ADVANCE QUEENSLAND

CLINICAL TRIALS

Queensland is one of the world's most attractive locations for clinical trials. Queensland is home to world-class researchers and clinicians, leading healthcare and research infrastructure, a stable socio-political environment, robust intellectual property system, and a simple and efficient regulatory framework for clinical research.

Queensland has an outstanding early phase research and clinical trial capability and landscape. There are several world-class universities, hospitals, infrastructure, academic centres of excellence, and clinical trial facilities for clinicians and researchers to conduct trials.

More than 85 core biotechnology companies and 80 biotechnology-related research organisations make up a dynamic early stage private sector engaged in collaborative drug development. It is supported by experienced private sector service providers covering all aspects of clinical trial management. With Australia recognised as a Tier 1 healthcare region, high-quality data generated with Queensland service providers are accepted in all international regulatory jurisdictions.

Queensland is internationally respected for its contribution to commercially driven drug development. Small to medium biotechnology companies and major multinationals are assisted by private sector organisations and government (including financial support through the $518M Advance Queensland initiative) in the planning and execution of their early stage development programs, to expedite and maximise investor value. Furthermore, eligible companies can take advantage of the Australian R&D Tax Incentive Program with a cash refund of up to 43.5% on qualifying R&D expenditure.

Queensland and Australia adopt a fast and pragmatic regulatory pathway for clinical trials. The regulatory framework is highly favourable, allowing rapid entry into clinical trials through streamlined processes, and attractive financial incentives. Under the Clinical Trials Notification (CTN) scheme administered by the Therapeutic Goods Administration (TGA), research proposals are submitted directly to human research ethics committees (HRECs), which assume the primary responsibility for ethical and scientific review. As a result, the usual review and approval cycle is significantly accelerated. Ethics review processes for multi-centre research also reduce unnecessary duplication in the review of research.

Discover more about the life sciences opportunities in Queensland

The **Queensland Science Capability Directory** provides information on Queensland's key research capabilities, science expertise, and collaboration and investment opportunities.

➲ www.qld.gov.au/ScienceDirectory

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Queensland Government Australia

A vibrant clinical trials industry

Clinical Network Services (CNS)

CNS is an integrated service group focused on product development, headquartered in Australia with offices in New Zealand, the UK and the USA. CNS creates value for small to medium-sized biotechnology companies by progressing early stage products through phase I/II clinical trials sooner. CNS offers a unique service where it integrates BioDesk, an intelligent global product development and regulatory affairs consultancy, with committed, highly experienced clinical services and biometrics teams. CNS's regional clinical advantage is driven by the extremely pragmatic regulatory environment in Australia and New Zealand that makes it possible for our clients to enter the clinic quickly, without prior regulatory approval. CNS has supported over 500 distinct projects, for over 250 clients across more than 30 therapeutic areas.

> "CNS is proudly Australian and proudly Queensland. CNS has enjoyed the continued support of the Queensland Government over its 20-year history and without initiatives such as the Queensland Clinical Trials Network, establishing the CNS brand globally would have been much more challenging."
>
> Russell Neal,
> Managing Director, CNS

Q-Pharm

Q-Pharm is one of Australia's largest and most experienced early phase clinical trials companies, forming the cornerstone for integrated clinical research at the QIMR Berghofer Medical Research Institute within the Royal Brisbane and Women's Hospital campus. Australian HRECs enable expedited trial approval and startup times through the TGA's CTN/CTX system. This approval system, combined with the Australian R&D tax incentive and Q-Pharm expertise, means that clinical trials conducted at Q-Pharm are not only faster, but can cost significantly less than US and Western European based trials. Over the past 15 years, Q-Pharm has successfully completed early phase clinical trials with more than 15,000 subjects in a broad range of therapeutics areas.

> "Clinical trials in Australia are an important offering to the world — the system is easy, efficient and rapid."
>
> Professor Frank Gannon,
> CEO QIMR Berghofer Medical Research Institute

ERA Consulting Group

ERA is an international biopharmaceutical product development and regulatory consultancy. ERA's Australian office was established over 10 years ago. ERA was the first global biotech/pharma consultancy to inwardly invest in Queensland. A specialised team of more than 30 professionals, including scientists with R&D and industry experience and former regulators, is spread throughout ERA's offices worldwide. ERA Consulting (Australia) specialises in phase I clinical trials and complex biotechnology-related medicines. The company is experienced in over 450 products, including rDNA proteins and peptides, vaccines, gene and cell therapy, tissue-engineered products and innovative new chemical entities. ERA can assist with product development from preclinical and chemistry, manufacturing and control (CMC), through to support with clinical trial design and applications, agency interactions (EU, US and Australia), and complete eCTD-based submissions to regulators.

Model Answers

Model Answers applies pharmacokinetic (PK) and pharmacodynamic (PD) modelling, simulation and analysis to assist clients in making the critical decisions that influence success across every stage of the drug development process.

Academic clinical trials facilities

The University of the Sunshine Coast's (USC) Clinical Trials Centre

The USC Clinical Trials Centre is developing an efficient and effective regional approach to conducting industry-sponsored drug and device clinical trials across the Sunshine Coast's healthcare system. This model also aims to grow the region's clinical trials ecosystem by supporting the training and development of clinicians, and expanding the region's capabilities and capacity to undertake an increased number of trials. The model involves partnering with and leveraging the existing health capabilities within primary care, specialist medicine, cancer centres and private hospitals to conduct a range of sponsored clinical trials. The roll out of the initial model design over two years has been successful in attracting 150 inbound trial opportunities, which ranged from phase I to IV drug and device clinical trials. Streamlined processes and timeframes include:

- ethics approval – less than two weeks using the external provider Bellberry
- governance approval – USC approval within two to five days (around 50% to 75% faster than most sites nationally)
- participant recruitment – consistently meeting or exceeding recruitment targets. Trials are chosen based on data-driven feasibility from electronic medical records, with a website screening tool to determine participant eligibility and register interest.

> "The USC Clinical Trials Centre is growing a vibrant clinical trials ecosystem on the Sunshine Coast, obsessed with efficiency and keen to bring the transformative benefits of new drugs and devices to our community."

Lucas Litewka
Director, USC Clinical Trials Centre

Griffith University's Clinical Trial Unit

Griffith University's Clinical Trial Unit is a core research facility within the 200 hectare Gold Coast Health and Knowledge Precinct, located in the heart of Australia's emerging global city. It is adjacent to the research intensive Griffith University, a clinically driven teaching hospital, a leading private hospital, and a range of prominent corporations. The unit is fitted with GCP-compliant, state-of-the-art facilities for phase I–IV clinical trials. It provides professional trial coordination services across a range of therapeutic areas to pharmaceutical, biotechnology, nutraceutical and complementary medicine companies, as well as clinical research organisations.

The Translational Research Institute (TRI)

TRI is a leading Australian innovative medical research, development and translation facility located within the Princess Alexandra Hospital campus. The TRI's Clinical Research Facility (CRF) is a controlled and safe environment within which to conduct research on human subjects. The CRF has ready access to hospital facilities and emergency response teams. There are currently around 40 studies underway at the CRF, including evaluations of treatments for a range of cancers; skin, respiratory, liver and brain disorders; obesity and rheumatoid arthritis.

Mater Research

Mater Research is a recognised leader in medical research, with more than 300 laboratory and clinical researchers working across Mater Health's hospitals and health services, and the world-class TRI. Mater Research has built a reputation for excellence both locally and globally in mothers', babies' and women's health, cancer biology and care, neurosciences and cognitive health, chronic disease biology and care, and optimising acute care. With expertise across all facets of medical research – study design, ethics and governance, data collection, biobank management, analysis, and implementation science – Mater Research is responsible for robust management of all research and clinical trials at Mater Health.

Industry infrastructure

> The financial incentives as well as the clinical trial access schemes allows our clients to fast track into Phase 1 clinical trials faster than anywhere else in the world.

Tertia Dex,
Director Project Management,
Patheon Biologics

Everything you need in one place

Bringing together financial, manufacturing, bioanalytical, clinical and regulatory experts, Queensland is the one-stop shop for clinical research and development.

Patheon Biologics and LuinaBio are the industry-leading biopharmaceutical contract manufacturing organisations.

TetraQ is state government-supported contract research organisation providing a range of integrated and tailored preclinical services to the global pharmaceutical and biotechnology industries.

Clinical Network Services is a uniquely integrated service group providing a comprehensive range of services in strategic planning, delivery of (CMC)/non-clinical development programs and rapid initiation of clinical trials.

Q-Pharm is a commercial phase I/II clinical trials facility, forming the cornerstone for integrated clinical research at QIMR Berghofer.

ERA Consulting is a leading independent regulatory affairs and product development consultancy specialising in complex biotechnology-related medicines, and assisting with preclinical services and CMC, and clinical trial design and applications.

Life Sciences Queensland Limited (LSQ) is Queensland's peak industry group, which grew out of the Queensland Clinical Trial Network established in 2005 for therapeutic product service providers. LSQ continues working to assist the growth of individual firms and organisations, and build the profile, capacity and capability of the sector to ensure long-term economic, social and environmental benefits to Queensland. ➲ www.lsq.com.au

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