Early Phase Facts

# A Preferred Choice for Early Phase Studies Across APAC

*Founded in Asia-Pacific and driven by scientific expertise and operational excellence, George Clinical is a leading, global clinical research organization with over 20 years of experience. We proudly employ over 500 experienced people in 40 locations who can manage clinical trials in up to 70 geographies throughout the Asia-Pacific region, North America and Europe. George Clinical provides the full range of clinical trial services to biotech, pharmaceutical, medical device and diagnostic customers, for all phases, registration and post-marketing trials.*

## Benefits At a Glance

Challenges to conducting trials in the West, especially recruitment difficulties, have made the APAC region a preferred destination for clinical trials. APAC offers a high availability of patients, worldwide accepted data quality, an increasingly high-quality infrastructure and access to key opinion leaders across therapeutic areas with global experience.

While it is widely known that APAC is a reliable destination for Phase II and Phase III studies, researchers are finding that success can also be achieved with early phase and first-in-human (FIH) trials. Early phase clinical trials form the very foundation of a drug's clinical development and have traditionally been performed in Western countries with their patient populations. Recognition of differences in disease epidemiology in different populations/geographical areas, and potential pharmacogenomic differences between ethnicities make the APAC region attractive—and important—as a trial location. Research conducted from the earliest phase of drug development on populations which will eventually have a high proportion of the use of such a drug has fortunately become more relevant to our industry.

### Why can you rely on George Clinical for early phase research?

- Extensive phase I experience for a wide range of clients
- Regionally based and savvy personnel
- Diverse, respected scientific leadership
- Proven operational excellence
- Broad APAC site and vendor network

According to the National Center for Biotechnology (clinicaltrials.gov), of the 6,900 early phase and phase I clinical trials conducted between January 2019 and January 2021, 1,470 were in East Asia, 47 in South Asia, 105 in Southeast Asia, 175 in Japan, 299 in Australia and 40 in New Zealand. That equates to roughly a third of all phase I clinical trials being conducted in the APAC region during the last two years.

As the region continues to grow in capacity for early phase trials there are many countries that have become choice locations, notably South Korea, Hong Kong, Taiwan, Singapore and Malaysia. Demographically these countries represent excellent recruitment participant pools—rich mix of ethnicities, growing health consciousness, and the right mix of ages and incomes. These countries offer competitive benefits including the ability to handle the specialized requirements of early phase trials including progressive healthcare systems, infrastructure, site experience, specialized trial centers and defined regulatory pathways.

George Clinical has been conducting trials in the APAC region for more than 20 years and offers, as a result of our long-standing footprint and familiarity, solid first-hand experience. Coupled with our depth of experience, we have developed site partnerships as well as a network of distinguished scientific leaders in both the early phase healthy volunteer trial space and the major therapeutic areas including but not limited to nephrology, oncology, cardiovascular, CNS, endocrinology, gastroenterology, infectious diseases and respiratory medicine, who guide clients with trial design and input into operational strategy.

With a deep and well-regarded history conducting early phase studies across the entire Asia-Pacific region, George Clinical stands as a leading global clinical research organization driven by scientific expertise and operational excellence. We help sponsors move through the regulation process to quick study startup and help them think through your early phase trial strategies, site selections and operational models. Using the combination of our scientific expertise and local knowledge, George Clinical managed trials maintain their focus on the scientific objective while maximizing the benefits of intelligent site selection, effective recruitment and overall trial efficiencies for the best result possible.

## Our Early Phase Services

- A one-stop-shop for early phase study conduct in APAC
- Medical writing services including protocol and investigator's brochure (IB) development and clinical study report (CSR) writing
- Identification and selection of early phase capable sites (healthy volunteers and patients)
- Study implementation and local regulatory coordination
- Comprehensive data management and biostatistics delivery
- Site management and monitoring
- Established relationships with third-party vendors able to perform laboratory analysis and reporting and to manage investigational product
- Medical monitoring and full safety services

## Take the Next Exploratory Step with Our International Team

Across the Asia-Pacific region, George Clinical teams have field-tested experience guiding studies to successful completion on time and on budget.

George Clinical
*Science. Service. Solutions.*
20+ years

Engage our business development team to scope your next early-stage study and leverage George Clinical's expertise in the APAC region.

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