APPLIED CLINICAL TRIALS

Expediting Study Startup Across the Globe

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By Craig Morgan

The need for more efficient clinical trials is driving greater use of cloud-based solutions, especially with the rise in globalization, a trend that is seeing participating sites venturing full force into regions such as Eastern Europe, Latin America and Asian countries. But this opportunity is not without its challenges. Conducting clinical trials in places with unfamiliar regulatory pathways, cultural differences, and limited infrastructure is highlighting the value of technology that streamlines a key bottleneck—study startup allowing stakeholders to better adhere to established timelines and budgets.

As globalization takes hold, stakeholders are embracing cloud-based solutions such as electronic data capture (EDC), clinical trial management systems (CTMS), and the electronic trial master file (eTMF), attempting to stem the average 6.7 year clinical development cycle, but study startup has been largely overlooked. Research from the Tufts Center for the Study of Drug Development (CSDD) indicates that it takes eight months to move from pre-visit through site initiation. This lengthy startup phase is not surprising, as many of the tasks associated with study startup remain paper-based or rooted in spreadsheets. Information is often shared using non-secure e-mail applications, and there are concerns about access to documents and storage. The costs associated with initiating one site have been estimated in the $20,000 to $30,000 range, plus another $1,500 per month to maintain site oversight. With dozens of sites often participating in the same clinical trial, the cost of initiating all of them is steep, further validating the need for process improvement.

This article explains how purpose-built technology designed to expedite study startup is addressing some of these seemingly intractable issues. Today's solutions are cloud-based and align with the goal of significantly impacting cycle times in clinical trials, a critical factor as the industry conducts more studies in non-traditional venues.

A Global Market

There is no doubt that clinical trials are moving outside the established markets of the United States and Western Europe. A report from the European Medicines Agency (EMA) states that the number of investigative sites involved in pivotal trials submitted in marketing authorization applications to EMA has changed dramatically in just six years. In 2005, 89.5% of sites conducting these trials were either in North American or the European Union. By 2011, that figure had dropped to 71.9%, with the rest of the world picking up the slack. Recent data from clinicaltrials.gov shows that of its 193,500+ registered trials, 46% are being conducted entirely outside the US, as compared to 39 percent taking place in the US exclusively. Moreover, research suggests that the 20 largest US-based drug makers conduct approximately one-third of their Phase III clinical trials outside the country.

There are many justifications for running clinical trials in emerging regions. Lower cost is often cited as the primary driving force, as clinical trials in low to middle income countries can cut costs in half and speed enrollment versus industrialized nations. Trials for rare disease could use many sites in diverse locations, leading to recruiting more patients in less time, and ultimately reducing duration of the trial. Also, conducting trials globally can help sponsors overcome regulatory barriers for drug approval in countries where large populations offer the promise of access to growing markets.

Cloud-Based Solutions

With globalization expanding its footprint, improved study startup is essential for building speed into the clinical development process. Continual reliance on standalone spreadsheets, multiple databases, and unsecured e-mail without audit trails is hardly adequate to manage study startup activities such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget execution, and enrolling the first patient. Overseeing these tasks from dozens or even hundreds of sites requires tracking and storing country-specific documents, ensuring that the most recent versions are being used, and identifying bottlenecks as the study startup process unfolds. From a management perspective, the degree of complexity is self-evident, and much time is wasted in status meetings because data contained in these documents and any subsequent analyses are not readily available.

Cloud-based solutions such as EDC, CTMS, and eTMF track ongoing studies, but a study startup solution is the missing piece designed to offer seamless sharing and visibility of study startup documents in real-time – globally. Purpose-built cloud-based study startup solutions are available, and using an application program interface (API), they can integrate with the other eClinical operations—the “clinical stack”—to optimize the flow of data among the various integrated components. They also enable better collaboration with sites, improve business processes, and avoid redundant processes. In addition, documents from the principal investigator’s database and the investigator portal can be accessed via a single logon. eClinical system providers extending their systems/services to encapsulate SSU activities, include Adobe Lifecycle, ePharmaSolutions, goBalto, NextDocs, Veeva and others.

With this solution, real-time viewing of study status is possible through smart workflows that standardize processes. Moreover, it serves as a repository for in-progress documents, and guides study teams to complete and track documents and tasks required for any site, country, or study based on company-specific standard operating procedures. Collectively, these benefits operate as significant timesavers in site activation.

Many elements make up the portion of clinical trials known as SSU, and using purpose-built cloud-based technology, it is possible to bring measurable change by impacting how these steps are performed and tracked from sites across the globe. Overall, the intent is to shorten clinical trial cycle time, reduce study costs, and ultimately speed much-needed therapies to patients.

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