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Life Saver

As clinical trials grow ever more complex, there are steps companies can take to keep their studies on track and on target

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Clinical trials are not for the faint of heart. Conducting even one clinical trial is a monumental task with complex processes and issues that can surface and derail a study's timeline. As a result, delays in regulatory filing, market entry, and ultimately, the delivery of new therapies to patients are all too common.

To address these challenges and to re-focus on their core strengths, sponsors are outsourcing clinical trials in large numbers to CROs. According to recently published research, by 2020 an estimated 70% of all clinical trials will be outsourced to CROs,[1] with hopes for better on time and on budget performance. Unfortunately, however, the CRO sometimes fails to adequately manage a study, and that study must be "rescued", which means corrective action is needed. This might involve adding more investigative sites, while terminating or retraining others. It could also mean that better operational processes need to be put in place, or more reliable and timely status reports from the CRO are required.[2]

Why Do Studies Need Rescuing?

Each clinical study presents unique challenges. Communication problems among stakeholders, employee turnover, recruitment and enrollment delays, overly complex protocols, poor site compliance… these are some of the factors that could necessitate a study rescue. Most often, a study needs rescuing when it is in danger of not being completed within an appropriate timeline, its quality is suspect or it has lost access to resources. One other possibility is that unexpected results have caused a regulatory agency to halt the trial.

The scope and type of CRO management deficiencies that could lead to rescue need to be assessed by the sponsor to determine the type of remediation required. Rescue support may be as simple as adding third-party experts to the sponsor project team to aid in the management and oversight of the CRO, or as complex as selecting a new CRO to assume all responsibility for the study.

To manage this issue, numerous CROs offer rescue services, a fact that is hardly surprising given that currently approximately 80% of clinical trials fail to meet enrollment timelines.[3] In addition, up to 50% of research trial sites enroll one or no patients,[4] and according to Cutting Edge Information, 72% of studies run more than one month behind schedule.[5]

These statistics cannot be ignored.

Intervene Before Rescue is Required

Key to avoiding the need for study rescue is the proper identification of red flags that signal the study is veering off course. To determine if remediation is needed, ask the following:

- What are the issues?
- Where are the bottlenecks?
- Has the clinical trial team been informed in time to take corrective action?
- How is the sponsor conducting oversight of multiple CROs?

For sponsors, this last question is particularly daunting. The complexity of oversight becomes evident when working with multiple CROs on multiple concurrent studies. Specifically, CROs' detailed reporting often masks risk identification for each individual study due to the use of siloed custom tool and processes. As a result, the correlation of data from CROs with different reporting formats makes timely oversight difficult. Also, too often, study startup (SSU) activities—one of the most inefficient and costly bottlenecks of clinical trial conduct—are still being handled via email and spreadsheets, yielding inaccurate, inconsistent and outdated data. Beth Harper, President of Clinical Performance Partners, a provider of services for study rescue and improved site performance, comments, "The more that the industry can move away from spreadsheets and trackers to more valuable dashboards to visualize and monitor site performance, the better position we'll be in to pre-empt issues and more effectively manage study performance, especially at the site level."

Because many tasks have frequently been performed without a consistent approach across CROs, resulting inefficiencies have led to missed timelines and cost overruns. In response, business intelligence initiatives are a growing priority for sponsors and CRO priorities,[6] as executives demand greater visibility into trial data—at a much faster pace. Against this backdrop and the volumes of information being generated, clinical project managers are expected to make smarter decisions on intelligence derived from clinical trial data.

Established eClinical systems—clinical trial management systems (CTMS), electronic data capture (EDC), the electronic trial master file (eTMF), and others—are in wide use,[7] but they can fall short on delivering rapid analytics and insight, and significantly, they do not address SSU.

Activities such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget execution, and enrolling the first patient typically define SSU. And for stakeholders, bringing a higher level of predictability and quality to this multi-step process is critically important,[8] as it could mitigate the need for many study rescues.

Recognizing this gap, eClinical system providers that are extending their technology solutions to include SSU activities are: Adobe Lifecycle, **goBalto**, NextDocs, Intralinks, ePharmaSolutions, and others. With real-time SSU data now available through these solutions, the project management team is free to focus on issues and bottlenecks affecting the clinical study. Time is no longer wasted assembling and discussing status updates. Instead, stakeholders can view this information in real-time, well ahead of any scheduled status meetings.

Another feature is real-time alerts, which help decision makers intervene immediately or before a major setback has occurred, instead of after the fact. This is crucial, since in conventional SSU, intervention usually happens after an issue has occurred, when it's too late to proactively avoid the problem, which may ultimately derail the study and necessitate a rescue.

Embracing Innovation

It is critical for sponsors and CROs to leverage new innovative technologies to aid in their goals of streamlining clinical trials by empowering oversight, casting light on bottlenecks, reducing study rescue, and ultimately, getting life savings drugs to market more quickly.

This works via true business intelligence—the ability to proactively identify and resolve bottlenecks in real-time, instantly view study status, quantify performance of the clinical team, and discover meaningful patterns in SSU data. Today's industry leaders in clinical trials recognize that CROs able to produce high quality data and visualization into study progress translates into a competitive advantage and is a critical tool in their fight against wayward studies destined for rescue.

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