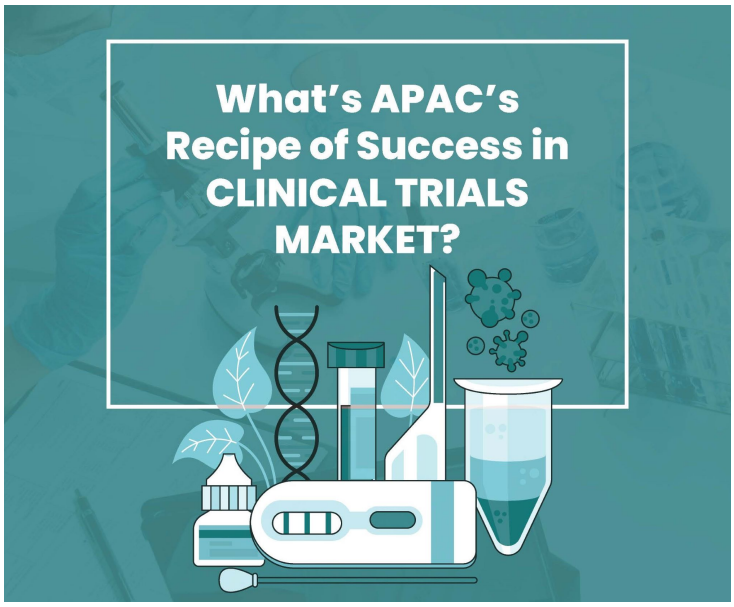
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

What’s APAC’s Recipe of Success in Clinical Trials Market?

01 May 2024 | Analysis | By Ayesha Siddiqui

Asia-Pacific (APAC) is emerging as one of the most promising and resilient markets for clinical trials. According toa 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.

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 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.

China’s dominance: It wouldn't be outlandish to say China has single-handedly driven the clinical trials landscape in APAC. The mainland China market is emerging as a strong driver of growth and innovation in the pharma and biotech space. There is a strong interest and increased appetite for newer therapy trials like cell and gene therapies, antibody-drug conjugates and devices. China is already running the largest number of cell therapy trials in the world. There are commercially approved home-grown cell therapies available in China, thereby greatly increasing the exposure of sites to these kinds of newer therapies.

“More and more global biotechs are looking at the co-development model whereby their China partner co-funds the clinical trial and sometimes also independently runs the ‘Greater China’ (mainland China, Hong Kong and Taiwan) component of the trial directly or through their preferred CRO partner. Often this comes with marketing rights for Greater China for the China partner. This further exposes the market to more innovation from global biotechs simultaneously giving more growth opportunities to Asian biotechs. In China, the number of clinical trials has risen year on year. In 2022 there were 3,318 trials on the clinical trial registry, increasing to 4205 in 2023. More hospitals in China are embracing the opportunities to participate in clinical trials,” said Suhail Ali.

Increased R&D efforts: Several companies in the region are actively developing newer therapies such as CAR-T, mRNA, and ADCs, reshaping the clinical trial landscape. Big pharma companies are announcing partnerships in the region practically every day, significantly enhancing clinical research capabilities.

Interest in newer geographies like Malaysia and Vietnam: “The last few years have seen significant improvement in the clinical trial landscape in newer geographies like Malaysia. Strong industry-friendly measures and improvements in the regulatory landscape have led to the placement of more and more trials in Malaysia. Malaysia also has two government-approved phase 1 trial centres. Vietnam’s large population with less exposure to clinical trials is attracting strong interest from the pharma world. Many pharma and CROs have established clinical teams in Vietnam, setting the stage for future growth there”, noted Suhail Ali.

Clinical research networks: Clinical research networks have emerged as an increasingly important platform for advancing clinical trials and research in the APAC region by providing engagement opportunities, especially for research into diseases of Asian significance. To leverage this growth, the Singapore Clinical Research Institute (SCRI), Singapore’s national coordinating body to implement the national clinical trial strategy and enhance Singapore's clinical trial ecosystem, coordinates and supports 11 of such networks across the region.

“These 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,” said **A/Prof. Danny Soon, the inaugural Chief Executive Officer at the Consortium for Clinical Research and Innovation, Singapore (CRIS) and Executive Director, Singapore Clinical Research Institute (SCRI)**.

For instance, the Asian Myeloma Network (AMN), established in 2011 and the first of its kind in the region, comprises myeloma experts from China, Hong Kong, Malaysia, Taiwan, Japan, South Korea, Singapore and Thailand. Another example is ADVANcing Clinical Evidence in Infectious Diseases (ADVANCE-ID) which involves more than 30 hospitals across Asia collaborating in the conduct of clinical research in infectious diseases.

“With this network, healthcare institutions in the region can come together and study how to change the way we prevent, diagnose and treat infections, which would not have been possible with single sites. This is a critically important and relevant area of prevention and management of infectious diseases,” said A/Prof. Soon.

Multi-site expansion: In a Novotech survey, one of the challenges identified was patient recruitment in clinical trials, particularly focusing on patient retention and addressing the diversity of the patient population (55 per cent of respondents). Historically, clinical trial populations were predominantly white, male participants, exacerbating gaps in knowledge regarding diseases, conditions, preventive factors, and treatment effectiveness. This is especially crucial for complex oncology trials involving newer and sophisticated therapies.

Regulatory framework

The rise of new regulatory challenges, particularly amidst the COVID-19 pandemic, is fueling the development of flexible regulatory frameworks. Countries across the APAC region, such as China, Korea, Thailand, Malaysia and Singapore, have introduced streamlined regulatory review pathways to accelerate the approval process. These initiatives are designed to reduce review times and improve overall regulatory efficiency.

“In South Korea, the Clinical Trial Authorisation (CTA) process was put in place to foster faster study startup times, with the goal being to get trials approved 30 days from the date of submission. The MFDS then either approves the trial or issues a request for additional information. The procedure allows sponsors to simultaneously submit trial requests to IRBs (Institutional Review Boards), ethics committees, and the MFDS, thereby reducing the time needed to get approval. Study startup is one of the most costly and time-consuming phases of clinical research. South Korea’s efforts have reduced this significantly,” said Suhail Ali.

Similarly, China's National Medical Products Administration (NMPA) has implemented fast-track pathways for innovative drugs, significantly reducing review times.

“Additionally, governments are promoting innovation and R&D through policies that offer incentives for local and foreign investment. This is fostering an environment that is more conducive to clinical trials and enhancing the region's clinical research capacity,” said **Ding Ming, Senior Vice President & General Manager, China Operations, Clinical Research Group (CRG), Thermo Fisher Scientific**.

Australia offers a Research and Development Tax Incentive (R&DTI) scheme which encourages innovation and growth. Similarly Taiwan offers incentives to those who wish to invest in Taiwan's healthcare industry.

“Health authority provides incentives to attract global clinical trials to Taiwan. If a company runs a global clinical trial in the country, the Taiwan Health Authority offers two extra years of market exclusivity and potentially a 10 per cent higher reimbursement rate for the drug,” highlighted Dr Bhalgat.

Regulatory bodies acknowledge the role of technology in clinical trials and have taken proactive measures in response. Governments have introduced various initiatives to encourage the utilisation of electronic health records (EHRs), telemedicine, and other digital health tools.

“Throughout the region, regulatory bodies are looking at how real-world data complements traditional development approaches, leveraging technology solutions to enable decentralised gathering of participant data, where appropriate, and what role patient advocacy should have in clinical trial design. Singapore is at the vanguard of regulatory innovation in the Asia-Pacific region, and the country is always looking to ensure that they are competitively positioned with the rest of the region and world. To that end, streamlining the ethics review process is one of the areas they are exploring,” said Spielman.

Countries are actively exploring the use of Decentralised Clinical Trials (DCTs) and digital health technologies in clinical research. Australia, Singapore, and China have all released frameworks for DCTs.

Lastly, with the increasingly global nature of clinical trials, robust data protection and sharing regulations are being prioritised to ensure privacy and security while facilitating cross-border collaboration.

“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. Streamlined approval processes, as seen in countries such as Singapore and Australia, are expected to accelerate the clinical trial timeline, making the region more attractive for trial conduct. Moreover, the adoption of international standards is enhancing the quality and

reliability of clinical trial data, boosting global confidence in the region's research capabilities," said Ding Ming.

The Tech Thrust

Moving forward, technology will play a crucial role in advancing clinical research. According to a recent IQVIA survey, 89 per cent of participants from West China Hospital embrace decentralised trials as a viable research option. Additionally, 98 per cent approve the integration of electronic diaries, 96 per cent endorse digital devices, and 90 per cent support telehealth visits in clinical trials.

Digital technologies offer immense opportunities for trial efficiency and access. The adoption of digitalisation has not only enabled trials to be conducted remotely but has also empowered participants through the use of wearable devices, which can provide real-time updates to both researchers and participants alike.

"This advancement not only enhances convenience by reducing the need for frequent site visits but also broadens the reach of trials, to be able to recruit from a more diverse participant pool across APAC, including those with limited trial infrastructure," said A/Prof. Soon.

Data analytics coupled with Artificial Intelligence (AI) will play a big role in shaping the clinical trials of the future. Already analytics and AI are used for site selection, patient recruitment projections, translation services and interpretation of diagnostics data like ECG, scans etc. Predictive analytics are also projected to grow at a faster rate making clinical trials more predictable in terms of timelines and cost.

As with all things technology, the implementation of robust data governance strategies is crucial. While data is a key driver of research insights, there have been rising concerns regarding access, security, and ethical use, which must be addressed.

"As the region continues to develop its health care infrastructure, the integration of these technologies will be crucial in expanding access to clinical trials and improving health care services, especially in underserved areas. In conclusion, digital health technologies are set to play a pivotal role in the future of clinical trials in the Asia-Pacific region, driving progress toward more efficient, patient-centric and data-driven research processes," said Ding Ming.

The Asian clinical research market has grown by leaps and bounds and is projected to be worth $7.47 billion by 2029 from $4.88 billion in 2024. As demand for new therapies rises globally, the region offers lucrative opportunities for all stakeholders to innovate and grow.

Ayesha Siddiqui