. Data may be siloed by study, kept in individual Excel spreadsheets, or stored in different instances of an electronic data system. Finding and collecting the data can be a challenge, and the lack of standardized data further complicates analysis. In addition, pharmaceutical companies lack the analytic tools they need to extract actionable meaning from their data.

All those factors make study management more difficult than it needs to be. Without the right data and tools to analyze it, study management teams (SMTs) at sponsor and clinical research organizations (CROs) have to rely on self-reported site feasibility survey data that lacks objectivity on site performance, for example. If that data was captured, stored, and properly analyzed, SMTs could instead be comparing site feasibility survey data with historic performance metrics. Another example is that country and site activation strategies are often based on existing relationships with sites and key opinion leaders (KOLs), rather than empirical enrollment rates or epidemiological data. The right data and analytic tools could easily highlight these gaps.

Beyond the implications for clinical trials alone, poor data and trial management impact the overall business by depriving senior leadership of visibility into how budgets are affected by study delays, over-enrollment, or the need to activate new sites. Clearly, there needs to be a unified

1 October, 2005. Hess, Jon. Web-based Patient Recruitment. Cutting Edge Information.

2 November, 2014. Tufts Center for the Study of Drug Development. Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion. Available online at: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

approach to tying these data sources together so that SMTs and their leadership can move toward a new, data-driven paradigm.

The solution for a data-driven paradigm

In this whitepaper, we describe a solution currently in production at a top-five pharma company today that harnesses trial data to improve planning, increase the accountability of research partners and sites, and give business decision makers the insights they need to make effective decisions. With this system, companies can:

- Track study progress over time
- Make sites accountable for patient recruitment performance
- Deliver a "single source of truth" for trial data
- Develop clear metrics to plan and manage current and future studies

Prerequisites for success

Before the system is implemented, unruly data must be tamed. The first step is to **define the key performance indicators** (KPIs) that measure success. Typically, these KPIs are tied to milestones such as First Patient In (FPI) and Last Patient In (LPI), but they can also be tied to patient enrollment, screening, and screen-fail rates. Defining metrics and KPIs early supports high-quality data collection and the ability to track progress over time.

Once that has taken place, **data standardization and collection** can proceed. In many cases, individual SMTs are responsible for determining how data is collected, classified, and named. This results in a hodgepodge of differently formatted electronic data capture instances, leading to disparities even within individual business units. Because analytics systems are not intelligent enough to reconcile disparate naming conventions, it's critical to develop uniform naming conventions and data fields and reconcile historical data with the new framework where possible to support richer insights. Once data collection is standardized, data entry administrators can be trained to input new data accurately based on the revised rules.

Making data work harder: the Slalom solution

Slalom helps global, mid-size, and small biopharmaceuticals conduct better trials. Our experts in data management, analytics, and visualization can help your clinical operation organizations build powerful analytic tools that support better trial management. Our life sciences experts work with you to develop tailored solutions that put the data and insights your SMTs and business decision makers need at their fingertips—all through a web-based interface that includes tools for entering study plans, tracking data, and accessing visualization tools.

Through the study dashboards, users can see KPIs, enrollment for escalations and expansion arms, screen fail percentages and reasons, and more. The system is fully customizable to show relevant metrics first and enable end users to view customized segments of the study, drill down to country or site-specific data, and gain visibility into project study outcomes and budgets. All these views can be customized to meet the end users' needs for relevance and data access.

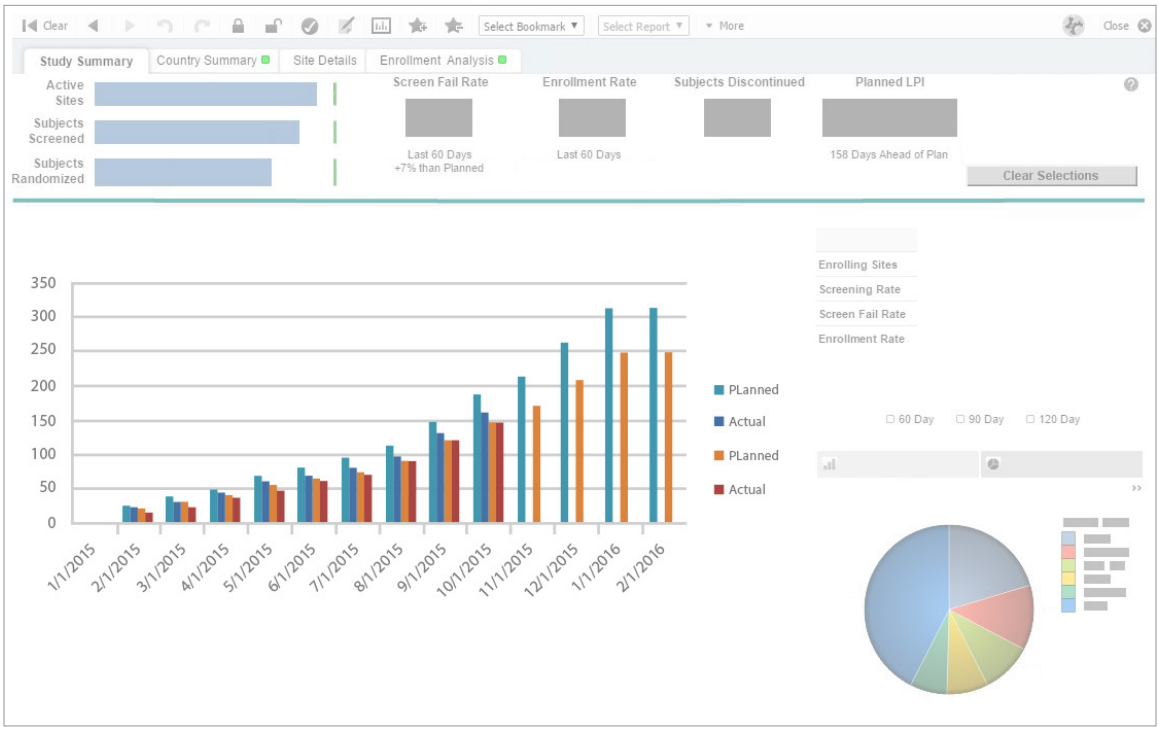

Figure 1: Study enrollment benchmarks from cleaned and standardized historical data.

We have built these data visualizations using the QlikView platform, a robust and dynamic system that allows for infinite permutations and customizations to meet each business need. Slalom's QlikView and clinical trial experience has led to several successful deployments. Our analytics and visualization tool can accommodate all types of data and be manipulated to display large data sets in a meaningful and relevant way.

Using data to drive decisions: study planning and projection

To demonstrate how the analysis delivers value, we'll walk through an example of a one-year, Phase II asthma study that intends to screen 225 subjects to achieve an enrollment of 200 subjects in five countries.

The anticipated screening and enrollment plan is reflected in Figure 1. The plan for this study has been informed by historical data from studies with a similar therapeutic area, cleaned and standardized for integration with current data. The ability to create this type of plan can serve as a baseline for comparison with the actual screening and enrollment rates, as denoted in Figure 1, providing more actionable comparisons. These numbers will help in allocating study budget, communicating with vendors, and anticipating any problems that may arise in the study.

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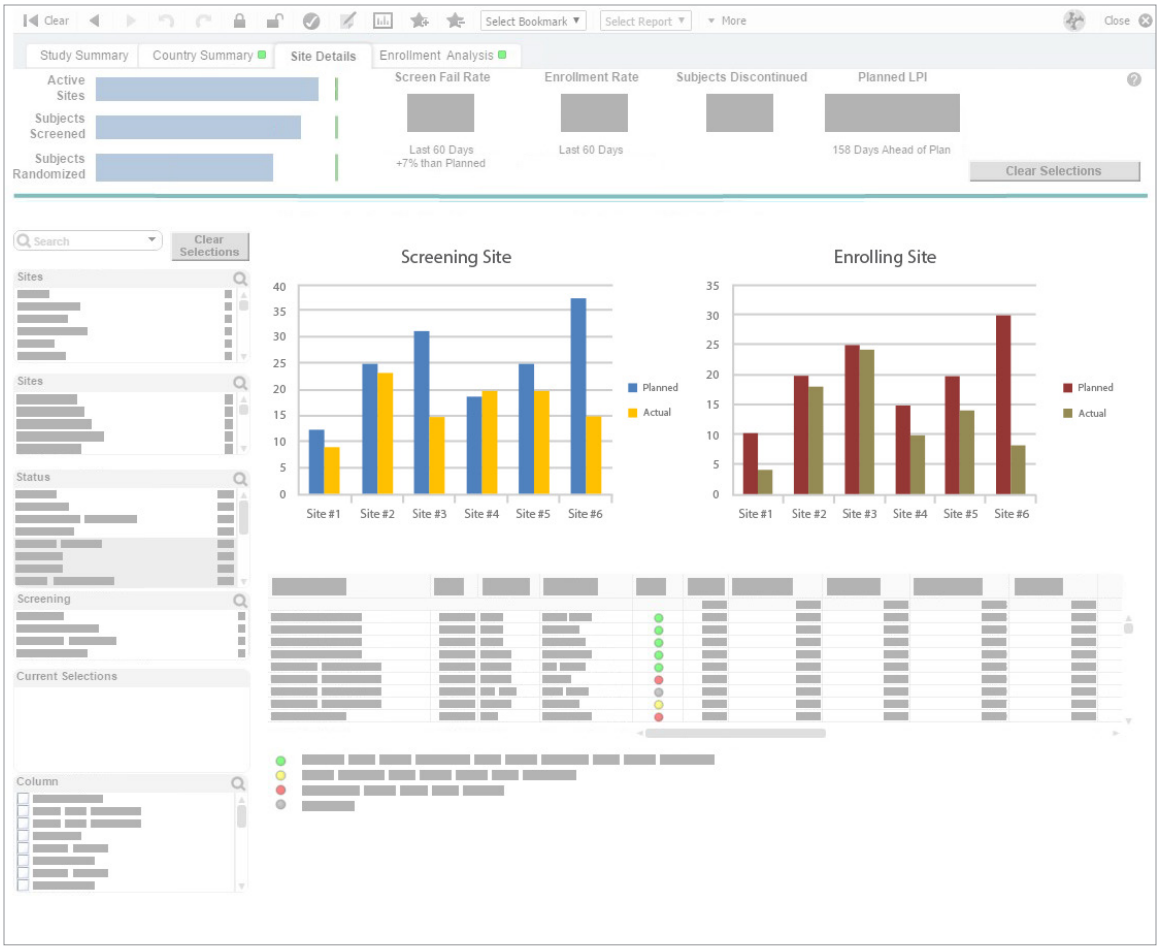

Figure 2A (left-hand graph): Site-level screening numbers compared to plan.

Figure 2B (right-hand graph): Site-level enrollment numbers compared to plan.

Additional data visualization can also be used to drive site-level accountability. Figures 2A and 2B show a site-level analysis of actual versus planned for both screening and enrollment rates in real-time, enabling the administrator to instantly pinpoint low-performing sites and mitigate the situation. Any disparities would prompt the SMT user to investigate the causes, address current issues, and make a data-informed decision regarding activating or deactivating sites to prevent further delays and waste of resources.

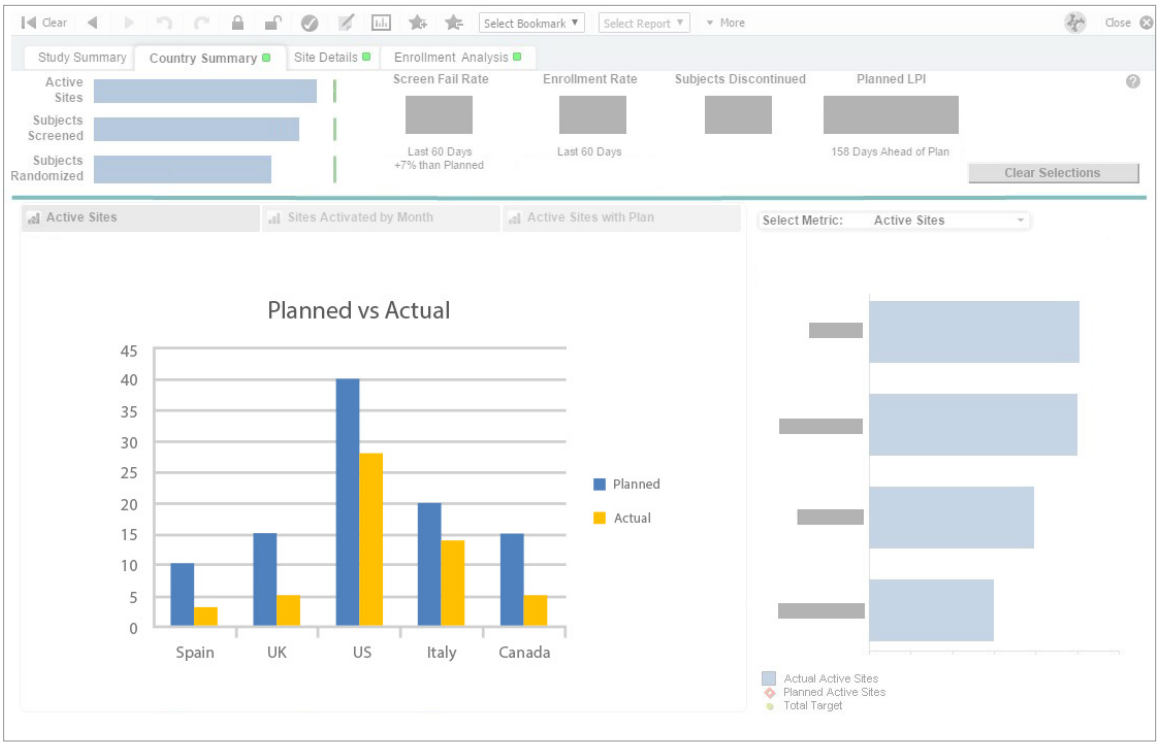

Figure 3: Enrollment by country compared to plan.

The same could be said of Figure 3, which shows planned versus actual data by country. Again, SMT members can now make country-level decisions based on the enrollment data captured here.

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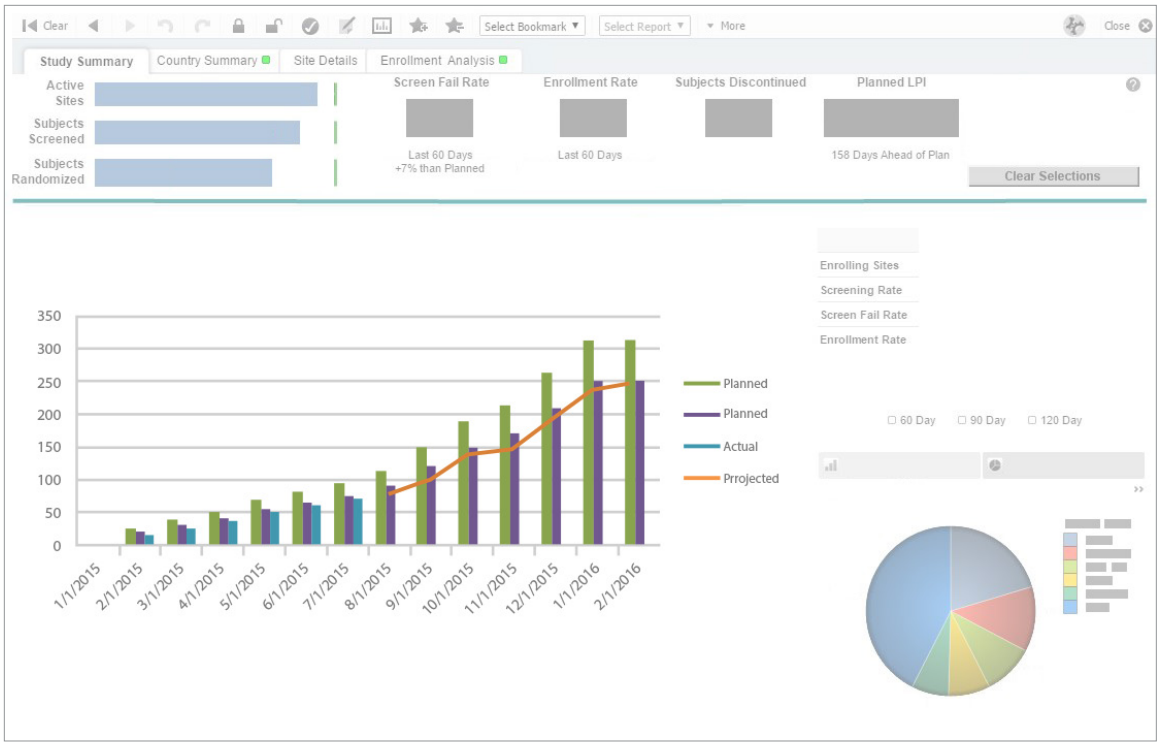

Figure 4: Enrollment projection compared to actual.

The system can also enable SMTs to project recruitment and study end dates throughout the process. Figure 4 shows that at the current enrollment rate, it will take until December 2015 to meet the targeted enrollment of 200 patients. Projections can be used to predict completion dates, and to prevent over-enrollment or further delays.

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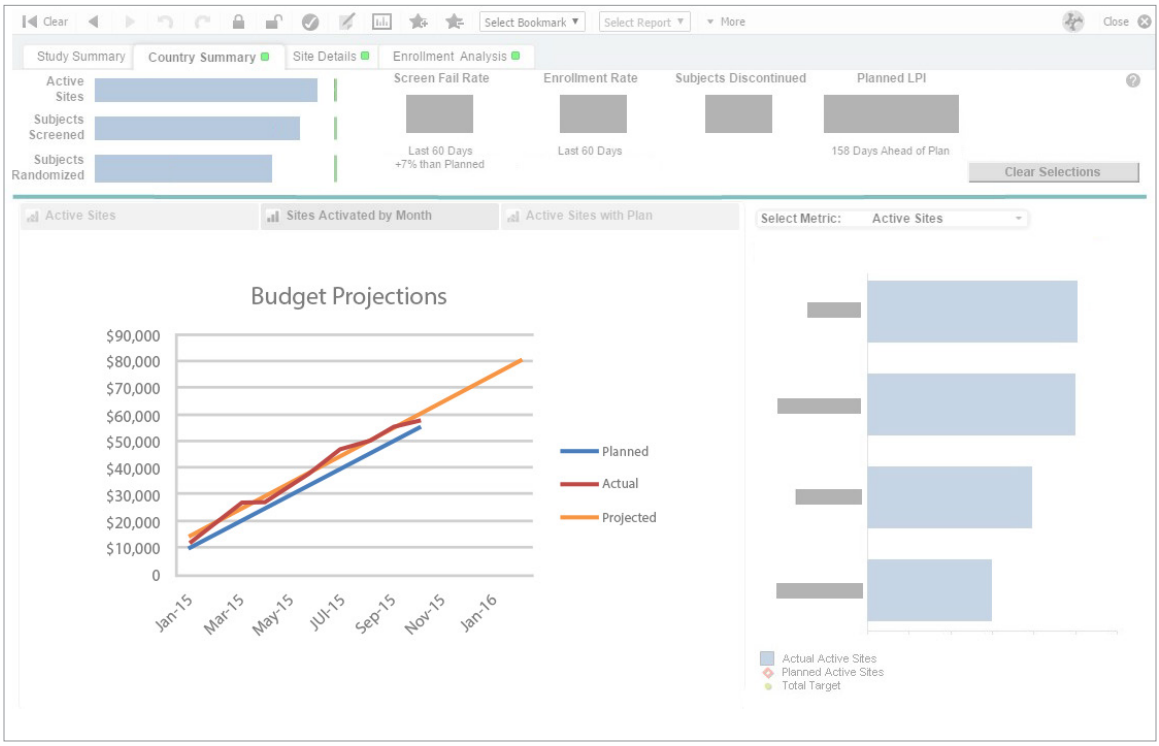

Figure 5: Budget projections for study.

Similarly in Figure 5, we can overlay budget information on top of our projections to provide a holistic view of how the budget is managed in relation to the study. Information like this enables leadership to re-direct and allocate resources across a program or portfolio.

These are just basic examples of how this system can be used day to day—the tool is highly flexible and customizable to meet unique needs. These models can be created for virtually any size study and can be built to accommodate any combination of parameters, including phases, molecules, indications, therapeutic areas, and demographics. The data is already being collected by SMTs; the value comes from implementing a standardized, user-friendly visualization tool that gives SMTs and senior leadership timely access to insights. And even once a drug has been marketed and no longer requires clinical study, this type of system can help track prescription data, financial data, supply chain, safety, and efficacy in real-time.

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Technology is only part of the puzzle

Implementing this new paradigm across an entire clinical operations portfolio requires more than smart software: it requires alignment of people, process, and technology. Particularly in older or larger organizations, addressing disparities in how data gets collected, stored, and used can take significant effort.

Targeted and relevant change management strategies can significantly accelerate adoption. In addition to being mandated from the top down, SMTs and CRO partners must feel that they have been consulted in the process and involved in the development, beginning with requirements gathering and continuing through the deployment of the solution. User experience testing is especially important for a positive outcome. SMTs and CRO partners will become the users and champions of the new system on a day-to-day basis, so their input is crucial.

Training is another aspect of change management that can support adoption and increase value. When users understand exactly how the solution makes their jobs easier, they're much more likely to use it. Ultimately, a cultural shift should take place in which SMTs and CRO partners become more data-oriented and make their vendors and sites accountable to that data. Data can also be used to support strategic conversations between leadership executives and SMTs about how to improve results going forward.

Conclusion

The right clinical trial management analytics support planning, projecting, and managing the cost and duration of studies. And from an operational perspective, the right intelligence drives better day-to-day decisions around site management, patient enrollment, and funding.

Data can also improve sponsor-site relations and site accountability, since both parties can track progress in a transparent and empirical way. SMTs can spend less time manipulating data and more time delivering good trials on time. From a strategic level, senior leadership can leverage analytics to help with scenario planning, pipeline management, and more effective resource allocation.

Well-managed clinical trial data can assist in predicting success and address many trial-related business challenges. The goal is to reduce the investment and time required to get to market, creating a lasting competitive advantage.

About Slalom

Slalom designs and builds strategies and systems to help clients solve some of their most complex and interesting business challenges. With over 3,500 consultants supporting seven practice areas worldwide, our team of experts are poised to develop your clinical trial solution.

About Anh Duong

Anh Duong is a life sciences consultant with Slalom's Delivery Leadership practice, focused on delivering successful outcomes for biopharmaceutical and healthcare clients. Anh's experience ranges across the drug development lifecycle, from discovery through drug commercialization.

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Samantha James is a life sciences consultant with Slalom's Delivery Leadership practice. Samantha has worked in the biotech and energy industries, leading IT teams to deliver innovative solutions for clients.