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ASIA EDITION

"Japan's success in digital health is attributed to the collaborative efforts between the government, private sector, and academic institutions"

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Dave Hanaman, president and chief commercial officer, Curavit Clinical Research throws light on Japan's digital health capabilities.



Could you elaborate on some of the most prominent trends shaping the landscape of clinical trials in the Asia-Pacific region?

At the geopolitical level, the rivalry and deteriorating relationship between the United States (along with its allies and partners) and China (the second largest pharmaceutical market in Asia) will continue to impact business between the two nations.

Japan remains the largest pharmaceutical market in Asia, and its improving economy and aging population will drive clinical trials for the foreseeable future. Japan also leads the region in innovation around digital health. In fact, Japan's digital health market is expected to show a compound annual growth rate (CAGR) of 7.29% from 2024 to 2028 versus 7.48% over the same period in the U.S. It's expected to reach $6.15 billion this year versus China, which is expected to hit about $54 million. The island nation's leadership in digital health reflects the country's unique blend of technological innovation, aging population, and proactive approach to healthcare challenges.

South Korea is another key player in the APAC region in biotech and digital health, and sits third in size behind Japan and China.

How do you foresee the evolving regulatory landscape in key Asia-Pacific countries impacting the conduct and efficiency of clinical trials for pharmaceutical and biotech companies operating in the region?

Australia remains a leader in clinical trials due to its world-class researchers, efficient approval process, and government support, especially in the form of tax breaks.

The Japanese government has been moving swiftly to upgrade its healthcare system with digital therapeutics and implementing forward-thinking policies and initiatives since revising its Pharmaceutical Act in 2014. The government has launched numerous initiatives over the years to promote the adoption of electronic health records (EHRs), telemedicine, and other digital health tools.

Japan's success in digital health is also attributed to the collaborative efforts between the government, private sector, and academic institutions. This collaboration has facilitated the integration of digital health technologies into the healthcare system, ensuring that innovations are effectively translated into clinical practice. Public-private partnerships are instrumental in driving the development and adoption of digital health solutions to improve healthcare – and an area where the US is still developing.

For example, CureApp, a startup company pioneering digital therapeutics in Japan, received Japan's first regulatory approval in 2020 for its "CureApp SC" nicotine addiction treatment app, followed by the world's first regulatory approval for hypertension in 2022 for its high-blood-pressure-management application. These efforts are supported by policies aimed at creating a favorable regulatory environment for digital health innovation, including streamlining the approval process for digital health solutions and providing financial incentives for their adoption.

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

The US digital health landscape experienced a major blow with the collapse of leader Pear Therapeutics in April 2023. Prior, many startup digital therapeutics and digital health companies looked at Pear as a bellwether for this fledgling industry so confidence was low. The challenges were largely financially driven by a lack of insurance coverage for these new, unproven therapies. Other companies like Akili Therapeutics took a different approach and started selling straight to consumers without a doctor's note.

In contrast, many APAC countries can move quicker than the US when it comes to reimbursement. Clinical trials must be done on the Japanese population for market authorization in Japan, so we are seeing large growth in Japanese companies that are focused solely on the Japanese market. And you can see this through more local associations like JaDHA (the Japanese digital health association). Japanese companies have big international footprints as well, so this will certainly influence global markets.

We are also seeing a renewed interest in large pharmaceutical companies globally that are increasing their investments in startup digital health firms and offerings. One example is Sumitomo Pharma who is collaborating with the U.S.-based BehaVR to develop three virtual reality digital therapeutics addressing social anxiety disorder, generalized anxiety disorder, and major depressive disorder.

Most recently, too, Otsuka announced Food and Drug Administration (FDA) approval of its digital treatment for major depressive disorder depression. Called Rejoyn, the smartphone-based treatment was developed with US-based digital therapeutics company Click Therapeutics, and it is intended for use by prescription alongside antidepressants and cognitive-behavioral therapy. Otsuka is the first drug company to receive FDA clearance for a digital treatment for a mental health condition.