CWeekly
A CenterWatch Publication

The Pulse on Study Startup Article Reprint • October 30, 2017

# Accelerating trials from the outset

*By Craig Morgan*

Research from the Tufts Center for the Study of Drug Development (CSDD) indicates that starting clinical trials from site identification through to activation is highly inefficient, with cycle times that have not budged in over two decades. Not surprisingly, study startup (SSU) has been receiving renewed focus from pharmaceutical companies under intense pressure to reduce timelines and abate the rising costs of drug development. The globalization of clinical studies has added an additional layer of complexity as differing regulations, limited infrastructures and cultural differences weigh heavily on study sponsors. These factors highlight the growing importance of technology solutions in stemming the tide.

The continual reliance on spreadsheets, multiple databases and unsecured email (Figure 1) without an audit trail is hardly adequate to manage SSU activities such as country selection, pre-study visits, site selection and activation, regulatory document submissions, contract and budget execution and enrolling the first subject. Overseeing these activities from dozens or even hundreds of sites involves tracking and storing country-specific documents, ensuring that the most recent versions are being used and identifying bottlenecks as the startup process unfolds.

From a management perspective, the high degree of complexity results in valuable time being wasted trying to find data buried in documents along with subsequent analyses that are not readily available. In this environment, a multitude of status meetings to understand the results and key metrics driving startup performance is routine. Using these archaic processes to manage activation of a site can increase risk and result in knock-on costs, due to poor site selection and under-enrollment. Though these costs are widely known, inefficiencies in startup continue to be largely overlooked, even as attempts are being made to taper the average 6.7 years clinical developmental cycle.

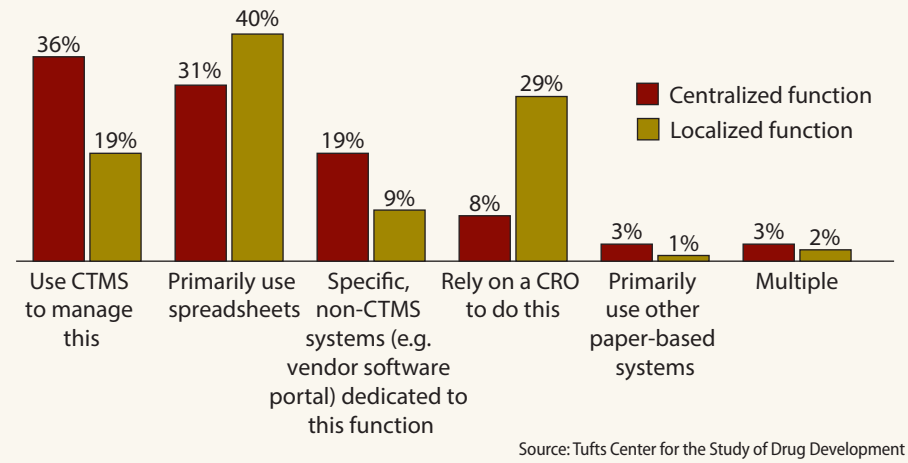
To tackle the plethora of SSU issues in a way that gains traction with clinical trial stakeholders, a collaborative approach has been deemed essential. One of the earliest efforts was undertaken by the Clinical Trial Transformation Initiative (CTTI), a public-private partnership representing academic institutions, biopharmaceutical sponsors, government liaisons, CROs and IRBs. The main conclusion from CTTI's research was that many stakeholders in the clinical trial process fail to routinely collect standardized measures of SSU cycle times, a practice that is common in many other industries. Metrics, though necessary, are not sufficient for driving down SSU costs and eliminating bottlenecks.

According to Tenley Koepnick, senior director of Clinical Operations at Transcatheter Heart Valves, the importance of embracing teamwork is key to mitigating issues that hinder SSU and derail timelines. Koepnick explains that teams should focus on:

- Proper planning and preparation
- Better protocol management to avoid amendments
- Improved site selection
- Strategic global considerations

Taken together, the need for metrics and streamlined collaboration underscores why the time is right for purpose-built, cloud-based SSU technology, the missing component in the eClinical stack of electronic tools that are being widely adopted for more efficient study conduct.

**Figure 1: Study Start-Up Management Technology**




Source: Tufts Center for the Study of Drug Development

Patients can't wait, nor should they have to because of the unwillingness of an industry to use existing technology to automate a cumbersome and error-prone manual process for starting trials. Vital data collected in real-time provides immediate status of how a study is unfolding. By ensuring global access and a platform for collaboration, SSU technology can bring measurable change at the inception of a trial, adoption which will shorten cycle times, reduce study costs and, most importantly, speed delivery of new therapies to patients.

*Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics to drug discovery. He leads the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times, improve collaboration and oversight in clinical trials. Email cmorgan@gobalto.com or tweet @goBalto.*