CALYX™

CASE STUDY

Driving Trial Efficiencies

SITUATION:

A leading pharmaceutical company is investing more than $2 billion in research and development and has more than 30 development projects in clinical trials worldwide.

CHALLENGE:

Managing and monitoring these trials is a resource-intensive effort. Extreme accuracy and precision are crucial for ensuring patient safety, accurately assessing and reporting outcomes, complying with regulatory mandates and, ultimately, generating revenues. It would be impossible to manage and monitor trials effectively without an advanced clinical trial management system (CTMS).

SOLUTION:

The company's solution of choice is Calyx CTMS. The system gives the company a single, centralized system for capturing data, monitoring trial progress, generating reports, and responding proactively to issues. It facilitates a database of approximately 11,000 trials, which helps maintain patient safety and meet transparency requirements.

RESULT:

With Calyx CTMS, the company now makes robust, data-driven decisions to ensure patient safety, increase the efficiency of its business processes, and contain costs — all of which enables timely trial completion and license filings.

EFFICIENT, COST-EFFECTIVE TRIAL MANAGEMENT

The company has used the Calyx system for nearly two decades, giving its clinical trial teams the tools they need to work as efficiently as possible while ensuring patient safety.

Clinical trial management has always been labor intensive and regulatory changes in recent years have made it more complex. Trial teams must collect huge volumes of data and comply with stringent reporting requirements as a trial progresses through site selection, patient recruitment, clinical monitoring, data collection, and oversight.

"When you're conducting a study across hundreds of sites and thousands of patients, you need a quick way to distinguish between sites that are having issues and need immediate intervention, and those that are functioning smoothly," says the head of clinical systems integration. "Calyx CTMS allows us to identify issues that might affect patient safety or data quality. In essence, the Calyx system enables us to create a score for each site, showing us where we need to apply resources to resolve issues and ensure the best outcomes."

Calyx reporting supports this risk-based approach by leveraging data to identify sites that are not performing up to par. Reports indicate if a site is behind in recruitment or start-up, or if it appears

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the site personnel need training to eliminate errors. In those cases, a site monitor can schedule a visit to investigate and resolve the issue and get the trial back on track. This approach helps clinical trial teams work as efficiently as possible, minimizing costs by increasing productivity and enabling each team member to manage more sites while maintaining exceptional quality.

DATA/REPORTING SUPPORT FOR BUSINESS PROCESSES

One benefit of Calyx CTMS is the ability to link data into critical processes. Pharmaceutical companies are mandated by law to publish clinical trial results through multiple channels, including the web. The company meets this requirement by publishing trial results to a variety of sites, such as those created by the FDA and the U.S. National Institutes of Health. Calyx CTMS provides the data that enables clinical trial teams to meet this requirement.

Pharmaceutical companies are also required to publish study results within specified time frames after a trial ends. The company uses Calyx to track all deadlines, with milestones along the way to ensure that reports are submitted to the appropriate government agencies on time. It also helps ensure that license applications are filed in a timely manner.

Maintaining proper insurance coverage is an important concern because it is critical to managing the risk associated with studies. The amount of coverage depends on factors such as the number of active trials and the number of participants. Arrangements with insurers are managed through the Calyx system, which keeps insurance partners apprised of ongoing trials, locations, patients, and other information that is required to maintain adequate coverage at all times.

Finally, the company uses Calyx data to develop a number of metrics for assessing the performance of its trials internally. Additionally, it shares the data with industry benchmarking organizations that collect data from multiple pharmaceutical companies, aggregate it, and generate industry benchmarks.

These benchmarks provide insight that supports better decision-making. For example, senior management might compare the company's average time between the completion of a trial and the final regulatory reporting and license filing with the industry average. If performance is below the industry average, management can take steps to shorten that time.

"This type of visibility is very important to us," the head of clinical systems integration remarks. "While our top focus is always patient safety, from a business standpoint we need to bring in revenues. That requires getting a license for each new drug. By speeding up the time it takes to obtain a license, we can start seeing revenues for the product sooner."

FOCUS ON SAFETY

Safety reporting is another example of the value that Calyx data and functionality delivers. If a trial participant experiences a negative reaction or some other issue arises during a trial, the clinical trial team must follow stringent reporting guidelines. Depending on the severity of the issue, it may be necessary to share the information with every investigative site and patient.

"Calyx tracks contact information for all stakeholders, including investigators and study participants," the head of clinical systems integration explains. "So it's very easy to create a list and then use mail merge to create communications that alert the appropriate people and let them know what actions they need to take. The ability to put together these notifications quickly and accurately has a direct impact on safety."

Even after a trial is completed, issues can arise regarding its integrity. If the competency or truthfulness of a particular physician or site investigator comes into question, patient safety could be at risk. So could the license for the product. The Calyx system provides robust historical data that enables the company to address these types of issues — whether it's an ongoing trial or one that occurred years in the past.

"If a regulatory agency notifies us that a particular doctor is under investigation, Calyx can tell us which studies that physician participated in so we can provide a report to the agency," says the head of clinical systems integration. "We can also track the role that physician played in any given trial and determine the impact not only on patient safety, but also on any risk to our license position for the drug."

KEY HIGHLIGHTS

- Enables data-driven decisions allowing people to focus their efforts where it matters most
- Safety reporting speeds notification of patients if issues arise
- Robust data supports decision-making and increases efficiency of business processes
- High productivity contains costs, ensures timely trial completion, and facilitates compliance and license filings

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- Head of Clinical Systems Integration

DATA FOR INFORMED BUSINESS DECISIONS

Calyx reporting also provides data for executive-level decision-making. On a regular basis, senior management asks questions about the types of trials and level of activity in various parts of the world. "A few years ago, senior leaders were considering increasing the company's presence in Asia. They needed insight into how many trials were going on in that part of the world and what percentage that represented of our overall business. Calyx provided the answers to their questions and played an important role in the decision to invest in opening a hub in Asia," concludes the head of clinical systems integration.

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