APPLIED CLINICAL TRIALS

Speeding Clinical Trials Through eClinical Systems

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Testing the safety and efficacy of new drugs is a costly and complex process for pharmaceutical organizations. The rising cost and complexity compromises profitability and can stifle research and innovation. Adding to that frustration is the fact that technologies companies use for specific phases of a clinical trial, such as clinical trial management (CTMS) and trial master file (TMF) systems, cannot be applied to the other phases. The fact is, there is no single magic pill that can accelerate clinical trials.

The initial wave of technology tools focused on the clinical study conduct phase, after subjects were enrolled in the study. Systems that came out of this included CTMS as well as interactive voice response systems (IVRS) and electronic data capture (EDC) systems. Today, 100 percent of large pharma, 80 percent of small to mid-sized sponsors and 42 percent of CROs, use a CTMS.

Many organizations have also started implementing technology for the IP approval submissions after closeout phase of the trials process. One-in-five CROs is currently using an eTMF application, while about 44 percent of sponsors are doing so.

CTMS and eTMF are specialized systems of critical importance, but neither looks at end-to-end improvements in clinical trials, especially in the early stages of study startup. ETMS, eTMF along with purpose-built study startup represent the eClinical stack. Each tool—eTMF, CTMS, and study startup (SSU)—plays a distinct role in optimizing the full clinical trials process; each performs separate functions but serves overlapping user groups.

eTMF: document management for audit-ready documents

A CTMS provides operational awareness to the clinical operations department to help manage all aspects of the trial process. CTMS solutions were built to be all encompassing, but over time the clinical trial space became too complex to model in a single system. Other functions started popping up that required purpose-built architectures. In response, CTMS solutions broke off some of these functions into modules of a monolithic CTMS, such as the medicinal product dictionary, planning, or finance.

A primary limitation of using CTMS as a single management tool is its reliance on outside systems and transcription from documents for its data, which prohibits the ability to provide accurate and reliable data for regulatory reuse and provide progress and real-time performance metrics out of the box. This hampers the ability of CTMS to drive extremely time-sensitive and complex parts of a clinical trial, including study startup.

Study startup: the fastest road to first patient in

The process leading to site activation is complex. It requires sponsors to select sites, negotiate contracts, fund and staff the trial, gain ethic committee and regulatory authority approvals in accordance with varying global requirements, obtain supplies of the drug to be tested, and comply with pre-enrollment regulations. Most pharmaceutical companies still track these site activation tasks and documents using email, spreadsheets, shared file drives, or homegrown applications, making it difficult to track the overall status of the project.

Historically the study startup process does not help companies manage SOPs, accomplish critical milestones, meet contractual commitments, and compare sites efficiencies, and cycle times. Overall, it is hard to activate sites on time and budget, especially on a global basis where the laws and requirements may vary.

Pharmaceutical companies are increasingly implementing study startup applications that are purpose-built to enable sponsors, CROs, and sites to get clinical studies started in the shortest time possible. Study startup applications support communicating, reporting, tracking, oversight, and data management to speed study teams through activation, while also reducing time spent assembling and discussing status updates. All stakeholders view information in real time and have one single view of the truth.

Study startup differs from CTMS and eTMF in its ability to automate not only document workflows but also activities, in order to analyze activation cycle times and suggest processes that are more efficient. For example, keeping content that is not ready for inspection out of the TMF provides tracking of the transactional process before critical points are reached. This allows companies to adapt and make adjustments to hold schedule.

Integrating and automating the exchange of information between study startup, CTMS, and eTMF can provide efficiency gains and cost savings, but companies need to be pragmatic about systems integration and which system should own specific records. The system that owns the data (the system of record) should “talk to” the other systems that use it so that users don’t waste time and possibly commit errors because they have to re-enter data.

It is imperative that pharmaceutical companies look at the overall process, identify where specific tools can help, determine how those tools interrelate, and implement good information governance across the eClinical stack. To keep costs low, maximize competitive advantage, and to deliver life-saving therapies to patients as quickly as possible the pharmaceutical industry must leverage technology to accelerate clinical trials.