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ASIA EDITION

“The ongoing alignment of clinical trial regulations across APAC with global standards is significant”

02 October 2024 | Opinion | By Ayesha Siddiqui

Celebrating 25 years of ground-breaking technological innovation across more than 34,000 trials and 10 million patients, Medidata, a Dassault Systèmes brand headquartered in New York City and having strong presence in the United Kingdom and the Asia Pacific (APAC) region offers industry-leading expertise, analytics-powered insights, and the largest patient-level historical clinical trial data set in the world. More than 1 million registered users across approximately 2,200 customers trust Medidata’s seamless, end-to-end platform to improve patient experiences, accelerate clinical breakthroughs, and bring therapies to market faster. In an interaction with BioSpectrum, Anthony Costello, Chief Executive Officer, Medidata shared insights on APAC clinical trial landscape, regulatory reforms and Medidata's growth strategy for the region.

Can you elaborate on Medidata’s growth strategy for the APAC region? What specific factors are driving the expansion of your business in this market?

Since entering APAC in 2005, Medidata has expanded into several key markets, including Japan, China, India, Korea, Singapore, and Australia. This growth has been driven by a deep understanding of the region's diverse regulatory landscapes and its market dynamics and specific challenges. With each country presenting their own unique opportunities, we've successfully developed tailored strategies to capitalise on their changing aspects. Factors driving our expansion include the rising demand for digital innovation in clinical trials, particularly in areas such as patient centricity, trial diversity, and AI integration.

Our Medidata Unified Platform is the cornerstone of our growth, offering a comprehensive, integrated solution that streamlines the clinical trial process from start to finish. Additionally, our AI solutions, and advanced wearable and sensor technologies are meeting the increasing need for complex data capture and personalised study designs in the region.

Medidata also benefits from strong local partnerships and a legacy of innovation that positions us to quickly adapt to a rapidly evolving healthcare environment. By focusing on these areas, Medidata is well-equipped to seize new opportunities and maintain its leadership position in the APAC region.

How do you see the role of APAC in the global clinical trial landscape evolving over the next few years? What factors contribute to the region becoming a more prominent hub for clinical research?

APAC is rapidly emerging as a central hub in the global clinical trial landscape, driven by its strong R&D capabilities, advanced technological infrastructure, and alignment with global regulatory standards.

One key factor is the impending expiration of over 50 blockbuster drug patents in the next decade, which will intensify competition among global pharmaceutical companies. This will likely expand the biosimilar clinical trial market, with APAC positioned to play a pivotal role.

Additionally, APAC's significance is bolstered by its vast population and economic growth, particularly in countries like India and China. These rapidly expanding markets are attracting substantial investment from multinational pharmaceutical companies eager to tap into the region's potential.

The region's technological and healthcare infrastructure, especially in countries like Singapore, Japan, and Korea, also plays a critical role. These nations boast world-class systems that are well-suited for conducting complex and sophisticated trials. Medidata's platforms, designed to streamline clinical trial data management, are well-positioned to capitalise on these strengths.

Finally, the ongoing alignment of clinical trial regulations across APAC with global standards is significant. Simplified approval processes and strengthened ethical standards are making the region increasingly attractive for global clinical trials. As these trends continue, APAC is expected to see a surge in research activities and investment, solidifying its position as a key player in global clinical research.

APAC has seen significant growth in clinical trials over recent years. What unique challenges and opportunities does this region present, and how is Medidata addressing them?

The APAC region's role in the global clinical trial landscape is growing rapidly. According to Clinical Trials Arena, clinical trials increased from 11,571 in 2019 to 14,346 in 2023. In 2022, 58 per cent of all global Phase I clinical trials occurred in APAC, driven by the region's strong R&D capabilities, vast talent pools, world-class healthcare infrastructure, and robust regulatory standards.

However, this growth has also brought challenges, particularly in navigating diverse regulatory environments, which can complicate cross-border trials. Medidata is helping to address these complexities with a unified platform that efficiently manages multinational trials, while adhering to each country's specific regulations.

As the clinical trial landscape evolves, companies must innovate and respond quickly to stay competitive. Rising costs and challenges in patient recruitment and retention demand new solutions. Medidata's AI tools streamline processes, ensure site consistency, accelerate insights, and even create synthetic patients to reduce exposure to experimental therapies.

APAC's diverse populations present challenges in data consistency but also offer opportunities to enhance participant diversity in clinical trials. Medidata's Diversity Program is addressing this by integrating diversity into every trial stage, ensuring that historically underrepresented groups are included in clinical research.

Given the diverse regulatory environments across APAC countries, how does Medidata adapt its solutions to meet the specific needs of different markets within the region?

Medidata's Global Compliance and Strategy (GCS) program is responsible for overseeing Quality Management and Regulatory Compliance for our customers. This team provides valuable insights into current and emerging policies, shapes regulatory strategies in collaboration with governing bodies, and advocates on behalf of our clients. They also manage Medidata's Quality Management System, ensuring that our products are developed, implemented, and maintained in strict compliance with clinical trial regulations.

Given the complex and ever-changing regulatory environment in APAC, Medidata has a dedicated team that actively monitors and evaluates the global regulatory landscape, focusing on the implications for R&D, legal/privacy, and information security. To ensure we remain compliant, we work with external providers to regularly assess our controls. Additionally, Medidata offers extensive resources to help customers understand and meet regulatory requirements in China, APAC, and the rest of the world.

How does Medidata collaborate with local partners, such as CROs and research institutions, to enhance the clinical trial process in the APAC region?

Medidata collaborates globally with over 260 CROs and more than 230,000 Rave (EDC) certified clinical research coordinators and principal investigators. This extensive network enhances clinical trial efficiency and quality at every stage, with partnerships that ensure smoother trial management across APAC while meeting each country's regulatory requirements.

Collaboration with stakeholders is crucial as trials grow larger, more complex, and globally distributed. Medidata supports stakeholders with comprehensive solutions that break down silos and provide real-time, data-driven insights. Our cloud-based Medidata Platform enables timely and informed decision-making, improving trial processes, and outcomes.

In APAC, we're streamlining clinical trials and helping customers bring new treatments to market faster. For instance, Japan's Kurashiki Central Hospital fully implemented our Medidata Rave Companion system, reducing query rates by 36 per cent and cutting data entry time per field by 19 per cent.

Medidata also prioritises a patient-focused approach, directly integrating patient perspectives into our software development through our Patient Insights Program. As the first company in APAC to formalise this process, we offer sponsors, CROs, and sites access to our proprietary Patient Centricity by Design process, ensuring that clinical trials are more inclusive and aligned with patient needs.

Any additional information to share?

Looking to the future, there are many opportunities for companies in life sciences that are willing to push innovation and consistently challenge traditional ways of collecting and utilising research data.The future of our industry requires a different type of relationship with patients—one that is less transactional and more longitudinal. One that finds creative new ways to develop trust so that patients are increasingly willing to share their vast healthcare data with researchers to create an ecosystem of new discovery that is mutually beneficial to both.

For example, rethinking the way we approach clinical trials recruitment with better AI predictive modelling, decentralisation of research into patient homes, utilisation of wearable data and electronic medical records systems, and signal detection algorithms for more complex trials—all require patient partnership and are all significant areas of focus for Medidata. Collectively, these initiatives have the potential to propel the industry forward in ways we've never seen before.

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