Outsourcing Pharma

goBalto goes for speed by reducing manual processes in study startups

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Study startup times can stifle clinical trials, but automating certain processes can help eliminate costly bottlenecks, says expert.

Historically, the study startup phase has been viewed as inherently inefficient and error prone – being labor intensive, costly, and time-consuming," Craig Morgan at goBalto told OutSourcing-Pharma.com.

A focus on study startup can reduce cycle times, mitigate risks, and ultimately eliminate operational bottlenecks, which can result in delays or derailment of clinical trials – it is the key to accelerating clinical trials, reducing costs, and speeding the availability of therapies to patients."

To improve upon the cumbersome process, ICON announced yesterday that it will be using goBalto's flagship product, Activate, a study startup document and activity workflow solution which helps Sponsors and CROs eliminate what Morgan calls the three evil "e's": *email, Excel, and e-rooms.*

This is achieved by using alerts, document collection, version control, and status reporting, all of which reduce the number of handoffs, errors, and downtime events that can occur during the startup phase of clinical trials.

The use of a study startup tool allows for the seamless sharing and visibility of documents and associated information in real-time – globally – facilitating handoffs," said Morgan.

According to Morgan, a study startup solution is the missing piece of the eClinical jigsaw; and while other cloud-based solutions, such as clinical trial management systems (CTMS), electronic data capture (EDC), and the electronic trial master file (eTMF) have come a long way, adoption rates vary, and more importantly, *"they do not address one of the most inefficient and costly bottlenecks of clinical trial conduct – study startup,"* said Morgan

Where are the bottlenecks?

It's an obvious question to ask," said Morgan. Unfortunately, there isn't an accurate answer, as traditional tools used to track clinical trials lack the required reporting capabilities.

Business intelligence initiatives continue to top Sponsor and CRO priorities, as executives demand greater visibility into trial data – at a much faster pace," Morgan added. Manually prepared data is often too old to reliably represent status, and readily proving you're on track can be an ongoing challenge Instead of one-dimensional, static reports – Sponsors and CROs need interactive, real-time answers about study startup statuses."

According to Morgan, the process is inefficient because of a lack of data availability related to operational cycle-times and site submission timelines.

Without this valuable data the Sponsor and CRO are at risk of selecting non-active or non-enrolling (NANE) sites, which ultimately drives up the costs and wastes valuable time in study startup," said Morgan.

Currently, 80 percent of trials fail to meet enrollment timelines and up to 50 percent of research trial sites enroll one or no patients.

Meeting timelines

When asked why it's so important for companies to accelerate the startup process,Morgan posed the question in these terms: Add one day to a clinical trial's duration and it could cost $1 million. Lose a day from your market exclusivity due to a submission delay and it could cost you $10 million – and according to Cutting Edge Information, 72% of studies run more than one month behind schedule.

Additionally, a recent research report from the Tufts Center for the Study of Drug Development indicated that the early stages of the site initiation process are areas that accounted for the majority of cycle time in clinical trials .

These findings are supposed by industry veterans, such as Jeff Kasher, the former VP Clinical Innovation and Implementation, Eli Lilly and Company, and the current president of Patients Can't Wait: *"Patients across the globe are waiting for new therapies, but complicated study protocols, globalization, and paper-based methods of conducting trials continue to delay market entry. Current thinking looks to an improved study startup process as holding great promise for accelerating clinical trials."*

After implementing a startup solution, ICON said they have seen a significant positive impact on cycle time, quality, and productivity.