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Accelerating Clinical Trials

There's great demand to simplify the process - and now there's a way to do it.

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With thousands of investigational pharmaceuticals, biologics and medical devices in clinical trials, there is constant, intense pressure to bring promising candidates to market as soon as possible. As seriously ill patients worldwide wait for these new therapies, complicated study protocols, globalization and paper-based methods of conducting trials continue to delay market entry.

Fortunately, the current approach to clinical trials - widely acknowledged as complex and slow - has been driving stakeholders to embrace cloud-based solutions that bring efficiencies to the process. Still, one key bottleneck that has been largely overlooked: study start-up (SSU). Many believe an improved SSU process holds great promise for accelerating clinical trials.

SSU refers to a series of steps performed before a clinical trial begins, typically including activities such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget negotiations and enrolling the first patient.1 Since each of these steps has multiple components, delays in study timelines are commonplace.

A Need for Speed

According to the Tufts Center for the Study of Drug Development (CSDD), it takes eight months to advance from the pre-visit phase through site initiation,2 which refers to a visit that prepares the site for conducting the study. Moreover, the mean clinical development time is lengthy (an estimated 6.7 years2), translating into lost revenue ranging from $600,000-$8 million daily because a drug is not yet on the market.3 Recently, The New York Times published two stories showcasing the pressure to speed the clinical trials process.

One story detailed an approach known as "compassionate use,"4 inspired by consumer demand for access to promising treatments before the drugs are approved or clinical trials are even completed. The other described five programs from the FDA that create special pathways for quicker drug approval.5 As explained in the latter article, one-third of recently approved drugs qualify for two or more of the special programs.

These two articles come on the heels of the 21st Century Cures Act,6 a controversial bill currently winding its way through Congress. The bill is designed to accelerate the discovery, development and delivery of new therapies through a series of steps, including modernizing clinical trials, helping the entire biomedical enterprise coordinate more efficiently to find cures faster and removing barriers to increased research collaboration.

“Modernizing clinical trials” involves implementing adaptive trial designs and deploying the most modern statistical and data tools, while significantly reducing existing or duplicative paperwork requirements. On July 10, 2015, the bill passed the House of Representatives by a vote of 344-77 and is headed for a vote in the Senate.7

Time for Disruptive Change

With a flurry of attention focused on speeding clinical trials, the need for collaborative, cloud-based solutions has never been greater. Research indicates that lengthy startup times are problematic for many stakeholders, including companies seeking to develop new treatments, insurers formulating policy, providers and patients.8

Addressing this issue is a challenge because too often, information needed to launch clinical trials still resides in multiple databases, leaving SSU activities to be performed on Excel spreadsheets, email and shared file drives.9 Consequently, too much time is spent on non-productive activities such as status meetings, because the desired information is housed in various locations and not readily available.

These inefficiencies can be minimized using a purpose-built SSU solution, the missing piece in a world of electronic tools that are becoming widely adopted to improve study performance. With this type of solution, real-time viewing of data and smart workflows that standardize processes become possible.

Streamlining Solutions

Some key advantages of the solution are that it functions as a single repository for study documents, information only needs to be entered once and documents from the study database can be accessed using a single log-on. Overall, the technology is designed to provide better collaboration with sites, improve business processes, identify bottlenecks and avoid redundant processes.

An SSU case study from a major pharmaceutical company conducting oncology trials showed that eight months after implementation of a cloud-based SSU solution in its U.S. sites, the company experienced a 32% reduction in SSU time.10 The company reported using manual processes before the implementation, which provided no way to identify bottlenecks.

In light of the ongoing pressure for faster-paced drug development, adopting cloud-based technology to improve the multi-faceted SSU process aligns with the goal of faster cycle times in clinical trials. eClinical solutions for SSU are poised to make a major impact in terms of cost savings and faster market entry, making valuable therapies available to patients sooner.

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