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"E-clinical trials are the logical enabler and consequence of the future of medicine"

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BioSpectrum Asia spoke to Ms Andrea Zobel, Senior Director of Product Management, Clinical Trial Supplies and Logistics at PAREXEL. Excerpts from the interview:



The rising cost and complexity of clinical research is compromising new drug research and development. Speaking to BioSpectrum Asia, Ms Andrea Zobel, Senior Director of Product Management, Clinical Trial Supplies and Logistics at PAREXEL, highlights the importance of E- Clinical trials and their role in speeding up clinical research and encouraging discovery of novel drugs.

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

The term “e-clinical trial” is used for clinical trials in which technologies are used for documentation, processes and communication. This includes e-clinical technologies which have been available for several years, such as clinical trial management systems (CTMS), electronic data capture(EDC),interactive response technology(IRT) systems, electronic clinical outcome assessments (eCOA), and e-diaries for patients. These solutions have replaced paperwork and manual processes while enablingan increase in remote activities, such as remote monitoring in place of frequent visits tosites and investigators by clinical research associates (CRAs).

Taking remote activities even further,a clinical site can be replaced by a ‘virtual site,’ with patients recruited prior to the study and connected to the investigator during the study conduct with the help of e-clinical technologies.In this situation, a patient is supplied with devices for communication, diagnostics,treatment, and the transfer of data and outcomes throughout the entirety of the study.

Technologies are also available and in development for the drug product itself. Smart packages can monitor various data points and provide information about drug intake and therefore compliance of the patient. In the clinical supply environment, various technical solutions are available for tracking the location and status (i.e., temperature) of the drug.’Smart labels’ can be applied, which allow label information to be changed electronically without the need for re-labelling. This allows just-in-time labelling in the case of pooled medication that can be assigned across multiple studies. It also enables the updating of expiry dates.Additionally, mobile applications connect drug packages via barcodes or sensors with databases and give patients, investigators, and all players in the supply chain access to important data.

- **Outline a few key trends in e-clinical trials space**

Two key trends in the e-clinical trials space arethe shorteningof timelines and the reduction of costs by replacing costly, manual processes with automated technologies. Patient and site centricity are also evolving due to e-clinical trials, with many sponsors considering how they can improve the patient and investigational site experience during a clinical trial.

Personalized medicine is another trend being altered by e-clinical trials. While this trendreduces the number of patients who can take a certain medication, it also increasesthe need to find patients for clinical trials. To encourage participation, clinical trials should offer patients a convenient environment, easy access to trial information, and the option for simpler travel. Not only do these factors allow patients to participate easily, but they alsoprovide specialized investigators with the option to expand the region from where they can enroll patients.All of this is only possible when e-clinical technologies are available.

- **Please highlight some of the key drivers of the e-clinical trials market**

Patient and site centricity are key trends in the e-clinical space and drive implementation of e-clinical solutions. Many consumers now use health technologies in their daily lives in the form of wearable activity trackers. Users are oftenactive on social media, sharing their health and activity data with their community of followers. This trend toward shareable e-health is an important trend in healthcare, with e-clinical trials now designed to offer a similar experience. For some disease indications, devices are already established and regularly send health data to the attending physician. This enables ongoing supervision and action, when necessary, improving patient safety, which is the most important detail in clinical trials.

Today, there is also a trend toward more outpatient treatment and homecare instead of hospitalization. E-clinical trials supportthis trend by enabling the treatment of clinical trial patients in outpatient environments or ambulatory care.

Orphan drug development and new drug types, especially Advanced Therapy Medicinal Products, also drivethe development of e-clinical trials. This is because the low number of patients and investigators with experience in these disease areas requires alternative methods for recruitment and treatment. Additionally, the unique nature of the trial drug influences the trial processes. E-clinical technologies enable the treatment of patients by fewer treatment centersbecause data collection and communication is possible via e-clinical technologies like patient mobile apps, eCOAs, wearables and smart drug packages, which send the data to central databases for automatic, central analysis. This eliminates the need for patients to visit treatment centers as often for check-ins and to retrieve new treatment materials.

- **Please elaborate the phrase ‘E-Clinical Trials is the way forward’**

E-clinical trials are the logical enabler and consequence of the future of medicine, as itmoves toward personalized medicine and e-Health. In a world that increasinglyrelies on social media, smart phones, and health trackers,it makes sense that these technologies should also be made available for patients and investigators in clinical trials. Their utilization can expedite trials, and therefore drug development, due to increased data quality and decreased costs and time effort.

- **In your opinion, what makes Asia an attractive destination for e-clinical trials?**

Asia is an attractive market for clinical research, accounting for 54 percent of the world’s population growth from 2010 to 2015. As an emerging market for pharmaceutical companies, Asia presents various advantages in countries such as India and China, which, with their large populations and genetic diversity, offer the opportunity to conduct global studies at a lower cost. The geographical distribution of potential patients makes the option of e-clinical trials most attractive to reach the most people.

As the pharmaceutical market expands in the region, challenges may be encountered at a regional or country level. In India, for example, there are local and global regulatory mechanismsas well as laws and guidelines with which companies must comply. Asian regulations related to the International Air Transport Association (IATA) also present challenges that have forced different parties, such as couriers, to adjust and specialize in the pharmaceutical logistics industry.

Another reason why Asia has become an attractive market is due to is the patient behavior and expectations during clinical trials. Patient surveys in Asia have shown that the individuals are interested in receiving instructions and reminders via e-communication, with a trend toward text messages and email. This preference for various communication methods is very different from E.U. and U.S. patient preferences,making Asia an attractive area for e-clinical trials.

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

Major challenges for the e-clinical trials industry are the requirements and regulations for data privacy. A patient in an e-clinical trial performs many activities in his home environment. This requires regular support to manage the e-devices, perhaps by a customer care center. It is also critical to supply all necessary devices and clinical trial materials to the patient’s home. That said, patient datamust be available but also secured and protected. As patient data should never be available to the sponsor (*Declaration of Helsinki, ICH*), CROs must have restricted access to this information.

- **Are pharma companies keen to adopt e-clinical solutions?**

From a biopharmaceutical service provider perspective,we are seeing significant interest in adopting e-clinical solutions. Pharma companies are driving this revolution by initiating pilot studies, such as those for wearables, smart drug packages, remote e-clinical trials with virtual sites and comparisons of the “traditional” study concept versus e-clinical trials. Some companies have even changed their company strategy towards the ‘site-less’ trial and smart drug packages, which track and send drug intake by patients.

- **Please shed some light on the regulatory aspects of e-clinical trials.**

In addition to the previously mentioned regulatory challenges for data privacy, import/export regulations make the usage of some technologies difficult, such as restrictions for import of RFID (radio-frequency identification) sensors, batteries, and IATAregulations.

Another regulatory hurdle is the absence of regulations for investigational medicinal product (IMP) deliveriesand storage and handling at a patient’s home. This is a requirement for an e-clinical trialwith remote patients, but local pharmacies and medicinal product regulations often do not allow this or do not provide clear directions as to how patients can maintain treatment by themselves.

The increase of regulatory requirements is also driving the use of e-clinical technologies. For example, the request for temperature monitoring of clinical drug shipments in E.U. GMP, Annex 15 is increasing the need for and usage of temperature tracking devices and systems. A change in the labelling requirements in the upcoming E.U. clinical regulations makes re-labelling at the clinical site nearly impossible and drives the development of smart labels to overcome this challenge.

- **In your opinion, will e-clinical solutions help in speeding up the clinical trials and encourage drug discovery?**

E-clinical solutions will help to speed up clinical trials by speeding updata collection and analysis and helping to provide the study results earlier.Trials will also be expedited when deployed technologies reach more patients to speed up enrollment. E-clinical solutions will enable patients to participatewho have currently no possibility of enrolling and will provide an environment that helps patients to integrate the clinical trial in their daily lives. With e-clinical trials,enrollment is increased, trial timelines are shortened, and earlier market access for new drugs is possible.

For some indications, e-clinical technologies enable clinical development where it would otherwise be difficult to execute, especially for orphan diseases, personalized medicine, and special drug products.