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“Regulatory encouragement of advanced tech, including AI will accelerate clinical trials in APAC”

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Lokavant Holdings, a US-based clinical trial intelligence technology company provides clinical trial intelligence that enables study teams to make data-driven decisions, as well as risk-based quality management and monitoring services to pharmaceutical companies and contract research organisations (CROs). Recently, the firm received $8 million in funding from Japanese behemoth Mitsui & Co. to bring its technology to APAC. Rohit Nambisan, CEO and Co-Founder of Lokavant, shares his perspectives with BioSpectrum Asia on the evolving clinical trial landscape in the region and the importance of digital health technologies for clinical trials.

Could you elaborate on the most prominent trends shaping the APAC clinical trials landscape?

One of Lokavant’s earliest customers, CMIC Group – the largest CRO in Japan – taught us a lot about this unique part of the world. Since then, we have received an $8 million strategic investment from Mitsui & Co. Ltd. to expand our AI-optimised platform across the Asia-Pacific (APAC) region. Today, three trends stand out:

The first is better regulatory alignment with international standards. Several APAC countries are reforming their regulatory processes to attract more trials to the region, which can lead to more competitive timelines for trial approvals and clearer regulatory guidelines. Korea, Singapore, and Australia standout here, with Japan also seeing similar regulatory shifts.

Multinational trial expansion is the second notable trend. Participant enrollment has become more difficult as clinical trials have evolved to focus more on specialised indications and sub-indications. Given their genetic diversity and substantial populations, APAC countries can support the acceleration of multinational trials.

Lastly, there's a growing focus on oncology and rare disease in APAC countries – Japan in particular – and this aligns with global research trends. These countries often have incentives for orphan drug development which is attracting more rare disease trials.

Will the evolving regulatory landscape in key APAC countries impact clinical trials for biopharma companies?

The region's increasing alignment with international guidelines will simplify the processes required to conduct multinational trials and achieve regulatory approvals in APAC countries. This will greatly benefit local sponsors who are planning niche-indication trials that depend on the recruitment of participants from various countries to meet their enrollment targets.

Additionally, streamlined regulatory processes may lead to faster approval times for clinical trial applications. This efficiency can attract more international clinical studies, and encourage local companies to invest in research and development, thus promoting business in local pharmaceutical and biotech firms.

How do you see the adoption of digital health technologies influencing the future of clinical trials in the region?

Regulatory bodies in several APAC countries are encouraging the use of eClinical data systems, remote monitoring tools, and virtual patient visits. These enhancements should improve patient access, participant retention and trial adherence, which can drive a greater consistency in study conduct for global trials.

Regulatory encouragement of such advanced technologies, including artificial intelligence (AI) and real-world data, will all help to accelerate clinical trials in APAC countries. We should see an increase in trial efficiency and a reduction in overall costs – including but not limited to applications in patient and investigator identification, automation in data quality, and dynamic and real-time reporting.

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