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Three Questions

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CWWeekly presents this feature as a way to put the spotlight on issues faced by executives in the clinical trials space. Jae Chung is founder and president of San Francisco-based goBalto.

Q As head of goBalto, a developer of cloud-based programs that accelerate clinical study startup, what specific steps can CROs take to lower startup expenses today that were not available 10 years ago and why is oversight such a hot topic with sponsors now?

A CROs should look to adopt cloud-based, custom-built study startup (SSU) applications for site selection, feasibility and activation.

While a one-stop shop sounds appealing, it simply is not possible today. Recognizing this, industry leaders are now using and integrating a small number of tools that are purpose-built for specific clinical operational objectives—a focus on combining "best of breed" applications versus relying on a "one size fits all" approach.

The need for more efficient clinical trials is driving greater use of cloud-based solutions, especially with the rise in globalization. Key reasons driving cloud-based adoption are: ease of deployment and management; greater flexibility in supporting evolving business needs from both a technical and business perspective; lower cost of operations; easier ways to scale and ensure availability and performance; and overall ease of use.

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With the flurry of attention focused on the issue of speeding clinical trials, the need for collaborative, cloud-based solutions has never been greater. Research indicates that lengthy startup times are problematic for many stakeholders. Addressing this issue is a challenge because too often, information needed to launch clinical trials still resides in multiple databases, leaving SSU activities to be performed using Excel spreadsheets, email and shared file drives. Consequently, too much time is spent on non-productive activities, such as status meetings, because the desired information is housed in various locations and is not readily available.

These inefficiencies can be minimized using a purpose-built SSU solution, which facilitates real-time viewing of trial statuses, business intelligence, and smart workflows that standardize processes.

Sponsors are embracing outsourcing of clinical trials to CROs in order to contain operational and infrastructure costs, as well as gain access to therapeutic and clinical trial expertise, with the potential to complete projects better, faster and more efficiency.

Q Is it possible to automate oversight?

A Yes. The complexity of oversight becomes evident when working with multiple CROs on multiple concurrent studies. The correlation of results from CROs with different reporting formats makes immediate oversight difficult. CROs' detailed reporting often masks risk identification and is based on their own "silos" of custom tools, processes and inaccurate, inconsistent and outdated data while the majority of SSU activities are still handled via email and spreadsheets.

What is needed is a centralized structure for communications, collaboration and escalation, enabling sponsors and CROs to operate as an integrated team with common goals, aligned structures and processes. Centralized governance and optimized operating models are needed to help realize the full potential of outsourcing arrangements.

Advantages for the sponsor include: saved CRO and site performance data for future reuse; standard, consistent reporting across all CROs; full transparency at portfolio, country, study and site levels; real-time visibility of progress and planning; proactive, advanced visibility into issues; and reduced rework and error rates.

Advantages for the CRO include: competitive advantage; gains in efficiencies; increased efficiency/speed; reallocated resources to higher value-add tasks; and improved trust/collaboration with the sponsor.

Q What steps should CROs take to evaluate investigative sites early in the clinical trial process to improve recruitment and create a shared vision of partnering and trust?

A CROs need to adopt a data-oriented approach to weighing selection and performance variables in the identification of study sites and target populations ideally suited to studies. In doing so, it helps to avoid non-active and non-enrolling sites by addressing the data "pain points" associated with dealing with disparate data sets. A data-oriented approach also overcomes a lack of institutional memory by eliminating manual processes for site selection.

Custom-built, cloud-based site selection and feasibility tools can combine internal and external data sources to create a complete target site profile and enable evidence-driven site selection processes. Ideally, these tools are integrated with a site activation tool to streamline activation and real-time reporting.

Technology can mitigate risk factors to recruitment and retention by finding the optimum alignment of top-performing sites with high patient availability and quickly assess which sites have performed best in past studies on a variety of performance categories, such as startup, throughput, retention and quality. It can also facilitate communications and a desire to build a collaborative, long-lasting partnership, fostering a foundation of trust and commitment.