

Ensuring On-time, High-quality
Project Delivery

Southeast Asia



Unmatched Experience. Proven Expertise.

Quintiles is Asia Pacific's leading provider of Phase II/III global clinical development in terms of staffing, experience and quality. With more than 600 employees across eight countries, we have the staff and resources ready to deliver on your objectives. For example, in Southeast Asia alone, Quintiles has an established network of 2,800 investigators adhering to FDA, EMEA and ICH-GCP standards. What does this mean to your organization? Huge potential and faster patient recruitment in *the New Health* landscape emerging in Southeast Asia.

Patient care in Southeast Asia is predominantly managed through hospitals, allowing rapid and efficient access. Thus, our investigators recruit a high number of patients per site, granting you significant time and costs savings. Large metropolitan, technologically advanced hospitals can also provide proven logistic resources to deliver your clinical trials successfully.

Look to Quintiles as your path to reaching more than 600 million potential patients, including high-density urban areas with populations up to 15 million.

Prevalent Diseases:

- > *Infectious diseases (including hepatitis B and C)*
- > *Cardiovascular disorders*
- > *Diabetes*
- > *Psychiatric disorders*
- > *Degenerative neurological disorders*
- > *Cancers*

Quality Data

- > *All processes in Southeast Asia, including data production and management, follow Quintiles' rigorous global SOP standards*
- > *97% of Quintiles' studies in Southeast Asia produced data for FDA and EMA (formerly known as EMEA) submissions*
- > *Fewer competing protocols in the region mean greater investigator focus on your projects*

Operational and Delivery Excellence

- > *Established track record of success in the region since 1995 with ample resources to manage your trials*
- > *Over 500 studies conducted and delivered involving more than 4,800 sites*
- > *Unparalleled clinical monitoring experience across all key therapeutic areas*
- > *Country-based Quintiles staff has a deep understanding of local cultures, regulatory issues and the healthcare environment*
- > *Our clinical staff are fluent in English facilitating communication between sponsors and Project Management teams*

Modern, Practical Environment

- > 100% of our Southeast Asian sites have Internet access enabling EDC trials
- > 24 / 7 communications from anywhere worldwide — study updates and patient recruitment data are uploaded real-time to a secure Project Communications Internet site giving you immediate access

Key Facts

Regional

- > Rapidly growing commercial markets where consumer power is strong
- > Fewer competing protocols

Quintiles

- > First global CRO in Southeast Asia
- > Leading Asia Pacific provider in terms of staffing, experience and quality
- > More than 600 employees across eight countries
 - Indonesia, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam
- > Singapore location serves as a hub for Asia, with a regional central laboratory, safety monitoring unit and a clinical supplies distribution facility

Assurance of Quality

| Year | Audit Type |
|------|---|
| 2002 | FDA inspection in Taiwan; product now approved in US and EU |
| 2006 | FDA audits in Taiwan and Thailand; pivotal hepatitis B study |
| 2006 | EMA audits in Thailand and China; successful with pending EU approval |
| 2007 | FDA inspection in Philippines for CNS; inspection successful, no findings |

The Resources to Deliver on Your Objectives

- > Low staff turnover quickly builds experience levels, assuring timely project delivery and increasing efficiency and cost savings
- > Project Management (PM)
 - Highly qualified PMs with pharmacy / life sciences backgrounds
 - PMs or CTLs from Quintiles Asia managing global studies
- > Clinical Research Associates (CRAs)
 - Multilingual, skilled and proactive CRAs
 - Pharmacy or life sciences background
 - Wide therapeutic area experience
 - Resourcing to stay ahead of client needs
 - Strong relationships with investigators

Global Laboratory Expertise Locally: Singapore

- > Delivering clean, reliable and comparable data through global network of wholly-owned, CAP-accredited central labs
- > Enhancing internal capabilities and ensuring quality from sample collection to data delivery through extensive scientific expertise
- > Validating and testing commercially available biomarkers and managing technical transfers through a proven test menu with assay development capabilities
- > Leveraging data-driven insights to design and run trials that reduce complexity and speed outcomes, all on a more predictable timeline

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Navigating the new health