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ADVANCING NEUROSCIENCE CLINICAL DEVELOPMENT BREAKTHROUGHS: OPPORTUNITIES IN THE ASIA PACIFIC REGION

The Asia Pacific region has 8 countries that rank among the top 30 globally in terms of population, with India and China occupying the first and second positions.[1] Access to potential participants is an important component for conducting successful clinical trials. The Asia Pacific region has historically been under-represented in clinical trials. However, Sponsors are increasingly interested in Asian markets due to the regional improvements in standard of living driven by a rise in GDP per capita and growing regulatory alignment and flexibility. These factors—in addition to aging populations and advances in health system and research infrastructure—led to clinical trial activities in Asia doubling in the last decade (Figure 1). Pharmaceutical and biotechnology companies are investing more money in this area to find ways to slow down disease progression and find cures.

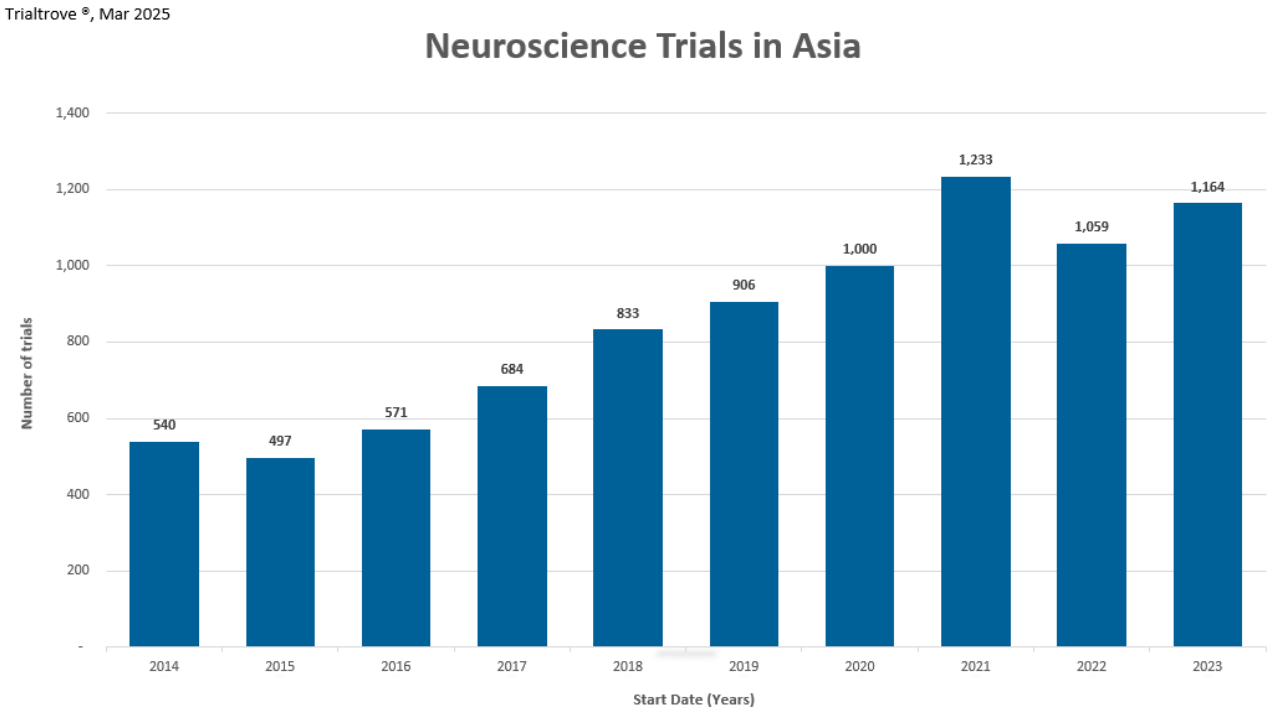

Figure 1. *Neuroscience clinical trial growth in Asia from 2014 to 2023*

As medical products become more advanced, and the scope becomes more global, clinical trials are becoming more diverse by including different regions and countries. Doing so improves knowledge on safety and effectiveness of medical products for populations across the globe. Many international regulatory bodies require clinical trials on their populations to ensure safety and efficacy.

In the following article, three Medpace neuroscience physicians, Dr. Filipe Rodrigues, Dr. Richard Scheyer, and Dr. Toshihiro Hokonohara share their expertise and experience in neuroscience and insights into the advantages of conducting clinical trials in the Asia Pacific region.

Filipe Rodrigues, MD/PhD
Medical Director, Neuroscience

Dr. Filipe Rodrigues is a MD/PhD pharmaceutical physician and academic neurologist with a decade of experience in drug development. His focus is CNS clinical development, having contributed to programs across development phases, therapeutic platforms, and routes of administration.

Richard Scheyer, MD
Sr. Vice-President, Medical Department, Neuroscience

Dr. Richard Scheyer is a board-certified neurologist and clinical pharmacologist with over 30 years of professional medical experience which includes over 20 years dedicated to clinical drug development. He has extensive experience in Phase I-III orphan neurodevelopmental and neurodegenerative diseases, including small molecule, antibody, oligonucleotide and genetic therapies, and with leading-edge approaches to confirming pharmacologic and clinical activity.

Toshihiro Hokonohara, MD
Medical Director, Neuroscience

Dr. Toshihiro Hokonohara is based in Tokyo, Japan. He has more than 10 years of experience working in the clinical research industry both in global CRO and biotech companies as a Medical Director in Japan. He has significant Phase I, II and III experiences in a variety of indications including Neurodegenerative Disease, Neuromuscular Disease, Stroke, Neuro-immunological Disease, Lysosomal Storage Disease, Epilepsy, Schizophrenia, and Major Depressive Disorder.

1. What are some advantages of clinical trials conducted in Asia Pacific region?

a. **Clinical study data from Asia Pacific region is accepted by US FDA, and EMA:** Majority of Asia Pacific countries/sites produce good quality data according to ICH/GCP international standard guidelines, and these are well accepted by international regulatory bodies.

b. **Tax rebates/tax credits:** Some Asia Pacific governments such as Australia, New Zealand, Korea, Japan, Taiwan, etc. are using tax rebate/credit as an incentive to increase drug research and development in countries.

c. **Less competition:** Clinical trials in Europe and North American countries face significant competition from available therapies and competing trials, with insufficient site resources to adequately conduct all potential trials.

d. **Cost efficiencies:** Lower operational costs position most Asia Pacific countries as attractive destinations for clinical trials when compared to Western countries.

e. **Japan advantage:** Previously, a Phase I study was required in Japan for all clinical studies. Now, Japan frequently participates in multi-regional clinical studies (MRCTs) without a prior Phase I study in Japan.

f. **China advantage:** China has made progress in shortening clinical study start-up timeline to an average of 8-10 months. HGRAC (Human Genetic Resource Administration of China) approval time is also simplified to 2 weeks now compared to 1-2 months previously. Furthermore, serum and plasma samples can be shipped out of China after a customs permit is obtained. Approval for whole blood and tissue samples is still difficult to obtain. Medpace has a wholly-owned Central Lab located in Shanghai, China, providing customized, high-quality laboratory services to support even the most complex trials.

2. What are the current trending research interests and key areas of focus in neuroscience trials?

a. Targeted therapies
    i. Expanded knowledge on disease pathophysiology
    ii. Small molecules and biologics, including monoclonal antibodies and RNA & DNA therapies

b. Focus on disease natural history modification in two groups of disease with important unmet medical needs:
    i. Common diseases with a multifactorial etiology and high individual and societal burden (e.g., Alzheimer's disease)
    ii. Rare disease with genetic etiology and high individual and carer burden (e.g., Huntington disease, monogenic autism, some forms of muscular dystrophy, Parkinson's disease or amyotrophic lateral sclerosis)
        1. Increased insight into genetic and molecular mechanism opens new avenues for targeted medicines
        2. Regulatory flexibility
    iii. RNA and DNA therapies including gene therapy
    iv. Direct CNS drug delivery methods (intrathecal, intracisternal, intraparenchymal)

c. Use of accelerated clinical drug development pipelines
    i. Not the traditional Phase I-II-III rule
        1. Adaptive designs, interim analysis
    ii. Biomarkers, including digital health technologies

d. Patient-centric drug development

e. Disease-modifying therapy—a treatment that delays, slows, or reverses the progression of a disease by targeting its underlying cause

3. What are the main challenges in neuroscience trials, and how can Medpace support overcoming them?

a. **Complexity of disease pathophysiology, Interindividual disease heterogeneity, study drug route of administration and target exposure, when to start intervention, and how to measure treatment effects:** Medpace can support and share regulatory precedents, provide medical expertise and training, and develop robust safety monitoring strategies. Medpace is also experienced in utilizing biomarkers to evaluate treatment efficacy.

b. **Recruitment of rare and ultra rare populations:** Medpace has extensive experience executing rare and ultra rare population studies. We have an in-house Patient Recruitment and Retention (PRR) team specialized in working with different patient advocacy groups and have innovative strategies to support sites in finding targeted patients.

c. **Navigating the global regulatory frameworks:** Medpace's unique approach has been preserved by 30+ years of organic growth since our inception in 1992. Our global presence and resources extend across 4 regions—North America, Europe, Latin America, and Asia Pacific. Our local experts across regulatory functions provide the insights and knowledge to navigate each country and region. Our regulatory affairs team has extensive experience navigating the global regulatory framework and can provide regulatory consultation and strategies for accelerating clinical development.

d. **Resource intensive routes of administration:** The Medpace medical team, including physicians and Advanced Clinical Practitioners, are embedded within the project team and are fully involved throughout the trial, working closely with clinical operational team. They have a deep understanding of the required process/preparation and can answer questions the clinical operational team, Sponsor, regulatory agencies, or sites might have. They also oversee the mock process or checklist to ensure the IP administration is done properly without issue.

e. **Navigating cultural differences and investigator relationships:** Medpace has several Medical Monitors specialized in neurology based in the Asia Pacific region. They can serve the needs of sites speaking Japanese, Mandarin, and Hindi, in addition to English and are accessible to global sites without time zone differences. Our Medical Monitors are available to discuss study questions directly with the site investigators, helping them understand the study better and clarify questions. This collaborative, culturally specific approach eliminates misunderstanding and increases the efficiency and success of the clinical trial.

MEDPACE ASIA PACIFIC CLINICAL TRIAL CAPABILITIES

Medpace has over 20 years of CRO experience in the Asia Pacific region. Leverage our country-specific experience and breadth of in-house expertise to navigate languages, cultures, and varied clinical and regulatory environments around the world. Streamline even the most complex clinical trials with a full-service, single-vendor outsourcing strategy. Our comprehensive CRO services are supported by our wholly-owned Central Labs with locations in the Asia Pacific region, including China and Singapore, as well as Imaging and ECG Core Lab, and a clinical trial management system, including IRT and ePRO.

LEADING NEUROSCIENCE CRO

Neuroscience is a key therapeutic focus for Medpace, and Sponsors from emerging biotechs to global pharmaceutical companies have trusted Medpace for over 30 years to lead their Phase I-IV neuroscience clinical trials spanning adult and pediatric populations in a wide range of neuroscience indications, therapeutic platforms, and routes of administration. As of March 2025, Medpace has experience conducting 207+ neuroscience studies across 6,100+ sites with 24,800+ patients in 64 countries.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

SOURCES:

1. Worldpopulationreview.com