

Asia-Pacific Trials

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What are some of the key trends impacting clinical trials in the Asia-Pacific region?

The Asia-Pacific (APAC) region is becoming increasingly influential in the global clinical trials landscape due to several key trends.

First, there is a notable surge in Phase I trials, with the region accounting for a significant global share. This growth is fueled by the region's ability to rapidly enrol patients and its focus on key therapeutic areas.

Second, the expansion of clinical trial infrastructure presents opportunities for multi-country trial growth.

Third, supportive government initiatives and regulatory frameworks are fostering a positive environment for clinical research.



Fourth, the adoption of virtual and decentralised trials, accelerated by the COVID-19 pandemic, is another trend enhancing the region's efficiency and patient diversity in trials.

Fifth, increased R&D investments by local pharmaceutical and biotech companies are driving the need for more clinical trials.

Sixth, the region's attractiveness for global clinical trials—due to its diverse patient population, skilled professionals and cost-effectiveness—is positioning it as a hub for complex clinical research.

These trends collectively contribute to the APAC region's significant growth and development in the clinical trials sector.

What is your outlook on the potential impact of the evolving regulatory landscape in key Asia-Pacific countries on the efficiency and execution of clinical trials for pharmaceutical and biotech companies operating in the region?

The changing regulatory landscape in the APAC region will have a significant impact on the efficiency and execution of clinical trials conducted by pharmaceutical and biotech companies. Notable trends include the harmonisation of

regulatory frameworks, which simplifies the process of conducting trials across multiple countries by reducing variations in requirements. Streamlined approval processes, as observed in countries like Singapore and Australia, are expected to expedite the timeline for clinical trials, making the region more appealing for conducting trials. Additionally, the adoption of international standards is enhancing the quality and reliability of clinical trial data, thereby increasing global confidence in the research capabilities of the region.

Regulatory bodies also are focusing on diseases prevalent in the region, leading to trials that are more relevant to the local population and potentially faster patient recruitment. The emergence of new regulatory challenges, particularly in response to public health emergencies such as COVID-19, is prompting the development of more flexible and agile regulatory mechanisms. These changes aim to balance expedited approval pathways with maintaining rigorous safety and efficacy standards. Thanks to governments incentivising local and foreign investment in innovation and R&D, the overall environment is much more supportive of clinical trials and expanding the region's clinical research capacity.

Lastly, with the increasing global nature of clinical trials, robust data protection and sharing regulations are being prioritised to ensure privacy and

security while facilitating cross-border collaboration. In conclusion, regulatory changes in the region are likely to make the conduct of clinical trials more efficient and effective, positioning the region as a hub for innovative clinical research and development. Companies operating in the region will need to adapt to these changes to fully leverage the opportunities they present.

What effect will the implementation of digital health technologies have on the future of clinical trials in the region?

The integration of digital health technologies is reshaping clinical trials in the Asia-Pacific region, offering new opportunities for efficiency and innovation. Decentralised trials facilitated by remote monitoring and telemedicine can reach a wider patient population, enhancing trial diversity and reducing the burden on participants. Real-time data collection through wearable devices and mobile apps improves data quality and allows for continuous health monitoring, which can accelerate the trial process. Artificial intelligence and machine learning can address large datasets to optimise trial design and patient selection, potentially leading to more effective treatments. These technologies also support virtual consultations, making trials more accessible and cost effective by reducing the need for physical site visits. Pharma/biotech and their clinical research service providers need to have clear strategies to manage the challenges that can accompany the adoption of digital health technologies, particularly in ensuring regulatory compliance, data privacy and security.

The integration of these technologies is vital for expanding clinical trial access and improving health care services, particularly in underserved areas. Bottom line, digital health technologies will play a pivotal role in the future of clinical trials in APAC, driving progress toward more efficient, patient-centric and data-driven research processes. ▶

Ding is a seasoned pharmaceutical executive with more than 25 years of pharmaceutical industry operational leadership experience. He joined the PPD clinical research business in 2019 to oversee the China operations, which include more than 1,500 clinical development and analytical services professionals. Prior to that, he served as vice president and R&D head for Emergent Biosolutions. He has worked at a variety of pharmaceutical companies, including GSK, Boehringer Ingelheim, Pfizer and Novartis.

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Which disease areas in the APAC region have the most potential for growth in clinical trials over the next few years?

The APAC region has seen significant growth in clinical trials across various disease areas in recent years and there are several that have the potential for further growth. Some of these include oncology (particularly lung, liver and gastric cancers), infectious diseases (such as dengue fever, tuberculosis and HIV), cardiovascular diseases (including hypertension and coronary artery disease), and neurological disorders (such as Alzheimer's disease and Parkinson's disease). Additionally, rare diseases and orphan indications are gaining attention in the region. It is important to note that the potential for growth in clinical trials can vary based on factors such as disease prevalence, emerging therapies, regulatory environment, and investment in research and development.

What models of collaboration and partnership are emerging in Asia-Pacific clinical trials?

As a global clinical research services provider, we have seen some emerging models of collaboration and partnership

- o Functional service provider (FSP) collaboration is surging ahead of full-service outsourcing (FSO) among companies of all sizes globally in the APAC region. Drug developers increasingly favour FSP partnerships and hybrid FSP/FSO models for their ability to deliver enhanced resource flexibility, global talent acquisition and efficient access to specialised skills.
- o The number of multi-regional clinical trials (MRCTs) in APAC has been steadily increasing in recent years due to the regulatory harmonisation, large patient populations, cost effectiveness, etc. Particularly in China, we have seen rapid growth in MRCTs trials, with more emerging China biotechs going abroad for their global development.

- o APAC, particularly China and South Korea, has emerged as a hub for biotech innovation. Local biopharma companies are developing novel therapies and technologies, leading to an increase in licence-out deals to Western markets. On the other hand, favourable regulatory changes in countries like China and Japan have facilitated faster approval processes for imported drugs, encouraging more licence-in deals to bring foreign innovations to local markets. The licensing landscape in APAC demonstrates a two-way flow of innovation, with companies both importing and exporting technologies and products to meet global health care demands. This trend underscores the region's growing importance in the global pharmaceutical ecosystem and its transition from being primarily a recipient of licensed technologies to a key player in the development and dissemination of innovative therapies worldwide.

What is the role of multinational collaborations in clinical trials in the Asia-Pacific region?

Multinational collaborations play a vital role in clinical trials in APAC. These collaborations involve partnerships between pharmaceutical companies, contract research organisations (CROs), study sites and regulatory authorities. Mainly reflected in following aspects:

- o Increasing diversity and inclusion
- o Promoting innovation and expertise sharing in the region
- o Improving efficiency and speed
- o Strengthening the region's influence in global R&D
- o Promoting the coordination of regulations in the region
- o Improving the quality of clinical trials.

Particularly for those innovative emerging biotech companies with global ambitions, working with a global CRO with a local presence could bring global expertise and experience, as well as local operational delivery, to shorten timelines and support cost-effective clinical development. ■