

FACT SHEET
Phase II/III Global Clinical Development

Same Language. Same Technology.
Same Quality Standards.

Australia and New Zealand



Save Time without Quality Trade-offs

Quintiles has more than 250 professionals in six offices throughout Australia and New Zealand. This means, with Quintiles as your ally, you gain instant, efficient access to a predominantly “Western” urban population with a broad range of disease profiles where speed of patient enrolment in key therapy areas can surpass that in other western populations.

Did you know Australia/New Zealand frequently enrolls the first patients worldwide for global studies? The region’s GCP was formally mandated by TGA in 1991 but a 3-year decline in the numbers of studies conducted in the region means the capacity exists to deliver studies on innovative medicines. The presence of a well established private ethics network can significantly reduce start-up time lines for appropriate trials. Australia and New Zealand also have more than 40,000 physicians providing high-quality medical care (comparable with the US and UK). With a southern hemisphere “reverse seasonality” you can boost your global recruitment – ideal for seasonal studies.

Choosing Quintiles’ global clinical development services provides you with the right operating environment and culture for success. Trust our expertise to mitigate risk and seize opportunity within *the New Health* landscape.

State-of-the-art Technology

- > 24/7 communications from anywhere in the world — study updates and patient recruitment data are uploaded real-time to a secure Project Communications Internet site giving you immediate access to data and reports anytime you need them

Operational and Delivery Excellence

- > *Quintiles provides fully integrated services for Phase I-IV studies in Australia/New Zealand*
- > *Proven track record in the region since 1993*
- > *Project Coordination Center (dedicated in-house monitoring)*
- > *Depth and breadth of services to manage your clinical trials*
- > *Trial experience across virtually all key therapeutic areas*
- > *More than 400 studies conducted in over 1,000 unique sites with over 30,000 patients*
- > *Highly experienced investigator network and well-established relationships with leading medical centers and site management organizations*
- > *All studies conducted to FDA, EMA and ICH-GCP standards*
- > *Only English language documentation required*
- > *Trial management experience across the Asia Pacific region*

Quality Data

- > *Consistent global data quality — we follow the same study protocols and deliver the same high-quality data as in Europe and North America*
- > *More than 90% of studies we have conducted support pivotal submissions in US and Europe*
- > *In 2010 there were no critical audit findings from 24 audits of our work in Australia and New Zealand*

Key Facts

Regional

- > *Over 26M people concentrated in major cities*
- > *Ethnic sub-populations*
- > *An ageing population with a high incidence of obesity, skin cancer and stroke*
- > *Established centers for vaccines research*

Quintiles

- > *Quintiles Australia / New Zealand established in 1993*
- > *More than 250 professionals in six offices throughout the region — Adelaide, Auckland, Brisbane, Melbourne, Perth, and Sydney*

Prevalent Diseases

- > *Cardiovascular disorders*
- > *Cancers*
- > *Respiratory diseases*
- > *Diabetes*
- > *Neurological disorders*
- > *Infectious diseases*

The Resources to Deliver on Your Objectives

- > *Our clinical research professionals are trained to meet the highest quality standards*
- > *Our CPMs and CRAs are among the most experienced in the region*
- > *All of our investigator sites have research staff/study coordinators*
- > *Our people understand the local cultures, regulatory issues and healthcare environment*
- > *Our Clinical Project Managers have experience managing projects across the Asia Pacific region and across integrated, full-service projects*
- > *Skilled employees on hand to lead and deliver your study with a robust ongoing training program*

Key Services Provided in Australia and New Zealand

Quintiles can provide fully integrated or stand-alone services for Phase I-IV studies

- > *Clinical Monitoring, on site and remote*
- > *Project Management*
- > *Quality Assurance*
- > *Regulatory Affairs*
- > *Medical Services*
- > *Biostatistics*
- > *Medical Writing*
- > *MediGuard*
- > *Data Management*
- > *Dedicated site start-up unit*

Global Laboratory Expertise Locally

- > *Delivering clean, reliable and comparable data through the largest global network of wholly-owned, CAP-accredited central laboratories including Singapore, China and India*
- > *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*

Contact Us:

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