

## Success in APAC region requires local knowledge and globally consistent execution

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Research and development activities are on the rise, clinical trials are proliferating, and outsourcing is becoming increasingly popular. While these trends are poised to fuel the market growth in the coming years, a significant factor driving this growth is the Asia-Pacific region's vast and varied patient population, which serves as a rich resource for clinical trials. A key player in this market is Caidya, a US-based clinical research organisation (CRO) with a strategic footprint across the Americas, Europe, and Asia-Pacific (APAC), including deep expertise in China. During a detailed conversation with BioSpectrum Asia, Barbara Lopez Kunz, Chief Executive Officer, Caidya spoke about the company's growth strategy in Asia, and about the challenges and opportunities that lie ahead.



**What are Caidya's major highlights for 2026 that will strengthen its presence in the global CRO market? And what are the company's growth plans for the next five years?**

The defining milestone for Caidya in 2026 is our strategic combination with Simbec-Orion. This combination significantly enhances our ability to serve as an agile, end-to-end drug development partner – from First-in-Human to registration – for biotech and biopharma companies advancing novel and innovative treatments.

Caidya brings together three organisations: dMed, Clinipace and Simbec-Orion, with deep roots in Asia, the United States and Europe, respectively. Sponsors gain direct access to experienced local teams, regional expertise and seamless coordination across major research markets, including significant experience conducting trials in China to serve the global market.

Our five-year strategy is centered on disciplined, sustainable growth, not scale for its own sake. We plan to strengthen Caidya's position as an agile drug development partner for innovative biotech and biopharma companies advancing scientifically and operationally complex therapies.

A central priority is to engage sponsors early and support them throughout the development lifecycle for complex trials. By integrating clinical pharmacology, laboratory services, medical and regulatory strategy, and global clinical execution, we can help clients make better, faster decisions from first-in-human studies through registration. Because of the high retention rates for the company, sponsors work with consistent teams, processes and quality standards that preserve knowledge and

momentum as programmes progress from early scientific and regulatory planning to registrational trials.

We will continue expanding our geographic reach by building on our strong regional foundations in China, the United States and Europe helping Asian innovators pursue development in Western markets while enabling Western sponsors to incorporate China and other APAC countries into global programmes.

In parallel, we will deepen our expertise in oncology, hematology, rare and orphan diseases, cell and gene therapy, CNS and cardio-metabolic interventions. Success will be measured by enduring partnerships, successful programme progression and our ability to help sponsors reach critical milestones efficiently.

#### **How has the company established its presence within Asia, and what is the way forward?**

Caidya's Asian presence was built through long-standing local operations, not a remote or partner-only model. Our heritage includes dMed, founded in China in 2016, and its 2021 combination with Clinipace, creating a drug development partner with deep roots in Asia and the United States and Europe.

Today, Caidya conducts studies across major APAC markets. In China, our substantial local team provides regulatory, clinical operations, project management, medical, pharmacovigilance, data management and biostatistics services. Local leadership combines multinational biopharma experience with knowledge of China's regulatory, clinical and cultural environment.

We use this infrastructure as a two-way bridge: helping Asian biotechnology companies build globally ready programmes and expand into the United States and Europe, while helping international sponsors incorporate APAC markets into globally synchronised development strategies. Our model combines consistent global standards with teams that understand local investigators, institutions, regulations and patient pathways.

#### **How do you view the current challenges and opportunities within the APAC region for the CRO sector?**

APAC offers diverse patient populations, strong investigators, sophisticated research institutions and a rapidly expanding biotechnology sector. China is central to this opportunity: recent reports indicate that more than a third of the global early-stage drug pipeline now originates there, highlighting China's growing importance to biopharmaceutical innovation.

China regulators are also working to accelerate clinical development. A new pathway may shorten IND reviews for eligible innovative therapies to 30 working days, making it easier to include China earlier in global programmes. However, large patient populations and faster reviews do not eliminate operational complexity. Sponsors must plan early for investigator engagement, ethics review, site readiness, contracts, data and biological-material requirements, and risk management.

Success in APAC requires local knowledge and globally consistent execution. Because Caidya's regional operations are integrated into our wider platform, we can help sponsors determine which Asian markets to include, when to include them and how to coordinate them within a cohesive global strategy.

#### **What are your thoughts on the growing use of AI and emerging technologies within the CRO segment? How is Caidya implementing these technologies?**

AI is rapidly moving from experimentation to practical implementation across clinical development. Its greatest near-term value lies in helping teams identify risks earlier, analyse complex information more efficiently, and make better-informed decisions. Across the drug development industry, AI is increasingly being applied to protocol and indication planning, feasibility, patient population analysis, site selection, recruitment forecasting, risk-based oversight, data review and operational analytics.

We collaborate with leading technology partners, including Medidata, to incorporate AI-powered insights into clinical trial management, and through Simbec-Orion's relationship with biotx.ai, sponsors can leverage causal modeling to support earlier decisions around indications, biomarkers, endpoints and patient selection.

In parallel, we have developed a growing portfolio of internal AI solutions that support both clinical operations and business functions, including biometrics, pharmacovigilance processing, medical writing and HR recruitment.

#### **How is Caidya contributing towards making cell and gene therapy more accessible to the Asian population?**

Caidya helps sponsors incorporate APAC countries into cell and gene therapy programmes earlier and more strategically. This includes feasibility and patient-pathway analysis, regulatory planning, qualified-site identification and preparation, investigator engagement, safety oversight and specialised operational coordination.

These trials may require complex manufacturing schedules, time-sensitive transportation, chain-of-identity and chain-of-custody controls, specialised storage, intensive monitoring and long-term follow-up. Caidya has experience with autologous and allogeneic cell therapies, including CAR-T programmes, and viral-vector-based gene therapies. Our China and APAC infrastructure pairs these capabilities with local regulatory and operational knowledge.

Accessibility begins with making clinical development more geographically inclusive. By opening appropriate APAC sites, preparing institutions, reducing patient burden and incorporating regional data into global programmes, we can expand trial participation and help build the evidence needed for future approvals.

**Please share your views on the growing complexity of oncology and rare disease trials across the globe, especially Asia.**

Oncology and rare disease trials are increasingly complex because scientific and operational decisions are closely interconnected. In oncology, biomarker-defined populations, combination therapies, dose optimisation and advanced modalities require early alignment across translational science, regulatory strategy, diagnostics, site selection and clinical operations. Sponsors must make critical decisions before enrollment and adapt as evidence emerges.

Rare disease trials face different challenges: small and geographically dispersed patient populations, limited natural-history data, uncertain endpoints, and substantial burdens on patients and caregivers. Success requires understanding the patient journey, engaging investigators and advocacy organisations early, and using flexible approaches that make participation more accessible.

Asia offers innovative science, specialist investigators and sophisticated institutions, but each market has distinct regulatory requirements, diagnostic pathways, standards of care and site-readiness considerations. Globally synchronised development—aligning protocols, regulatory planning and site preparation from the outset—can expand patient access and data diversity without creating sequential delays.

These studies require an agile drug development partner combining scientific and clinical insight with patient-centered planning, local expertise and consistent global execution.

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