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ASIA EDITION

Clinical research is becoming more disintegrated with the influx of data from different sources

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Edwin Ng, Vice President, Field Operations, APeJ, Medidata spoke to BioSpectrum about how disruptive technologies are setting the future for clinical trials.

Asia Pacific is expected to become the destination of choice for clinical trials due to its fast-growing pharmaceutical market, dynamic healthcare landscape and access to patient pools. To capitalize the business opportunities from this growing market, keep up with healthcare needs and market demand, healthcare providers are turning to technology and digital platforms to bring drugs to patients faster and to generate much needed insights to address evolving healthcare challenges. Medidata solutions is one such prominent participant in the clinical trials IT solutions market that is making headway by applying

artificial intelligence and advanced analytics to deliver meaningful insights to the industry. Medidata was recently honored with the Asia Pacific Clinical Trial IT Solutions Provider of the Year Award at the annual Frost & Sullivan Asia-Pacific Best Practices Awards held at Singapore.

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Edited Excerpts-

What are the basic services being provided by Medidata Solutions to the healthcare industry?

At Medidata we transform clinical research with cloud-based technology and pioneering analytics via a unified platform. We work closely with pharmaceutical, biotech, medical device companies and academic institutions to provide solutions from enhancing clinical trials design and planning with scientific insights, bringing greater efficiencies, quality and cost savings to clinical trial data capture and management, to minimizing risk and optimizing outcomes of clinical trials to bring new drugs to the market faster. By utilizing our unified platform, pioneering analytics, and our expertise in big data and artificial intelligence, we drive end-to-end value from study start to finish. Our offerings span from applications to analytics and benchmarks that make current trial processes more efficient, productive and streamlined. We also work with clinical trial sponsors and contract research organizations (CROs) to deliver patient-centric clinical trials, leveraging mobile health technology and patient cloud solutions. Medidata has the capability to support researchers with unmatched flexibility to conduct clinical trials virtually, on-site, or as a hybrid with eConsent and eCOA. By equipping patients with mobile health solutions such as sensors and wearables, it reduces patient burden and creates better insights from data.

Asia Pacific is expected to become the destination of choice for clinical trials. What are your views on this, and what are the challenges you foresee in this regard?

I agree that Asia Pacific (APAC) is set to become the destination of choice for clinical trials with its fast-growing pharmaceutical market, access to patient pools, skilled talent, strong intellectual property (IP) and legal infrastructure, and regulatory reforms. For example, with nearly two-thirds of the world's population based in Asia Pacific, the region provides researchers with a large pool of patients to tap on patient recruitment. Additionally, governments are also realizing the region's potential and needs, and have been investing into their local industries for growth. Take Korea for example. In 2018 the Ministry of Health and Welfare proposed a 64.24 trillion won ($56.8 billion) budget that includes the spending of 11.5 billion won to build a big data platform for healthcare, 3.6 billion won to create a bio-health technology business ecosystem and 4.6 billion won to strengthen the competitiveness of medical device industry. This investment is up 11.4 per cent from 2017, accounting for 15 per cent of the total government expenditure of 429 trillion won.

On the regulatory reform front, China has and continues to introduce new guidelines to encourage more innovation in the life sciences industry. One example is that by deregulating some of the requirements for conducting clinical trials in-market, China is making room for domestic trials to take place, and thus increasing market potential.

While the region as a whole is becoming attractive for clinical trials, a key challenge is that clinical research is becoming more disintegrated with the influx of data from different sources. CROs and sponsors also face high level of operational complexities due to cross-country differences in terms of varying factors from culture and language, to policies and regulations. There is a disparity in financial, commercial and environmental conditions that companies must adapt to. For regulations specifically, while there is an increasing convergence in standards globally, there remains considerable difference around what is permissible in different territories. Compliance with national laws and pharmaceutical industry marketing codes is of utmost importance.

Patient recruitment for clinical trial is also a common challenge for sponsors and CROs particularly in markets with limited patient pool such as Singapore.

How is Medidata Solutions addressing the current challenges floating in the clinical trials landscape globally?

To address the challenge of operational complexity, and capture, manage, and analyze this data correctly, clinical trials must move away from the traditional paper-based practice, and fully capitalize the technology-powered solutions such as electronic

data capture (EDC), clinical trial management system (CTMS) and electronic trial master file (eTMF). These are all available – and seamlessly connected – as part of the suite of solutions on Medidata Rave.

The second challenge is patient retention. It is estimated that patient drop-outs in studies can be as high as 30 per cent, potentially disrupting the research. To help with this, Medidata has a few solutions that engage and empower patients along their clinical trial journeys.

Firstly, Medidata's eConsent solution is a patient-friendly electronic informed consent and patient enrollment system that eliminates the risk of paper consent. Not only does it give patients, sites, CROs, and sponsors a unified enrollment system, but it also ensures participants are informed and understand the risks and benefits of the study, through an intuitive and engaging mobile application. This informed consent process is a critical element of running both ethical and effective trials which is particularly important in APAC, as traditionally many patients have gone on trials without consent.

To further support and enhance participant experiences, Medidata's RAVE suite offers Electronic Clinical Outcome Assessments (eCOA) / Electronic Patient Reported Outcomes (ePRO), which allow patients to track and submit their data daily via phones and tablets anywhere, anytime. This empowers and saves time for patients by eliminating the need to physically visit a site. Because it is part of the Rave architecture, it's beneficial to sites, CROs and sponsors too as the patient data seamlessly integrates right into an eClinical system, reducing cost and accelerating study time, while remaining totally compliant.

How can machine learning and AI improve clinical trial data quality, integrity, and efficiency?

Technology is an essential driver in improving outcomes, efficiency, and decreasing cost and risks across all phases of clinical trials. In fact, using artificial intelligence (AI), drugs and therapies can actually be brought to market quicker by preventing delays in approvals. Today, the industry's current practices used to evaluate protocol adherence and data entry may be inadequate, as it can potentially lead to missed adverse events and data anomalies, resulting in delays to the approval process.

By switching to technology that has automated statistical analysis, sponsors and CROs can identify potential errors early, which under normal practice may slip through. Medidata's Rave Trial Assurance is one such example, providing extra analysis to identify data anomalies by contextually comparing lab and clinical data patterns, often revealing data quality issues the customer may be unaware of. Ultimately, this increases the inspection-readiness for submission to regulatory agencies. Medidata's machine learning capabilities is also improving outcomes for clinical trials globally. For example, using Medidata's Rave Omics, a machine learning-based solution, the Castleman Disease Collaborative Network (CDCN) discovered new patient subgroups for Idiopathic Multicentric Castleman Disease (iMCD), a rare, difficult to diagnose, life-threatening disorder. These discoveries provide novel insights into treatment response and potential new drug targets, highlighting the value of precision medicine.