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Hybrid DCTs Set for Surge as Innovation Outpaces Regulatory Hurdles

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APAC's openness to innovation, combined with its large population and low trial density, creates strong potential for expanding decentralised clinical trials (DCTs), especially for patients with limited trial access. While regulatory diversity and operational challenges will continue to hinder fully decentralised models, the region is expected to adopt more digital technologies in clinical research. As a result, hybrid DCTs will keep gaining traction, and effective management of digitally collected data will remain a central focus for data science teams.



In today’s global, multi-provider clinical trial environment, sponsors need to rapidly and accurately assess vast volumes of data. This has driven a switch – from resource intensive manual methods to the application of artificial intelligence (AI) tools. In 2025, Asia Pacific (APAC) was expected to be the second largest region in the AI in the clinical trials market. China, Japan and South Korea led this growth, which looks set to continue well beyond 2026.

While previous technological advancements have often been too expensive or too narrow to change the status quo, the latest advancements in AI are not just feasible but usable. These tools can, for example, automate data processing and search public data via specifically trained models which read-in data through API-like connections.

API integrations enable the connection of previously siloed systems. This allows data workflows to become tool-agnostic, supporting not only the integration of diverse data sources but also the delivery of real-time insights to a wide range of users and for varied purposes. The process is further enhanced by AI-driven analytics.

Although differing data structures and characteristics can make it challenging to uncover meaningful insights, large language models (LLMs) and machine learning (ML) can facilitate data processing, forecasting, and pattern recognition. These

capabilities help fine-tune ongoing clinical trials and prevent missed opportunities.

Looking ahead to 2026, we expect to further refine our use of AI. For example, LLMs and emerging Large Concept Models (LCMs) will transform data interpretation, reporting and decision-making, significantly reducing the need for manual effort. The continuous improvement in real-world data availability within the APAC region will further support AI-enhanced patient population selection and stratification in clinical trials.

Increasingly, electronic source data solutions are being adopted in APAC clinical trials – often powered by LLM technology. From trial design and risk mitigation to patient recruitment, optimisation, and results reporting, AI components are becoming integral across the entire clinical trial lifecycle.

However, the adoption of AI also presents challenges. These include ensuring that humans remain in the loop, integrating AI solutions into existing workflows, and detecting AI hallucinations – when an AI model generates false, inaccurate or misleading information and presents it as fact. These are all issues that more advanced LCMs are expected to help address.

Ultimately, behind every data point is a patient waiting for treatment. The APAC region, home to over half of the world's population, continues to see growth in clinical trials and is emerging as a key hub for AI research. Yet, APAC's rich cultural and linguistic diversity, along with fragmented research policies, presents unique challenges. To overcome these, AI tools, digital solutions, and decentralised trial models will play a critical role in advancing clinical research and patient outcomes.

Decentralised Trials

Decentralised clinical trials (DCTs) have undergone a period of rapid growth in the APAC region. While China and India have accounted for the majority of this growth so far, other countries, including Japan, have begun to push for more DCTs which could drive further growth in the region.

DCTs offer the opportunity to lower the burden of clinical trial participation. This can, in theory, increase engagement among diverse patient groups and remove historic barriers to participation, particularly for those in locations with limited access to clinical research. In many APAC countries, clinical research is only carried out in major hospitals. This means even people who live in well populated cities in town may struggle to access clinical trial sites, not just those in remote areas. However, for the benefits of DCTS to be realised, we need to understand the specific challenges in the APAC region and how to mitigate them.

Research has found that patients and sponsors in APAC see the benefits of virtual and hybrid trials; almost 9 in 10 patients think DCTs are acceptable in China. However, concerns persist around regulatory gaps, digital divide, data collection quality and study logistics. For example, eConsent is not necessarily feasible in all APAC countries, adoption of technology can be uneven in cross patient populations and home nursing is not always viable. There are also challenges around data collections that require constant internet connection and difficulties managing tele-patient visits.

Addressing Challenges

There are also challenges in both planning DCTs and analysing DCT data which need to be addressed. Remote procedures can introduce higher level variability which can lead to inconsistent data quality and outcome measurement errors. Accessing more diverse patient populations and using novel endpoints and digital measures can lead to inaccurate assumptions on variability and treatment effect size. Increasingly complex data collection and the risk of missing data can lead to challenges in performing analysis. There is also a risk that reduced direct contact with healthcare professionals may result in a lack of patient motivation, leading to increased premature withdrawal rates. In addition, the variability introduced by remote data collection or digital data collection also leads to concern in study result comparability among different trials.

To mitigate these challenges, we need to standardise remote processes and provide clear, protocol-defined training for both subjects and telehealth staff. Adaptive sample size reassessment should be built into trial design, and a detailed data management plan ensuring integration of wearables, apps and patient-reported outcomes (PROs) is crucial. To defend the robustness of key conclusions, any higher-than-expected rates of premature withdrawal should be proactively addressed in analysis plans prior to unblinding. Just like traditional trials, statisticians should also pay close attention to data variability and distribution and study discontinuation rates throughout the study.

Sustained Growth of Hybrid DCTs

APAC consumers and industry leaders are known to embrace innovation. That, combined with the region's large population and relatively low trial density, means DCTs offer opportunities to bring more clinical trials to patients with limited access. Diverse regulatory environments and hurdles in operation logistics are likely to remain roadblocks for 100 per cent

decentralised trials. However, we do expect to see more technologies applied to clinical research. Therefore, hybrid DCTs will continue to be a growing space in APAC and how to process digitally-collected data properly will remain a key data science topic.

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