

THE BENEFITS OF RUNNING CLINICAL TRIALS IN AUSTRALIA

QPS is a leading full-service global CRO with extensive experience conducting complex clinical trials offering comprehensive services to ensure successful drug development. Our experienced and dedicated global team provides unmatched support, from preclinical studies to bioanalysis and all phases of clinical trials.

WHY CHOOSE QPS FOR CLINICAL TRIALS IN AUSTRALIA?

QPS is ready to manage your whole clinical program (full service) including qualified sites in Australia (Perth, Adelaide and Melbourne). Australia is a great location to run a clinical trial due to the country's continued commitment to reduce drug development time.

Important Benefits

1. Rapid Trial Initiation via the CTN Scheme

Australia allows clinical trials to begin without direct regulatory approval from the authority. Only ethics approval and Clinical Trial Notification (CTN) to the TGA are required. Start-up typically takes just 6 – 8 weeks.

2. Globally Accepted Data Quality

Clinical data generated in Australia is accepted by major regulatory agencies such as the FDA and EMA, making it suitable for global new drug applications (NDA/BLA).

3. Patient Recruitment and High-Quality Clinical Infrastructure

Australia, known for high medical standards and robust GCP compliance, offers strong patient recruitment potential for specific indications such as oncology, rare diseases, and respiratory conditions.

4. Incorporating Australia into MRCTs or Global Pivotal Trials

China pharmaceutical companies are incorporating Australia into their Phase II/III trials as part of global or multi-regional clinical trial (MRCT) development strategies.

Financial Incentives

- ▶ Australia offers up to 43.5% R&D tax rebate for eligible expenditures, particularly for small to mid-sized enterprises.
- ▶ Research and Development (R&D) Tax Incentive
- ▶ Cooperative Research Center (CRC) Grants
- ▶ Export Market Development (EMDG) Grants
- ▶ Accelerating Commercialization Grants
- ▶ Medical Research Future Fund (MRFF)
- ▶ Collaboration with Research Institutions

Companies considering trials in Australia should carefully review the eligibility criteria and requirements for these incentives. Additionally, consulting with tax professionals and legal experts familiar with the Australian Regulatory landscape is advisable to ensure compliance and maximize the available benefits.

It is important to note that while Australia offers many advantages, each clinical trial's unique and factors such as specific research requirements, patient population, and regulatory considerations should be carefully assessed.

A GLOBAL FULL SERVICE CRO ACROSS USA, EU, ASIA, AND AUSTRALIA

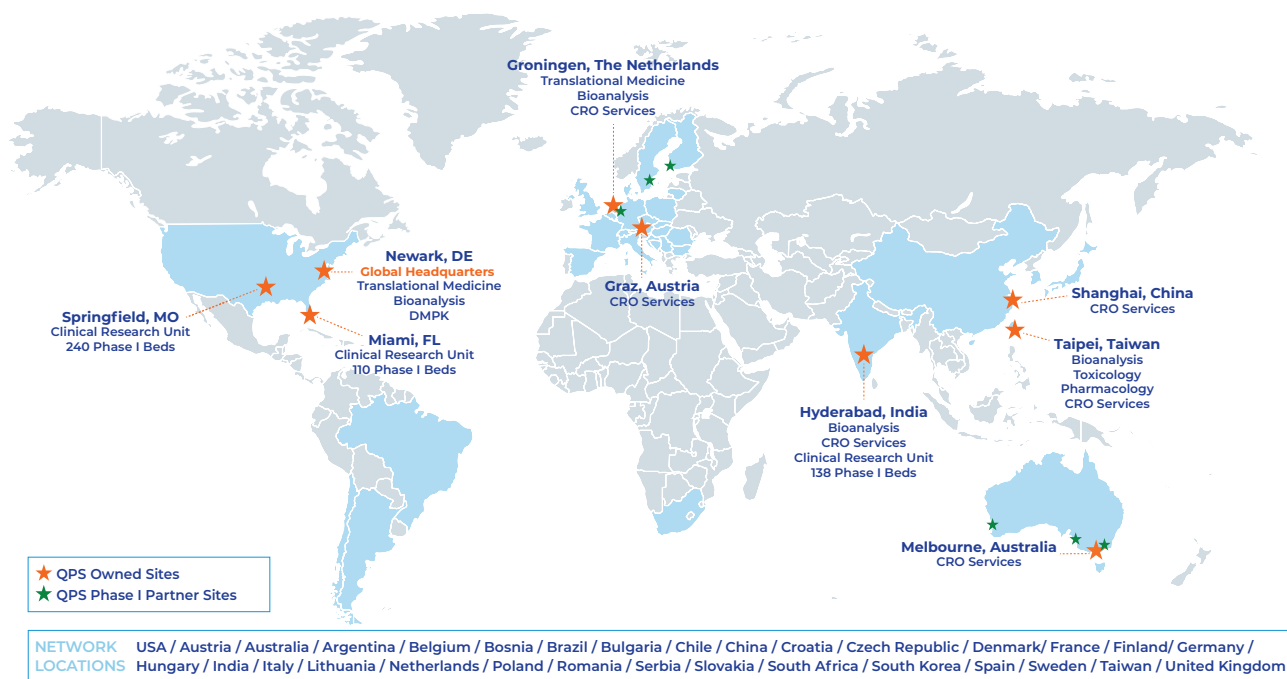
QPS CLINICAL RESEARCH OPERATIONS SERVICES

- ▶ Project Management
- ▶ Site Selection & Monitoring
- ▶ Clinical & Medical Monitoring
- ▶ Data Management & Biostatistics
- ▶ Medical Writing
- ▶ Central Lab Services
- ▶ Regulatory & Medical Affairs
- ▶ Safety & Pharmacovigilance
- ▶ Clinical Program Management

QPS SITE NETWORK IN AUSTRALIA

- ▶ Nucleus: Melbourne, Australia - <https://www.nucleusnetwork.com/us/>
- ▶ CMAX: Adelaide, Australia – <https://www.cmax.com.au>
- ▶ Linear: Perth, Western Australia - <https://www.linear.org.au/>

ONCOLOGY CLINICAL TRIALS SITE NETWORK LOCATIONS



Pharmacology



Toxicology



DMPK



Bioanalysis



Translational
Medicine



Phase I Clinics



Regulatory &
Medical



Central Lab
Services