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e-clinical trials will speed up trials, lower costs, improve data quality and compliance

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Ahead of Clinical Trials Day celebrated on May 20, BioSpectrum Asia speaks to eClinicalHealth and Quintiles IMS experts to highlight the benefits and challenges in adopting e-clinical solutions



Clinical research is one of the most expensive areas of drug development. Bringing an approved new drug from initial private investment to a patient takes over 10-13 years and involves huge amount of capital investment. Pharmaceutical companies are grappling with these huge costs and constantly in search for inefficiencies in the clinical trial process, in hopes of streamlining it by focusing on key elements, like management models, new technologies and creative study approaches. With many new viruses and bacteria daunting the globe, there is an increased necessity to innovate and develop new drugs and safeguard public health. Also, with patent cliff looming large, pharmas need to evolve their R&D efforts to ensure that the core of their business keeps pace with the changes. Many firms are already looking at clinical trials in new ways and adopting technologies to speed up the process and contain costs. In order to leverage the high growth opportunities, 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 e-clinical stack. To keep costs low, maximise competitive advantage, and to deliver life-saving therapies to patients as quickly as possible, the pharma industry must leverage technology to accelerate clinical trials.

A new market research report by Global Industry Analysts states that Asia Pacific is the fastest growing market for e-clinical trials with a CAGR of 13.6 per cent. Driven largely by the huge number of clinical studies and pressure to expedite clinical trials, the global e-clinical trials market is projected to reach $3.7 billion by 2020. The adoption of novel software solutions during clinical research and rising government funding to support clinical trials and encourage drug development are few key factors fuelling the growth of the market. Emerging markets, including China, South Korea, Taiwan and India are attractive destinations for outsourcing clinical trials due to the presence of a large patient population and the low operating cost of conducting clinical trials in these countries.

Less stringent regulatory guidelines compared to developed nations, shortage of trial volunteers in Europe and North America, and the growing number of life sciences research companies and contract research organisations (CROs) are the other factors propelling the demand for e-clinical solutions in these emerging markets.

Excerpts from the interview with Kai Langel, Director (Patient and Technology Solutions) and Co-Founder of eClinicalHealth, and Mike Montello, Vice President, R&D Solutions IT, Quintiles IMS:

What are e-clinical trials and how are they conducted?

Montello: e-clinical trials are technology-enabled trials, whereby software systems are leveraged in clinical development to automate processes. Over the past 20 years, technology providers have made great strides designing tools aimed at streamlining clinical development, such as Electronic Data Capture, e-Trial Master File (eTMF), Clinical Trial Management System (CTMS), and Safety Database solutions, which offer capabilities that allow us to digitally maintain and manage all aspects of clinical development operations. Now, as technology matures, many companies are taking e-clinical trials to the next level by harnessing the latest digital advancements and massive amount of data captured over the past 20 years and applying them to clinical trials in much more innovative ways.

Langel: Patient-centric e-clinical technology can be used to conduct clinical trials using different models. The traditional trial model is very site-centric, where typically a CRO is responsible for selecting a large number of clinical trial sites, who will then recruit and manage patients. The model can be improved by utilising technology to make the process slightly more efficient by capturing data electronically or by using digital patient recruitment tools.

However, with a little more strategic planning, the technology can be applied also in a different way. Rather than doing most things manually, sponsors can consider how to best use technology to achieve their goals. Many trials processes can be highly automated using the right technology. For example, site training and payments, patient education and consenting, site payments and patient reimbursements, direct-to-patient data capture can all be automated to a large extent. This will make the site's work much more efficient and reduces the manual work required by the CRO, the sponsor and the sites. This can help save significant costs as well as improve data quality and trial operations transparency.

Technology can also be used to completely transform the trial model to be patient / technology-centric, rather than site centric. Virtual / remote trials can operate without relying on the services of traditional physical sites. Patients can get improved service levels (24/7, fast response times) from a technology-driven virtual site. The virtual site can conduct e-visits with patients, support them through consenting and trial conduct, without the patient ever having to travel to a study site. Many trials can benefit from this model, either by making them completely virtual / online trials, or by utilising home nursing services where nurses can visit the patients to conduct tasks like ID check, physical exams and blood draws for lab tests. This model allows studies to start up very fast and be conducted very efficiently as most of the study data will be e-source. Overall, this will help dramatically reduce the trial cost, but at the same time it can improve compliance and data quality as the data is captured using a direct-to-patient model and will be captured in a more real time manner and checked for consistency at the point of entry.

Key trends in e-clinical trials space

Montello: A noticeable trend is a shift away from large, monolithic software packages for e-clinical solutions and towards modular technology that targets specific clinical challenges, such as accelerating site and study start-up and investigator payments. In addition to simply optimising operational processes, forward-thinking companies are using novel applications of technology to drive investigator and patient engagement and reduce paper-based and manual tasks. However, perhaps the biggest trend we are seeing is around the application of data. The industry has collected a significant amount of operational data over the years, at the country and therapeutic level, and in a controlled and real world environment. The next generation of clinical development is going to be driven by our ability to harness that data and use it to glean insights that can optimise and accurately predict, a clinical trial's trajectory.

Langel: Most sponsors today are moving more towards patient-centric trial designs, including fully remote patient-centric trials as well as using more patient-facing elements in clinical trials. New clinical trial regulations require lay summaries to be shared with patients. Patients are also very interested in the research and the study's results and having access to this information is a key motivator. The technology exists today to make this process very easy and efficient for sponsors.

Highlight some of the key drivers of e-clinical trials market

Montello: The cost of executing clinical research is continuing to rise, while at the same time, our approach to developing new therapies for various rare diseases is becoming more complex. Continuing to digitise and make clinical trials more electronic offer several benefits, including speed, quality and lowering cost. They allow us to more intelligently design our studies to minimise protocol amendments, which are both timely and costly. It offers novel and effective approaches for finding patients and speeding recruitment. And, most importantly, they enhance our quality, enabling us to bring safer, more effective therapies to patients in need.

Langel: There is much more focus on the patients across the life sciences industry. Pharmaceutical companies are developing "beyond the pill" solutions. The FDA has also been sending a very clear message to the industry that they expect patients to

be much more engaged through all stages of drug development, including protocol design and feedback. Clinical trials also suffer from recruitment and retention challenges, and making trials more patient centric and convenience are key steps in addressing this. Focusing on patients will result in several downstream benefits as well, including reduced costs, faster trial completion and increased compliance and data quality.

What makes Asia an attractive destination for e-clinical trials?

Montello: Asia has been a high growth region for executing clinical studies, but it is a particularly attractive destination for e-clinical trials because participants there are early adopters of technology, including mobility. The Asia region has generated new and innovative ways of working and we have piloted new applications on smartphones and tablets to enable researchers in the field to enhance productivity.

Langel: Asia has very high technology adoption and infrastructure in most countries. There are also lots of local trials that need to be completed relatively fast. There are many opportunities in local clinical trials in Asia to use e-clinical technology to conduct trials faster while lowering trial costs.

What are the major challenges for e-clinical trials industry?

Montello: As we apply new technology to streamline and optimise clinical trials, we are going to encounter global regulatory challenges related to data privacy, security, consent and more. These are important issues to work through as we need to always ensure compliance with local and global regulations. At the same time, emerging technology is key to unlocking speed, lowering cost and driving higher quality. It’s incumbent upon those of us in drug development to drive operational and regulatory adoption of these new approaches.

Langel: The biggest challenge is change management within the pharmaceutical companies themselves. They are large organisations with strict operating procedures that are not easy to change. Even though everyone might agree that technology solutions and process innovations make perfect sense, it can be sometimes too difficult for companies to purchase the technology and services they need to operationalise the trials. It is also not just about the technology, there is a significant design and support element too, the technology must be applied the right way and sponsor companies themselves often lack this expertise. They must rely on an experienced technology partner that can actively guide them through the process.

Are pharmas keen to adopt e-clinical solutions?

Montello: Both pharmaceutical companies and CROs are embracing e-clinical solutions, and it is easy to understand the appeal. The potential for accelerating and improving clinical trials via these solutions is tremendous, and as technology continues to advance exponentially, the possibilities only get more interesting. One area where we will begin to see significant gains to advance drug discovery is around optimising the clinical trial process for patients. For example, some biopharma companies are beginning to explore the potential use of virtual reality to educate patients about new trials and bring to life processes that were previously confusing and burdensome to patients, such as informed consent. At the same time, we are expanding the scope of e-clinical solutions to not just improve the processes we already have in place, but also to look ahead and predict performance using machine learning. As we layer machine learning on top of the existing, digitised processes, we will embark on a new level of clinical development performance.

Langel: They are, but it can still be a slow process to adopt these solutions beyond small pilots. In a recent webinar about remote / virtual trials with more than 230 registrants, we surveyed the audience about their plans in the next 12 months to adopt remote / virtual trial models and 40 per cent of the respondents said that they have plans to start virtual trials within that period. It is a very promising result and shows that the industry is taking concrete steps in this direction.