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SmartViews:

The unsexy plumbing of clinical trials

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By Craig Morgan

New technology could dramatically speed up the clinical development process



There is no doubt that clinical research is critical to advancing medicine and public health. Clinical trials play an essential role in drug development by effectively demonstrating the efficacy and safety of a pharmaceutical compound, yet they are not for the faint of heart. Conducting even one is a monumental, complex and resource-intensive endeavour that relies on a multitude of stakeholders, workflows, processes and information systems. At any point, issues can surface that derail a study's timeline and result in all-too-common delays in regulatory filing, market entry and, ultimately, delivery of a new therapy to patients.

With a large number of drugs rushing towards the patent cliff, there is intense pressure to speed clinical trials and control costs, yet inefficiencies tied to complicated protocols, globalisation and paper-based methods have stalled such efforts. Companies are also in need of an efficient process to eliminate unsuccessful trials earlier and intervene before a 'rescue' is required, enabling resources to be more effectively deployed.

Since clinical trials are a major overhead, effective management of resources is a key corporate objective; according to the Clinical Trials Transformation Initiative, the majority of the costs incurred in clinical trials are associated with human time and effort making unnecessary complexity burdensome and expensive.

Technology to the rescue?

For some years, Dr Janet Woodcock, director of the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA) has been calling for "transformational change" in the way clinical research is conducted. She describes a vision for clinical research akin to the national highway system or the energy grid, where infrastructure links research and community practice, and facilitates universal participation in the creation of clinical evidence and its subsequent adoption by physicians.

But what is clinical trial infrastructure? In 2010, the National Academy of Sciences took a look, publishing the results of a workshop conducted by the Institute of Medicine (IOM). Participants lamented that most clinical trials were conducted in a 'one-off' manner, where the necessary trial components were brought together for a set period of time then disbanded once the trial was complete.

Attendees suggested a streamlined clinical trial infrastructure that would enable investigators to draw on existing resources rather than reinvent the wheel each time. Sadly, the situation is much the same today as it was in 2010, but growing discontent, dismal performance metrics, financial pressures and new technologies are starting to move the needle. With technology transforming other sectors, its application to clinical trials is long overdue, especially considering that it is one of the most manual, error prone, complex, bureaucratic and, above all else, expensive bottlenecks in the creation of new medicines.

Recently, we have seen a number of technological solutions aimed at automating clinical operations – clinical trial management system, electronic data capture, electronic trial master file and study start-up – each of which represents a quantum leap forward. Technology brings its own share of challenges, of course, not least the need for integration of different systems, but clinical research paradigms are shifting as new technologies move the focus from loosely integrated back-office data capture and aggregation tools to cloud-based apps and development architectures that enable teams to collaborate in real-time.

Start at the very beginning

“With globalisation expanding its footprint, improved study start-up is essential for building speed into the clinical development process,” says Jeff Kasher, president of Patients Can’t Wait and former vice-president of clinical innovation and implementation at Eli Lilly. “Conducting clinical trials in places with unfamiliar regulatory pathways and limited infrastructure is highlighting the value of study start-up technology that allows for better standard operating procedure and regulatory compliance.”

While study conduct has been the main focus of automation, awareness is building among stakeholders of the need for better study start-up processes – a perpetual bottleneck in clinical trials. Here, automation of activities, such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget execution, and enrolling the first patient, has been linked to shorter clinical timelines, better study quality and fewer costly one-offs. Such technologies represent the transformational change envisioned by Woodcock, combining data integration with innovative cloud-based solutions for seamless integration. As clinical trials continue to evolve, drug companies will no longer be able to rely on existing, tried-and-tested manual methods, yet technology integration in the eClinical stack – though a necessary component of the solution – is not sufficient to deliver the needed productivity step change.

It is not enough to be able to access the same data; companies need the ability to translate data into targeted information based on user roles and to distribute work throughout a team with appropriate approvals and audit trails along the way through configurable workflows. The new paradigm of end-to-end clinical trials infrastructure utilising ‘best of breed’ technologies driven by cloud-based solutions leave the unsexy plumbing of traditional clinical trial systems behind and give us the tools we need to tackle the formidable challenges that lie ahead.



Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics and bioinformatics to drug discovery. He currently heads up the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times and improve collaboration and oversight in clinical trials.