The Clinical Development Market in APAC: *Opportunities, Growth and Challenges*

The Asia-Pacific (APAC) region has rapidly emerged as one of the most dynamic markets in global clinical development. Over the past decade, demand for innovative therapies, a large and diverse patient population and favourable government initiatives have transformed APAC into a preferred destination for conducting clinical trials. According to Grand View Research, the APAC clinical trials market was valued at USD 12.1 billion in 2024 and is projected to grow at a compound annual growth rate (CAGR) of approximately 8.4% from 2025 through to 2032.

For biopharmaceutical companies in the U.S. and Europe, expanding into APAC offers significant strategic advantages: faster patient recruitment, reduced operational costs, access to treatment-naive and large populations, with the potential to accelerate drug approvals. Yet, the region also presents challenges, such as complex regulatory frameworks, infrastructure disparities and cultural diversity that can affect trial execution.

This article provides a deep dive into the APAC clinical development landscape, highlights country-specific opportunities, explores drivers of growth and examines the challenges and concerns that sponsors must navigate.

The Evolving Clinical Trial Landscape in APAC

Rapid Market Expansion

The APAC region has become increasingly important in the global R&D ecosystem. As the burden of chronic and lifestyle-related diseases grows, demand for innovative therapies has spurred investments in clinical research infrastructure across the region. Countries like China, India, Japan, South Korea, Australia, Singapore, Thailand, Taiwan and Malaysia now account for a significant share of global clinical trials, with China and India, in particular, seeing double-digit growth in recent years.

APAC has transitioned from being a cost-driven outsourcing destination to becoming a global leader in clinical research innovation. The region hosts over 100,000 active clinical trials as of 2025. China and India dominate in trial volume, while countries like Singapore and Australia lead in regulatory speed and specialised early-phase studies. This list highlights the regional distribution:

Active Clinical Trials by Country (2025)

- China (36,000 active trials) leads due to a huge patient base and regulatory reforms.
- India (18,000) continues to attract large-scale phase III studies.
- Japan (15,000) remains dominant in high-quality trials, particularly oncology.
- South Korea (11,000) has invested heavily in biotech innovation.
- Australia (8,000 trials) is strong in early-phase and oncology studies.
- Singapore (6,000) focuses on precision medicine and rare diseases.
- Thailand (5,500) leverages its medical tourism ecosystem for patient recruitment.
- Taiwan (7,000) thrives in oncology and cell/gene therapies.
- Malaysia (4,000) emerges as a cost-effective destination.

Increased Regulatory Harmonisation

Historically, fragmented regulatory systems were a barrier to efficient trial operations in APAC. Today, initiatives such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and region-specific reforms are streamlining approval timelines. For instance, China's National Medical Products Administration (NMPA) has dramatically shortened trial approval timelines, while India's regulatory transformation is encapsulated in the New Drugs and Clinical Trials Rules 2019, a decisive shift from the former Schedule Y. These rules embody a renewed commitment to participant protection, procedural transparency and regulatory agility which creates more simplified processes to attract more foreign-sponsored studies.

Technology Integration

Digital health technologies, including decentralised clinical trials (DCTs), real-world data (RWD) and electronic data capture (EDC), are rapidly transforming trial operations in APAC. Japan and South Korea are helping lead the way in leveraging artificial intelligence (AI) and big data analytics, enabling faster patient recruitment, more accurate monitoring and efficient data collection. The (APAC) region is becoming a global hub for AI-driven clinical trials, leveraging large datasets, diverse populations and government support for AI and digital transformation to accelerate drug development. AI applications in APAC clinical trials include optimising patient recruitment and selection, automating data analysis, improving protocol design and speeding up overall trial efficiency and cost-effectiveness. While facing some ethical and regulatory challenges, the region's strong IT infrastructure, government initiatives like China's 'Healthy China 2030' and increasing outsourcing make it a key player in the future of AI in global clinical research.

Drivers of Growth in APAC Clinical Development

Several key factors make APAC a highly attractive region for clinical research:

1. Large and Diverse Patient Populations

APAC is home to 4.5 billion people, nearly 60% of the world's population. This provides an extensive pool of patients across diverse genetic backgrounds, disease profiles and socioeconomic conditions. For rare diseases and oncology, where patient recruitment is often challenging, APAC offers unparalleled opportunities.

2. Rising Disease Burden
The region faces increasing rates of cancer, cardiovascular disease, diabetes and neurodegenerative disorders. According to the World Health Organisation (WHO), non-communicable diseases account for nearly 74% of deaths in APAC. This surge in demand for effective therapies has created fertile ground for clinical research.

3. Cost-Effective Operations
Operational costs in APAC are generally lower than in North America or Europe. For example, the cost of running a Phase III oncology trial in India can be 40–60% lower compared to the U.S. Lower investigator fees, infrastructure expenses and patient compensation contribute to these savings, allowing sponsors to stretch R&D budgets further.

4. Expanding Clinical Research Infrastructure
Governments across APAC are investing heavily in healthcare infrastructure and research capabilities. High-quality clinical research organisations (CROs), globally recognised hospitals and accredited laboratories now support international standards, making APAC increasingly competitive with Western markets.

Country-Specific Highlights

Japan: Quality-Driven Research
Japan is known for its robust regulatory framework, advanced medical infrastructure and highly experienced investigators. The Pharmaceuticals and Medical Devices Agency (PMDA) has accelerated approval pathways, especially for breakthrough therapies, making Japan a critical hub for precision medicine and rare disease studies. Japan offers a high-quality environment for clinical trials due to its strong regulatory framework, including strict adherence to J-GCP, a well-established healthcare infrastructure and a commitment to patient safety and ethical standards.

Notably, Japan leads APAC in integrating real-world evidence (RWE) into clinical development and offers strong IP protections for innovative therapies. However, high operational costs and slower patient recruitment compared to China and India can limit its competitiveness. An experienced Japanese CRO partner can help in navigating the nuances of this market.

South Korea: Innovation and Technology Integration
South Korea has positioned itself as a leader in clinical trial innovation, driven by government funding and world-class healthcare infrastructure. Seoul, in particular, is a top-ranked city for clinical research globally.

Key Strengths:

- Rapid adoption of AI, big data and decentralised clinical trials.
- High participation rates among patients.
- Strong presence in biologics, cell therapies and oncology trials.

The challenge lies in balancing growing international demand with limited site capacity, which can strain timelines.

Australia: A Gateway to Global Approvals
Australia offers unique advantages, including rapid regulatory approvals, access to highly diverse patient populations and the ability to generate data accepted by the U.S. FDA and European Medicines Agency (EMA). Its Clinical Trial Notification (CTN) scheme allows approvals in as little as 4–6 weeks, making it particularly attractive for early-phase studies.

Government incentives, such as the Research & Development Tax Incentive, further reduce costs, making Australia a preferred destination for first-in-human and adaptive trial designs.

Singapore: Asia's Precision Medicine Leader
Singapore has evolved into a strategic clinical research hub:

- **Regulatory Excellence:** The Health Sciences Authority (HSA) offers fast-track approvals in 8 weeks, among the region's quickest.
- **Therapeutic Niches:** Oncology, rare diseases and cell and gene therapies.
- **Research Infrastructure:** Cutting-edge facilities at the Biopolis and partnerships with leading pharma companies.
- **Cost Considerations:** While costs are higher (85% of U.S. levels), sponsors benefit from superior quality and early-phase capabilities.

Taiwan: Bridging Innovation and Efficiency
Taiwan is increasingly viewed as a gateway for APAC clinical development, particularly for innovative therapies.

Key Strengths:

- Highly efficient and centralised healthcare systems.
- Strong track record in oncology, immunology and rare diseases.
- Highly educated clinical research workforce and advanced hospital networks.

Taiwan's balance of speed, cost and quality makes it a hidden gem for sponsors seeking high-value trial environments.

China: The Regional Powerhouse
China has emerged as a clinical research leader, fueled by government reforms, significant investment and a growing biopharma ecosystem. The NMPA's regulatory modernisation and China's accession to ICH standards in 2017 reduced trial approval times from 12–18 months to as little as 60 days.

Key Trends in China:

- Strong growth in oncology and rare disease trials.
- Increased acceptance of foreign-sponsored studies.
- Accelerated approvals through programs like the Priority Review Pathway.

However, navigating China's regulatory environment still requires local expertise and partnerships, including an experienced APAC-based CRO, particularly given evolving data privacy laws.

India: A Cost-Competitive Hub
India combines a large patient pool, cost advantages and skilled investigators, making it one of the fastest-growing clinical trial markets globally. After a slowdown earlier in the decade due to

ethical concerns and regulatory scrutiny, reforms introduced in 2019 revitalised the industry.

Key Advantages Include:

- Access to treatment-naive patients across multiple therapeutic areas.
- Clinical trial costs up to 60% lower than Western counterparts.
- Government incentives to attract foreign sponsors.

Challenges remain around infrastructure variability and ensuring consistent adherence to Good Clinical Practice (GCP) standards, particularly across rural regions.

Thailand: A Rising Medical Research Destination
Thailand is gaining attention for its affordable trials and large patient pool:

- **Medical Tourism Advantage:** With over 3 million international patients annually, recruitment is streamlined for certain therapeutic areas.
- **Therapeutic Strengths:** Infectious diseases, oncology and regenerative medicine.
- **Regulatory Framework:** Approval timelines average 16 weeks.
- **Cost Efficiency:** Trials are 40% cheaper than in the U.S., making Thailand attractive for late-phase studies.

Malaysia: An Emerging Cost-Efficient Hub
Malaysia is rapidly positioning itself as a cost-effective alternative for sponsors targeting Southeast Asia.

Key Strengths:

- 55% lower trial costs than U.S. averages.
- Multilingual workforce and strong government backing for biopharma growth.
- High prevalence of diseases like diabetes and cardiovascular conditions, enabling rapid recruitment.

While smaller in scale, Malaysia's strategic location, cost advantages and growing clinical infrastructure make it increasingly attractive for global trials.

Challenges and Concerns
While APAC presents compelling opportunities, sponsors must address several key challenges:

1. Regulatory Complexity
Despite progress, regulations still vary significantly across APAC countries. Sponsors must manage inconsistent timelines, language barriers and data-sharing rules. For example, China's data localisation requirements can complicate global data integration.

2. Infrastructure Disparities
Although major cities boast world-class research facilities, rural areas often lack adequate resources. Ensuring uniform trial quality and compliance across diverse geographies remains a challenge.

3. Ethical and Cultural Considerations
Cultural attitudes toward clinical research vary widely. In some countries, patient scepticism and limited awareness about clinical trials can hinder recruitment efforts.

4. Counterfeit Drugs
In some APAC markets, the presence of counterfeit drugs poses a direct threat to patient safety and drug quality. Collaboration between international regulatory agencies, such as the FDA and EMA, can help in knowledge-sharing, strengthening quality assessments and inspections globally.

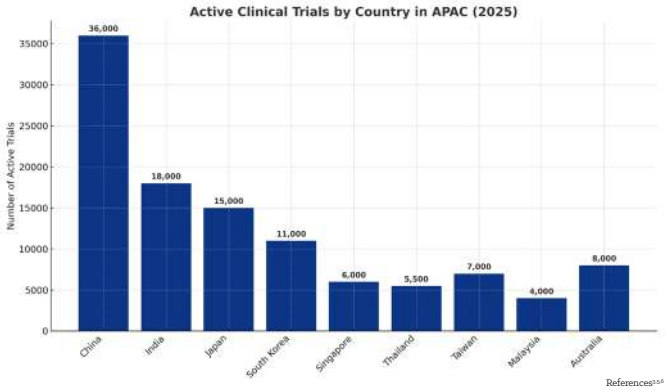
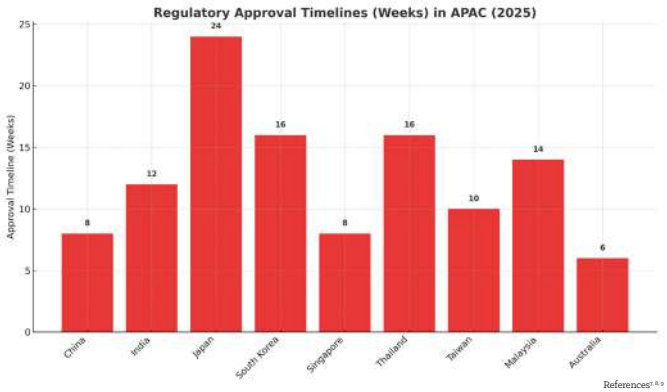


Figure 1



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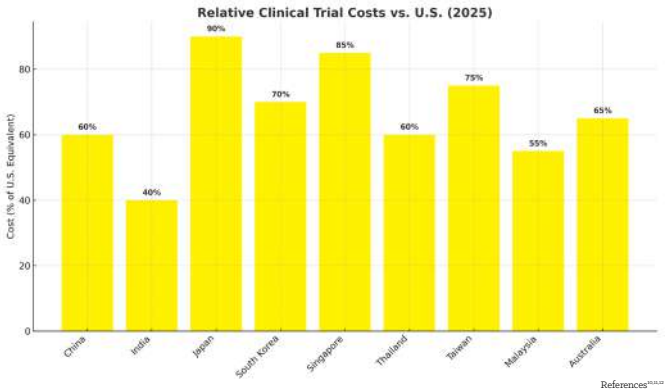

Figure 3

5. Supply Chain Risks
Over-reliance on certain pharmaceutical suppliers and potential vulnerabilities in the supply chain can affect the quality and availability of ingredients and finished products. Organisations like ISPE and PDA are helping to improve quality management practices in pharmaceutical manufacturing, potentially leading to fewer defects and recalls.

6. Data Privacy and Compliance
Evolving data protection laws, such as China's Personal Information Protection Law (PIPL), require careful planning around data collection, transfer and storage to remain compliant.

7. Intellectual Property and Quality Concerns Across Some Countries
Conducting clinical trials in China may present challenges for intellectual property (IP) protection, particularly for foreign

biopharmaceutical companies. Awareness creates opportunity for improvement.

While significant efforts, including the New Drugs and Clinical Trials Rules 2019, aim to address these issues by improving Good Clinical Practice (GCP) standards and ethics oversight, the ongoing quality of trials depends on continued regulatory consistency, robust infrastructure, better-trained personnel and a deeper understanding of ethical principles to ensure participant protection.

Overcoming Challenges

The focus on improving the quality of pharmaceutical clinical development in APAC is a keen area of focus for 2025 and beyond. However, obstacles such as standardising adherence to international regulations and improving local regulatory systems will remain key focus areas.

The trajectory of APAC's pharmaceutical market remains strong and addressing quality concerns will be paramount to ensuring patient safety and the growth potential of this key market.

The Future of Clinical Development in APAC

Looking ahead, APAC's role in the global clinical development ecosystem is expected to grow significantly. AI, decentralised trial models and real-world evidence will drive efficiencies, while continued regulatory reforms and infrastructure investments will enhance competitiveness.

Partnerships between global sponsors, local CROs and healthcare institutions will be critical to navigating the region's complexities. Biopharma companies that adopt a region-specific strategy, embrace technology and invest in patient engagement will be best positioned to capitalise on APAC's growth potential.

Conclusion

The Asia-Pacific region offers an unparalleled opportunity for clinical development, combining vast patient diversity, rising disease prevalence, cost efficiency and increasing regulatory harmonisation. While challenges persist, from navigating complex regulations to ensuring consistent quality, APAC's clinical trials market is poised for sustained, long-term growth.

For U.S. and European biopharmaceutical companies, success in APAC requires more than simply entering the market; it demands a deep understanding of local ecosystems, strategic partnerships and adaptive operational models. By leveraging the region's strengths and proactively addressing its challenges, sponsors can accelerate drug development timelines and bring innovative therapies to patients faster.

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Challenges in the Post-marketing Investigations for Medical Devices

As the European and overall worldwide regulation strives to become clearer, unambiguous, harmonised and as a result, more restrictive and demanding, this tendency still seems to leave behind the post-marketing studies for medical devices.

The European Union Medical Device Regulations 2017/745 entered into force in May 2021 and significantly improved the clarity about the expectations imposed on manufacturers in the post-marketing period.

The MDR's increased requirements for clinical evaluation aim to ensure safer medical devices for consumers and users. However, this in parallel, leads manufacturers to new challenges related to the preparation of robust Clinical Evaluation Reports for their medical devices.

The possibility of some undesired consequences for the European market is a highly discussed topic, as for some manufacturers, the cost of generating the required clinical data will outweigh the potential return on investment. Consequently, the manufacturers may discontinue certain medical devices or remove them from the EU market, leading to a device shortage.

The general consensus among manufacturers is that the heightened requirements for clinical evaluation, particularly for high-risk medical devices, which had not been present to this extent before, are creating challenges.

The necessity to perform clinical investigations in the post-marketing period becomes evident in some cases, while in others, the manufacturers would rather avoid such and a resort, to alternative methods of data collection.

Still, everyday practice proves to provide numerous scenarios and topics that lack consideration in the regulation.

Challenges Related to the Data Collection Programme for CER

Determining the scope and amount of data needed to generate sufficient clinical evidence, accepted by the respective Notified Body, is one of the most prominent challenges in the eyes of the manufacturers.

Per the MDR, 'clinical evaluation,' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report with only limited exceptions.

Determining the appropriate data sources can prove to be a challenging and time-consuming process. On the one hand, the manufacturers struggle with some uncertainty regarding the regulatory expectations. Some inconsistencies have been suggested in the amount of clinical data accepted by the different notified bodies. Still, there are no actual guidelines on what constitutes sufficient clinical evidence, hindering all stakeholders and possibly leading to exceeding expectations or wasting time in evaluating insufficient reports.

This is particularly true for manufacturers with medical devices that changed their class due to the MDR's new classification rules and even products that were previously considered a cosmetic product but are now under the MDR jurisdiction. Such manufacturers had to initiate processes that were not previously required for products that had been on the market for years. There is less uncertainty for the high-risk or invasive medical devices, as they are under stronger regulatory oversight and rigorous requirements.

Identification of the Most Appropriate Clinical Evaluation Pathway

On one end of the spectrum is opting for a safer method to collect high-quality data from a comprehensive PMCF investigation, which can ensure the acceptance of observations, but it demands significant resources, including time. In some cases, a market shortage may occur because a device is recalled while under proactive observation.

Choosing methods that depend on less relevant sources, like complaints or vigilance systems, increases the risk of not sufficiently justifying the device's safety and performance assessment. Over-reliance on reactive data may lead to rejection by the Notified Bodies.

Reactive or Proactive PMS Data?

Reactive PMS data are passively collected information, sourced by external unsolicited sources such as complaints, vigilance reports, etc. In contrast, Proactive PMS data are actively, deliberately and systematically gathered. This may include PMCF, including studies, users or consumers surveys, structured literature review, etc. The MDR requires manufacturers to integrate both within their programme to confirm persistent safety and performance, with emphasis on proactive data.

Reactive PMS data alone is insufficient, and often it is hard to obtain. In Europe, there are still no publicly available consolidated data sources. Depending on the region, the doctors and the patient are, to various degrees, unaccustomed to using the vigilance systems. Unfortunately, this raises doubts that the lack of complaints genuinely reflects the real picture of the device's safety and performance.

The MDR requires manufacturers to actively and systematically gather, record and analyse relevant data (information). Thus, Proactive data collection is essential to confirm the benefit-to-risk,