CWeekly
A CenterWatch Publication

The Pulse on Study Startup Article Reprint • August 7, 2017

Upfront planning crucial to process improvements and quality in clinical trials

By Craig Morgan

If you fail to plan, you are planning to fail. These words ring true when it comes to study startup (SSU), especially as the clinical trials sector embraces planning as key to boosting study quality. With research showing a continually stagnating timeframe for conducting clinical trials and a trend toward overhauling study performance, quality improvement is moving to center stage. With the availability of workflow-based SSU tools (Figure 1), proactive planning, process optimization and quality improvements—as measured by audit-readiness and the likelihood of passing regulatory audits—are within reach.

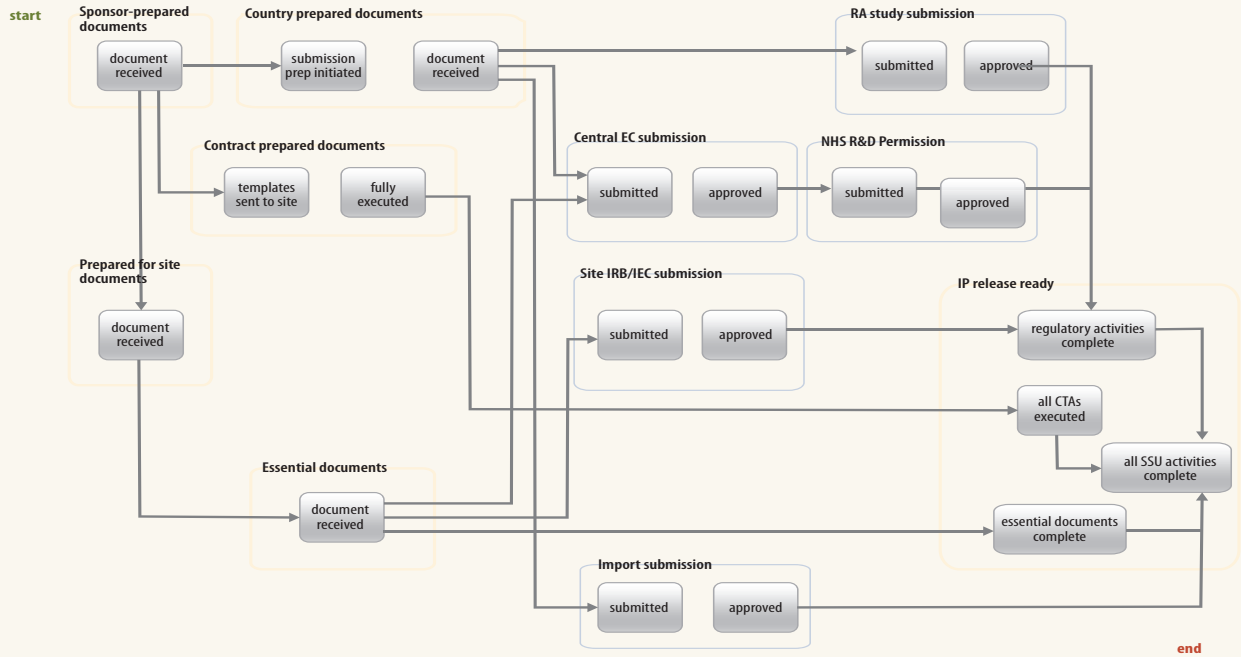
Planning works by getting it right from the beginning—prior to study activation—requiring sponsors and contract research organizations (CROs) to identify what is needed up front to reduce risk.

Too often, these planning aspects are not hammered out in the beginning, which results in problems not being identified until much later, after completed documents, artifacts and metadata have already been released to the electronic trial master file (eTMF). A better strategy is to employ processes that take an up front approach to preventing or mitigating problems associated with document completion.

Using a workflow-based approach to SSU critical indicators of trial quality can be assessed on an ongoing basis so that corrective actions can be made earlier; study quality improves by greater adherence to timelines, and ultimately by the percentage of artifacts flowing into the TMF that meet quality standards. This leads to a sharp improvement in quality as the study activation portion of SSU generates an estimated 40% of all TMF artifacts in the study lifecycle.[1]

As the industry turns its attention to better planning, regulatory bodies are spearheading efforts to ensure study quality, most notably via the November 2016 release of the first new Good Clinical Practice guideline (GCP) in twenty years, which states that the sponsor should implement a system to manage quality throughout all stages of the

A country-specific workflow.



trial process, including the beginning.

Through workflows, it is possible to launch the planning process by structuring artifacts specific to study activation, facilitating the exchange of data among systems, such as electronic data capture (EDC), clinical trials management system (CTMS) and principal investigator databases. With this capability, any and all needed documents can be defined. This is a major first step because on average, more than 400 artifacts within those documents can be structured using a workflow-based tool in accordance with a company's standard operating procedures (SOPs). From this group, an estimated 60 artifacts will ultimately flow into the eTMF, representing only those that are final, such as the completed clinical trial agreement (CTA), for example, which is composed of numerous sub-artifacts, including contract language, indemnity, confidentiality agreement, data privacy agreement and budgets.

Importantly, artifacts and documents can be created 17 weeks before site activation, making it possible to ensure the quality of these artifacts and associated metadata downstream, facilitating audit readiness at the site level.[2] Making this process change can yield significant improvements to study execution. Specifically, the regulatory quality assurance process, which should occur four weeks after site activation, involves a 21-week lag between the development of the artifacts and documents and the regulatory quality assurance review. This can be eliminated with the use of upfront workflows, which provide stakeholders with insight months earlier.

Quality is a major predictor of study conduct as it is key to reducing risk as the eTMF, the repository of completed documents, lacks the ability to track a study in real time. SSU empowers process optimization as evidenced by better cycle times and substantial improvements to TMF quality, i.e., fewer errors, and data that are more easily retrievable. Too often, this is not happening, as many companies still rely on homegrown systems that lack the capacity for up front planning, as well as data exchange among eSolutions and audit readiness.

1. Trial Master File Reference Model. Available at: https://tmfrefmodel.com/2015/06/16/version-3-released/. Accessed April 19, 2017.

2. Study startup around the world: A preliminary view from goBalto. ChromoReport. March 2017. Available at: https://www.gobalto.com/chromoreport-mar2017. Accessed April 18, 2017.

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.