Mitigating Unexpected Trial Disruptions With a Flexible CTMS Delivery Model

As we enter the eighth month of the COVID-19 pandemic, businesses in numerous industries are feeling the financial consequences of the disruption of normal operations. For clinical trials, many studies have been either slowed, suspended or even terminated due to safety precautions for participants and study staff as well as clinical sites that have shifted their resources to urgent COVID-related needs. Therefore, investment in new technologies now likely seems frivolous. Yet, some technologies, such as a clinical trial management system (CTMS), can improve efficiencies in clinical trial conduct and oversight, ultimately reducing costs.

Cost and Time Considerations

As with all procurement decisions, there are important factors to consider in your choice of a CTMS. Commitment to a long-term, fixed-cost contract can be detrimental when studies are paused. Therefore, a system that offers a pay-as-you-go business model, such as Bioclinica CTMS, allows the flexibility to scale down your CTMS use (and associated cost), which can be particularly useful in situations such as pandemics or natural disasters, and then scale up again when needed.

According to Guy Crossley, President of Software Solutions at Bioclinica, "Bioclinica has a robust, scalable solution and a deployment model that requires a small initial investment. If studies are delayed due to COVID-19, sponsors and CROs only pay for what they use without the financial consequences of unused software."

However, even a flexible business model can be offset by high, up-front costs, which can be more than US $1M for licensing and implementation of other industry-leading CTMS. That's why Bioclinica pairs their use-based pricing with only a small procurement cost of less than US $100K. Additionally, out-of-the-box configurations enable system deployment in as little as 2 weeks, with additional integrations taking up to only 5-6 weeks. It really is a low-risk decision, which is critical in lean times.

Mr. Crossley said, "A customer needed a system in place within a month to start their study. We contracted quickly and were live for their first patient in, meeting the customer's accelerated timeline."

Critical and Value-Add Features

Although a CTMS is often on the lower end of the priority list in terms of clinical trial software purchases, the functions are critical to efficient, accurate study management, including enrollment, clinical site oversight, study monitoring, protocol deviations, study milestones, investigators, action items, safety events, inventory and payments. Try manually coordinating this across multiple sites around the globe, with the vast number of people and data sources involved, and it quickly becomes unmanageable.

For most purchases, lower cost and faster timelines mean compromising features. Because of the best-practice configurations, Bioclinica CTMS is a full-featured system from the beginning, integrating seamlessly with EDC and IRT systems and providing a consistent view of the study regardless of data source.

Consolidation of study data and the centralized dashboard help automate remote monitoring and provide a common view of master lists, libraries and calendars for site monitors and their managers. The monitoring visit report (MVR) module facilitates this process, with support for offline use and automated review and approval.

Ease of Use

User adoption is a common issue with many CTMS solutions, which is why the Bioclinica CTMS was designed to be Office-Smart, which means users interact with the system through SharePoint portals and Microsoft Office applications enabled by a seamless bi-directional integration via SharePoint. Users don't have to learn a new system, making it easier for them to use the system immediately.

An Attainable CTMS

Based on their team's experience in clinical trials, system architecture and customer feedback, Bioclinica has created an intuitive CTMS solution that provides the functionality needed for the management of today's studies with low-risk procurement that puts a CTMS within reach for companies large and small — a system with the flexibility to handle unexpected circumstances. And the soon-to-be released SharePoint-based eTMF will continue to simplify study management for sponsors and CROs.

"Because there is market demand for an eTMF capability in conjunction with CTMS, Bioclinica will release SharePoint-based eTMF functionality in the upcoming release of our CTMS solution," stated Mr. Crossley.

For additional information regarding Bioclinica CTMS, visit bioclinica.com/ctms.