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Challenges in mHealth integration'

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Singapore: Medidata Solutions is a provider of cloud computing-based solutions for clinical development process to improve study design, protocol development, trial planning and management, electronic data capture (EDC) and management of patient clinical data. In an interview with BioSpectrum Asia, Mr Motohide Nishi, VP of R&D APAC, Medidata, Japan talks about the prospects of mobile technology in healthcare delivery and challenges in building mHealth landscape in Asia.

How significant are mhealth solutions and how far have the Asian countries integrated mobile technology for healthcare delivery?
As the drug development market continues to expand globally, more clinical trials are being conducted across Asia. China alone is expected to become the world's second largest pharmaceutical market after the US by 2020, with spend projected to reach $260 billion according to the Journal of Pharmaceutical Policy and Practice.

However, with this increase in activity comes increased costs and the need for additional resources. That's why leading life sciences organizations in Asia are beginning to recognize the potential new mobile technologies have to help bring novel and important medicines to patients faster, safer, and more efficiently and are embarking on the early stages of exploring these devices in clinical development. mHealth technologies have the capability to collect powerful data that can reveal what is and what isn't working in a trial, providing insight needed to make changes early, saving time, money and resources. Additionally, mobile devices help reduce the burden on those participating in studies by streamlining routine procedures, eliminating

unnecessary ones, and reducing clinical trial site visits.

While the use of wearables is exploding globally, the opportunity for mHealth data to advance clinical trials seems particularly prevalent in South Korea, China and Japan.

South Korea is one of the world's most technologically advanced and digitally connected societies. Almost 80 percent of South Koreans have a smartphone, and 97.7 percent of 18 to 24-year-olds do. South Korea is already leveraging innovative technology to drive scientific discovery and has the healthcare infrastructure needed to hit the ground running (for example, the Severance Hospital in Seoul has a dedicated facility for clinical trials, a large medical tourism practice and a robotic surgery center). With South Korea's high level of digital connectedness and its rapid growth in the life sciences space (Seoul is currently the #1 city for clinical trials in the world), South Korea may soon be a driving force in the adoption of mHealth technology in drug development.

In China and Japan, wearable devices and apps are getting more and more popular among consumers to collect and analyze their health data. This growing trend is beginning to pave the way for such technologies to be incorporated in clinical trials and for patients to play a more active role in the drug development process and managing their own health. Many Chinese tech companies are launching mHealth-focused products that are revolutionizing the way patients engage in and receive healthcare services and information. For example, a company called Haodf.com launched an iPhone app in March 2011, which collects basic information from hospitals and doctors (therapeutic specialty, rankings, etc.) for users' reference and allows them to rate a doctor's performance. Additionally, the Spring Rain Doctor app claims to have 45,000 doctors online and can be connected to patients for phone inquiries. This app also provides advice and medical information in conjunction with Spring Rain's online information database.

A number of academic organizations across Japan, including Saga, Tokyo, Jyuntendo and Mie University, have recently incorporated mHealth technologies into clinical trials, using data generated from these devices to assess such correlations as activity level and pain relief, and the effectiveness of self-care among Type 2 Diabetes patients. mHealth is even presenting the opportunity to help reduce the suicide epidemic in Japan (the nation's seventh highest cause of death) by providing real-time insight into sleeping patterns of young adults suffering from depression. Identifying outliers in this kind of objective data can allow for faster intervention and the ability to save lives.

Do you think rest of Asia can also integrate wearables devices in their healthcare delivery ecosystem?
Yes. As wearable devices and connected biosensors become more sophisticated and easier to use, there is strong potential to use them in clinical trials to gather better data on patient response to therapy and progression of disease. Pharmaceutical companies both in Asia and around the world are excited by the potential for 'digital biomarkers' to provide insights that they would not have been able to identify with traditional clinical data. At Medidata, we believe mHealth clinical trials will soon be the standard of practice around the globe. Asia and other leading clinical trial markets that marry the 'connected world' of smart phones and wearables to their drug development program may soon be gathering better data, creating enhanced patient experiences, and ultimately conducting more efficient trials.

What is the regulatory landscape of mobile health technologies?
While mHealth holds the promise of new insights and research endpoints, its use in the highly regulated, scientific environment of clinical trials requires rigorous diligence and protections. Currently, there is no global standard for mHealth in clinical trials, and the use of wearable devices raise regulatory challenges as sponsors question whether regulatory agencies in Asia and globally will accept mHealth data.

Of particular concern are the expectations around safety monitoring. Sponsors may wonder: am I expected to identify adverse events (AEs) in a certain amount of time, and how quickly are they to be reported. Another regulatory concern is around ensuring the security, confidentiality, and availability of data captured via mHealth technology, which is key to compliance with GCP.

It's imperative that we start working through these regulatory challenges now so that the industry can soon begin to reap the benefits of mHeath trials. Investing in robust technology infrastructure will ensure the security and privacy of this data, as well as allow for real-time visibility to gain actionable insights that can be used to conduct faster, more patient-centric research.

What are the other challenges in mHealth?
In addition to the regulatory challenges, there are a number of operational and technical challenges that life sciences organizations in Asia must consider before incorporating mHealth technologies into clinical trials: device failure, user error, lack of eligible subjects with 'bring your own' devices (like cell phone apps) and so on. The industry must ensure investigative

sites are prepared to train patients on using and wearing devices, as well as ensure patients are using the technology in the proper, compliant way. This requires a new level of commitment from patients, as they must keep their devices charged, connect them to the internet and download necessary mobile apps.

From a technical perspective, sponsors in Asia may struggle to identify a device that is both easy to use and can collect high-quality data. Another challenge is the shear volume of data that's recorded with wearable devices.