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Better Study Startup Means Less Study Rescue

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By Craig Morgan

When a clinical trial does not unfold as planned, it may be heading for rescue. Communication problems among stakeholders, patient enrollment delays, overly complex protocols, and poor site compliance are just a few of the many reasons why rescue action is needed. The issue of study rescue is increasingly faced by contract research organizations (CROs) as it has been estimated that by 2020, 70% of all clinical trials will be outsourced to CROs, a trend that frees sponsors to re-focus their energies on core competencies. With this model, the goal of better on time and on budget performance—essentially avoiding rescue—has often become the responsibility of the CRO. But what happens when a rescue is needed and what can CROs do to avoid it?

For starters, to streamline the clinical trial process, CROs have adopted various technologies, namely electronic data capture (EDC), clinical trial management systems (CTMS), and the electronic trial master file (eTMF) to name a few. But, these solutions are not designed to address study startup (SSU), a multi-step process that is among the most challenging aspects of clinical trial conduct. It typically involves country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget execution, and enrolling the first patient.

This article takes a look at the causes of study rescue and the red flags that CROs should heed to mitigate risks related to SSU. As part of this effort, there is discussion on leveraging innovative technologies that empower oversight and cast light on bottlenecks that traditionally stall adherence to study timelines and budgets.

When Does a Study Need Rescuing?

Because there is a broad spectrum of studies across all therapeutic areas, there is no one-size-fits-all metric that indicates when and why a study needs to be rescued. Typically, however, a study is heading for rescue when there is a threat of its not being completed on time, the quality of the clinical trial data or protocol compliance is suspect, or a regulatory agency has stepped in to stop the trial based on unexpected results.

As the types of risk vary, the requisite remediation varies, as well. It may involve adding more investigative sites, while terminating or retraining others. It may also make sense to hire third-party experts to join the sponsor project team to help management CRO oversight. And, in particularly serious situations, the decision to choose a new CRO may be the right corrective action.

To manage the challenges posed by study rescue, numerous CROs offer these services, a reflection of the fact that the mean clinical development cycle is nearly seven years, a stagnant number, and upwards of 80% of clinical trials fail to meet enrollment timelines. Also, an estimated 72% of studies run more than one month behind schedule, and nearly half of investigative sites enroll one or no patients.

Intervene Before Rescue is Required

The key to avoiding study rescue is the proper identification of red flags signaling the study may be veering off course. These include:

- Failure to receive timely status reports
- Slow query resolution
- Concerns that data are being collected in spreadsheets instead via data collection technology
- Poor communication among stakeholders

All of these issues can be more easily deflected if data are used to identify the flags as early as possible. A recent article discusses this fact, highlighting how “leading with data” from the beginning of a study results in better decision making, and ultimately, less study rescue. This data-driven approach involves examining accumulated data in real-time and using analytics to help stakeholders evaluate risks and determine if remediation is needed, starting with SSU.

As part of this effort, stakeholders need to use data to answer questions, such as where the bottlenecks are, or the best way for the sponsor to conduct oversight of multiple CROs. For sponsors, the issue of oversight is particularly unnerving, especially when working with multiple CROs on multiple concurrent studies. Specifically, reports from CROs often mask risk identification for each individual study due to the use of siloed custom tool and processes.

And for study startup (SSU)—one of the most inefficient and costly bottlenecks of clinical trial conduct—activities are still being handled via email and spreadsheets, yielding inaccurate, inconsistent and outdated information. Research from the Tufts Center for the Study of Drug Development, in collaboration with 11 biopharmaceutical sponsors, documented that SSU is problematic, with early stages of the site initiation process accounting for the majority of cycle time. Their data from 105 global clinical trials found that in Phase II – IV studies, leading up to first patient in, nearly 60% of cycle time was taken up by the time period from pre-visit activities to contract or budget execution.

SSU Technology

Established eClinical systems—CTMS, EDC, eTMF, and others—are used extensively, but they tend to fall short on delivering rapid analytics, and they are not designed to address SSU. For stakeholders seeking a higher level of predictability and quality to the multi-step SSU process, purpose-built SSU technology is critical, as it could mitigate the need for study rescue.

In keeping with the “lead with data” concept, real-time SSU data are available through these solutions, allowing the project management team to focus on issues and bottlenecks affecting the clinical study. Time is no longer wasted assembling and discussing status updates, and stakeholders can view updates in real-time, prior to any scheduled status meetings.

A key feature of SSU technology is real-time alerts, which help decision makers take action immediately or before a major setback has occurred, instead of after the fact. This is crucial, because with conventional SSU methodology, intervention typically happens when it is too late to avoid the problem, possibly derailing the study, and necessitating a rescue.

Beth Harper, President of Clinical Performance Partners, a provider of services for study rescue and improved site performance, acknowledges the value of SSU technology in improving risk identification. “There’s no question that sponsors, CROs and sites alike, recognize the value that technology brings to the clinical trial enterprise by providing actionable insights from all of the data collected, starting from the beginning of the study. In addition, the technology facilitates much needed communication among stakeholders to enhance site engagement and relationship management, which can improve site performance, and ultimately, reduce the chance of rescue.” Harper remarks.

Avoiding Rescue

The issue of reducing study rescue is of great interest to clinical trial stakeholders, and using innovative technologies and their data analytics to identify risk is key to making this happen. This approach provides true business intelligence by empowering oversight, casting light on bottlenecks, reducing study rescue, and ultimately, getting life savings drugs to patients more quickly.

The technology achieves these goals by facilitating meaningful communications and building strong collaborative efforts among stakeholders who want to be proactive in viewing study status in real time, particularly the meaningful patterns in SSU data. For CROs, being able to produce high quality data and visualization into study progress provides a competitive edge and is key to preventing underperforming studies from sliding into rescue mode.

Craig Morgan *is a technology and life sciences management professional with more than 15 years experience in the application of informatics and bioinformatics to drug discovery. He currently heads up the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times and improve collaboration and oversight in clinical trials.*

Craig Morgan
Head of Marketing | goBalto