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What's APAC's Recipe of Success in CLINICAL TRIALS MARKET?

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What's APAC's Recipe of Success in CLINICAL TRIALS MARKET?

Asia-Pacific (APAC) is emerging as one of the most promising and resilient markets for clinical trials. According to a report by Clinical Trials Arena, between 2017 and 2022, the region posted growth in clinical trials of around 10 per cent, outstripping growth in other major regions including the US, Europe and the rest of the world (RoW). Asia's growth far exceeded the overall average figure of 5.3 per cent per year. As of 2023, the number of trials reached 14,346 in APAC. Let's delve into the thriving clinical research landscape in the region and explore the trends driving its growth.

The APAC region continues to rule the roost in clinical trials, experiencing dramatic growth rates surpassing those in the US and Europe. Various reports highlight APAC's emergence as a pivotal hub for clinical trials, with almost half of the world's trials now conducted in the region.

"The number of clinical trials conducted in the APAC region has shown consistent growth over the past five years, with a significant increase from 11,571 trials in 2019 to 14,346 trials in 2023. China leads in the number of clinical trials conducted, followed by India and South Korea," said Gowri Prasad Gutti, Director of Pharma Intelligence at GlobalData.

Earlier considered the hotbed for late-stage multinational trials, early-stage trials are picking up. Between 2013 and 2022, the APAC region emerged as the fastest-growing area for early-stage clinical trials, with a combined annual growth rate 12 times higher than that of the United States and four times higher than Europe. By 2022, APAC accounted for 58 per cent of all global phase I clinical trials, according to a recent report from GlobalData and Novotech. This indicates higher levels of innovation within the region, focusing on the development of novel therapies.

"The transformation of the APAC region in the past decade is remarkable. Traditionally known for later-phase studies due to regulatory advantages and patient availability, we've witnessed a significant shift towards conducting early-phase work in countries like South Korea, Japan, and China. This transition is fuelled by regulatory reforms facilitating faster approvals, the expertise of local sites, and the burgeoning presence of APAC-based biotech companies eager to conduct trials in their home region. This evolving landscape not only underscores

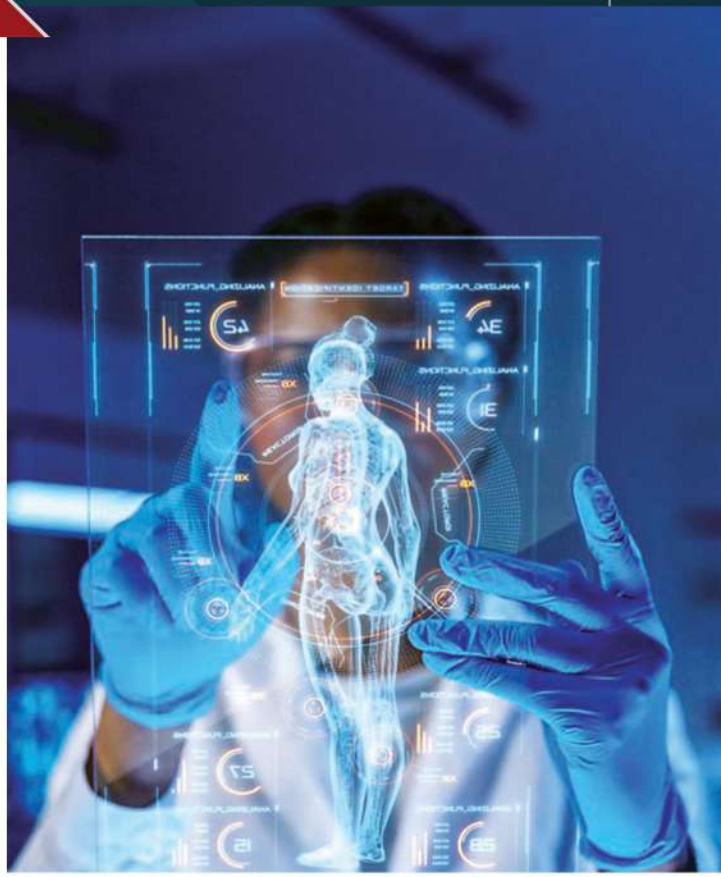
the region's growing importance in global clinical research but also highlights the collaborative efforts driving innovation across borders," said Megan Morrison, Vice President, Commercial Strategy Lead APAC at Worldwide Clinical Trials. US-based Worldwide Clinical Trials is a leading full-service global contract research organisation (CRO).

China has stood out in the APAC region due to its significant growth in clinical research over the past decade. Unlike its counterparts, China predominantly conducts domestically sponsored trials, with over three-quarters of trials being initiated by local companies. In contrast, Japan, South Korea, and India see between 56 and 67 per cent of trials initiated by foreign sponsors. Australia presents a stark difference, with 95 per cent of trials being initiated by foreign companies. Australia also leads the APAC region in the number of first-in-human (FIH) trials, constituting 7 per cent of its total, according to a recent report from Citeline.

"There has been tremendous growth in the mainland China market with biotechs developing novel therapies. The large domestic market also serves as low-hanging fruit for these biotechs. South Korea and Taiwan have also consistently produced good quality biotechs with regional and global ambitions. As a result, you see rapid growth of early phase trials in APAC. This has also led to the development of a large number of sites in the region with strong phase 1 capability and experience. While most of the global pharma companies automatically involve China for their late phase global trials in recent years, more and more global pharma companies are involving China for their early-stage studies for global simultaneous development," said Suhail Ali, Vice President & Head, Clinical Delivery APAC, ICON. Headquartered in Ireland, ICON plc is a world-leading healthcare intelligence and CRO.

South Korea is also emerging as an important country for clinical trials and has ramped up its clinical infrastructure. The country has positioned life sciences and biotechnology as key focus areas, experiencing rapid growth thanks to continuous investment and government support through funding programmes to foster research and development activities.

"Apart from the strong contributions to multinational clinical trials funded by foreign companies, a notable trend in the South Korean pharmaceutical industry is the growth potential for domestic pharmaceutical companies including biosimilar development. The focus of the Korean clinical trial community and the Korean government in clinical trials has been shifting to support drug development by Korean companies evidenced by the fast-increasing number of phase 1 FIH trials approved by the Ministry of Food and Drug Safety (MFDS)," said Suhail Ali.



"The evolving regulatory landscape in the region is poised to significantly influence the efficiency and conduct of clinical trials for pharmaceutical and biotech companies. Key trends include the harmonisation of regulatory frameworks, which simplifies the multi-country trial process by reducing variability in requirements across different countries."

- Ding Ming,
Senior Vice President & General Manager, China Operations, Clinical Research Group (CRG), Thermo Fisher Scientific, USA

Beyond China, there remains significant interest in clinical trial activity throughout the region. India, for instance, ranked third globally in new trials, following China and the US, and experienced a 5 per cent compound annual growth rate (CAGR). Additionally, the proportion of planned trials in India

"The clinical research networks provide a key platform for clinician scientists and researchers to connect with other principal investigators beyond their countries to share best practices and stay updated on the latest developments as well as how effective certain therapeutics have been among their patient cohorts."

- Asst Prof. Danny Soon,
CEO, Consortium for Clinical Research and Innovation, Singapore (CRIS) and Executive Director, Singapore Clinical Research Institute (SCRI), Singapore

"The proactive measures taken by APAC regulatory authorities to support the local CROs to undertake global clinical trials is an ideal situation for global pharma companies to launch their products in APAC markets for wider reach and access to medical therapies to a large patient population."

- Dr Mahesh Bhalgat,
Group CEO, Veeda Clinical Research Limited, India

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Vice President & Head, Clinical Delivery APAC, ICON, Singapore

was three times higher than in the US, as reported by GlobalData.

"Indonesia, Malaysia, and other countries that have large populations and historically have had less exposure to clinical research are looking to improve their capabilities and attractiveness to the life sciences industry. More mature markets, such as South Korea and Australia, continue to attract clinical research through their cutting-edge healthcare facilities, domain expertise, and overall regulatory attractiveness," said Bryan Spielman, Chief Growth Officer at Advarra. US-based Advarra is the market leader in regulatory review solutions and clinical research technology for sites and sponsors.

Area of focus

Oncology remains the dominant therapeutic area in the APAC region, followed by Central Nervous System (CNS) disorders and Infectious Diseases. Notably, COVID-19-related trials have been prominent in Infectious Diseases in the past few years.

"Oncology clinical trials dominate the pipelines for Japanese and Chinese pharma companies; while India, with a younger population, has a greater variety of indications dominating their pipeline including metabolic, autoimmune, and infectious disease targets," said Spielman.

In terms of indications, gastrointestinal tract cancer, blood cancer, post-operative pain, and lung cancer are among the top indications for clinical trials in the APAC region.

Various Asian countries provide favourable regulatory landscapes for rare diseases and regenerative medicine. Japan, China, Singapore, and South Korea lead in stem cell therapy, benefiting from supportive government regulations and funding.

"The proactive measures taken by APAC regulatory authorities to support the local CROs to undertake global clinical trials is an ideal situation for global pharma companies to launch their products in APAC markets for wider reach and access to medical therapies to a large patient population," said Dr Mahesh Bhalgat, Group CEO, Veeda Clinical Research Limited. Veeda Clinical Research is an Indian CRO and offers a comprehensive portfolio of clinical, preclinical and bio/analytical services

Trends shaping clinical trials landscape

In addition to the region's appeal for global clinical trials - attributed to its diverse patient population, skilled professionals, and cost-effectiveness - it is positioning itself as a hub for complex clinical research. Recent years have seen several significant trends, accelerated by COVID-19.

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