CLINICAL INFORMATICS NEWS

Speeding Study Startup Through Better Collaboration and Data Flow

16**NOV**2015
By Barry Milton

A critical question facing many sponsors and contract research organizations (CROs) is whether another system to support study startup (SSU) is really needed. It's a fair question in the clinical world where the urgent need for better execution of clinical trials has led to a proliferation of technologies, namely the clinical trial management system (CTMS); the electronic trial master file (eTMF); electronic data capture (EDC); and others. Each of these solutions focuses on specific pieces of the clinical trial continuum, yet, they overlook aspects unique to SSU, a complex process that continues to stumble and stall clinical trial timelines.

The driving force behind better SSU is the need to jump-start trials at the site level, so trials can get to patients faster, a step that accelerates enrollment. Currently, the industry is honing in on the 50% of sites that fail to meet enrollment targets, resulting in a waste of human, financial, and timeline resources.

Research from the Tufts Center for the Study of Drug Development (CSDD) shows that in addition to this chronic under-enrollment, 11% of sites fail to enroll a single patient in a clinical trial, and a mere 13% exceed their enrollment target. Still, sponsors and CROs must manage these non- and under-enrolling sites while deciding whether to terminate them or recruit rescue sites, an activity that occurs in some 20% to 50% of clinical trials.

These are costly decisions, as evidenced by research indicating that site activation accounts for two-thirds of enrollment cycle time. Significantly, a 50% reduction in site activation time could reduce enrollment cycle time by approximately 30%.

With clinical trials costing millions of dollars, this reduction offers big potential for cost savings. These savings could be invested in recruitment and enrollment strategies—actions that support reduction in overall timelines. Achieving this goal starts with facilitating the SSU processes and interactions among team members and systems.

SSU is very complex, and a recognized bottleneck whose functions are performed by multiple people in multiple locations at the sponsor, CRO, and site levels, all of whom need to communicate and share data. To make this happen, a dedicated SSU system integrated with the other clinical trial technologies is essential, and represents an unmet need that is being addressed using cloud-based technology.

Improving Study Startup

There is no industry-wide definition of SSU, but this activity generally refers to a series of steps performed prior to the start of a clinical trial. These typically involve tasks such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget negotiations, patient recruitment efforts, and enrolling the first patient.

Managing these steps requires a solution that can handle input generated from all of these activities, allowing for real-time visibility into SSU status, while also receiving and sending information to and from cloud-based technologies already in place, such as the CTMS, and eTMF. Deciding to move forward with an SSU-specific system stems from the recognition that current systems are not designed for this purpose and do not offer this functionality.

A purpose-built SSU solution can add value as it uses an application program interface (API) to integrate with the other eClinical operations—the “clinical stack”. This approach optimizes the flow of data among the various integrated cloud-based technologies, improving business process and collaboration with sites, while avoiding redundant processes. Information only needs to be entered into the system once, allowing it to function as a single repository for study documents. Also, the technology allows for viewing of global study status, predict progress more accurately, and set global milestones.

Alistair MacDonald, COO, INC Research, acknowledges the value of a purpose-built SSU solution. “We chose to go this route because it offers enhanced visibility into the traditionally cumbersome process of activating sites for clinical trials. The system creates efficiencies through streamlined communication among sites, sponsors and CROs. This ultimately drives shorter timelines and cost savings for our customers,” he comments.

This need for better clinical trial execution is a recurring theme in the literature, and is the focus of a piece by Kramer and Schulman, who suggest that new technologies coupled with process change will drive a much needed transformation in how clinical trials are conducted. Simply adding new technologies without changing the business model will not unlock the desired economic and timeline benefits. Rather, they point to a business approach that uses technology to help stakeholders collaborate and share information.

Applying this strategy to SSU, one of the key bottlenecks of clinical trials, it seems that a new approach is needed to streamline site activation. With the advent of purpose-built cloud-based technology, better collaboration among stakeholders and data flow among integrated solutions becomes possible, allowing for a smoother rollout of the complex SSU process while reining in costs.

Barry Milton *is a director at GoBalto where he focuses on clinical trial start-up, site selection and patient selection technologies that bring clinical trials to patients faster.*

Barry Milton
Director | Pre-sales/client engagement | goBalto