Industry Drive to Improve Information Exchange and Speed Study Start-up

Last year, the European Medicines Agency recommended 84 medicines for marketing authorisation. Half of these medicines (42) contained a new active substance that had never been authorised in the EU before[1]. Furthermore, in the last 10 years, the number of registered clinical trials globally has increased five-fold[2]. Innovation is accelerating, yet the time it takes to run a trial is no faster. As life sciences companies take action to speed up study execution, there is a significant opportunity to make clinical research processes more efficient.

Industry adoption of function-specific technologies is improving clinical trial execution and fuelling progress, according to the Veeva 2019 Unified Clinical Operations Survey. The research shows that standalone applications such as electronic data capture (EDC), electronic trial master files (eTMF), and clinical trial management systems (CTMS) are now utilised by the majority of sponsors, CROs, and research sites. However, fragmented processes and siloed systems are still slowing trials. These fragmented processes cause numerous issues, including making reporting across different applications difficult, according to survey respondents. This reinforces the need to move to unified systems for better visibility and faster execution.

With advances in science revolutionising the clinical industry, there are now even more opportunities for research sites, academics, CROs, and sponsors to automate information exchange, streamline processes, and utilise new technology and data to increase the speed of drug development.

The two key areas that present a tremendous opportunity to drive greater efficiency and speed trials are improving information exchange among study partners and accelerating study start-up.

Improving Information Exchange Boosts Collaboration

Developments in personalised medicine, genomics-based research, and immuno-oncology, have revolutionised the clinical industry. However, there is still room for evolution in sharing information between organisations working together across the clinical environment. The industry's increased interest in a new class of medicines is also leading to new challenges across the drug development process that slow down trial execution. One of the main issues affecting speed is collaboration.

Survey respondents identified information exchange during trials as a major challenge. In fact, all respondents highlighted it as an area for improvement. Sponsors, CROs, and research sites still struggle to exchange the most basic of information in a standard, consistent way. They are motivated to improve information exchange by the potential to reduce manual processes, improve collaboration, and increase visibility and oversight, during clinical trials.

Efficient Collaboration is Key to Reducing Trial Times

Sponsors are increasingly partnering with CROs to drive greater efficiency, augment available resources, and leverage best trial practices. CROs have helped to make trials more efficient but adding partners to the mix has also introduced growing complexity. Sponsors and CROs use an average of three methods to share trial data and documents, including email, portals, and file share.

Exchanging information with sites becomes even more complex, with 78% of sponsors and 74% of CROs relying on email to share information with sites. And many still rely on paper shipments. In fact, half of sponsors, and a third of CROs, reported this as a major method to exchange with sites. Not surprisingly, due to manual methods of data exchange, respondents have challenges with tracking, reporting, and misfiled and/or missing documents. These traditional administrative methods stifle the ability for sites to quickly execute trials.

Streamlining Information Exchange

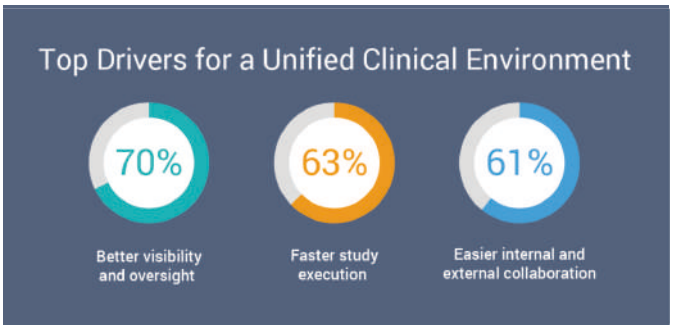
Without connected technology systems, clinical research sites also find it difficult to share data seamlessly with trial partners. Therefore, sponsors must invest more into sophisticated technologies that will help to make sites more efficient.

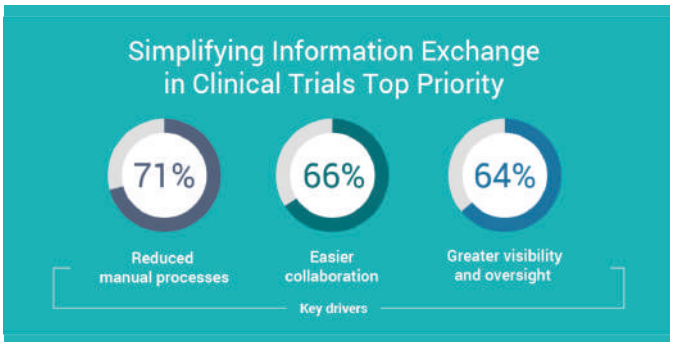
Sites are forced to learn the systems and adapt to different ways of formatting and submitting information depending on which sponsor they are working with on any given trial. Multiple systems mean multiple, individual logins are required to manage trials, which also slows trial execution.

Adopting a streamlined approach to exchange information can enable sponsors, CROs, and sites to improve collaboration and speed trial execution by reducing administrative burden.

How to Accelerate Study Start-up

Study start-up is one of the most critical parts of the study process





and can have a significant impact on the overall speed of a clinical trial. While science has rapidly advanced, the resource-intensive study start-up phase of clinical trials still runs at the same speed as a decade ago[3].

Frustration with study start-up is widespread, likely due to the heavy reliance on manual processes. Most still use spreadsheets to manage this area, with 81% of respondents reporting spreadsheets as their primary start-up tool. The use of spreadsheets in the study start-up phase is a challenge because manual methods slow down processes and limit visibility into status.

Utilising digital tools in the study start-up process enables CROs to be more responsive and coordinate actions more efficiently. A recent global survey carried out by Deloitte and MIT Sloan Management Review[4] found only 20% of biopharma companies are expanding their use of digital tools. This highlights the extent to which the life sciences industry still trails other industries in adopting new technological solutions to enable timely delivery of information to stakeholders.

The shift to adopt study start-up applications is also on the rise. In fact, nearly a quarter of respondents reported adoption of newer, purpose-built study start-up applications to speed cycle times. This shift will streamline study start-up, enable trials to run more quickly, and allow for faster enrolment of patients. This was reflected in the majority of respondents citing faster study start-up times as the primary driver to improve the study start-up process.

The use of e-signatures can also facilitate faster trial execution. Studies are further slowed down when sponsors and CROs are forced to wait for signatures on financial disclosures. E-signatures allow stakeholders to sign off documents instantly. Eliminating siloed systems, like manual signatures, in favour of streamlined applications allows for greater agility and stronger collaboration, whilst enhancing compliance and end-to-end control.

Digitisation and Developments in Healthcare Technology will Impact Trials

The life sciences industry gathers large amounts of data during the development of a treatment or therapy. With advances in personalised medicines, telehealth and medical devices, there is potential for new technologies to change the way we conduct trials. Using wearables, for instance, could help to extend the scope to enrol patient populations that are smaller and widely dispersed. Used effectively, data from these types of technologies can help the life sciences industry learn how to best develop trials that maximise the patient's utility. In addition, wearable tech can help to further understand disease states and how drugs function.

The Journey to Streamlining Study Execution

Sponsors and CROs recognise and are committed to the significant opportunity to improve the way trials are run and are committed to improving trial efficiency, visibility, and collaboration. Therefore, we are seeing progress in the adoption of advanced clinical applications. Better alignment amongst stakeholders will make drug development more efficient and accelerate time to market.

The continuous advancements in scientific innovations will mean that advanced cloud-based platforms and data analytics technology can help processes to keep up with speed drug development. Time is crucial; manual processes can affect patients awaiting life-saving therapy. The move to a unified clinical landscape offers a solution.

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