Conducting clinical trials in Queensland
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Queensland has the bioanalytical, manufacturing, clinical, regulatory and marketing capabilities to provide a one-stop-shop for clinical research and product development.

High capacity

Queensland is an attractive location for clinical trials. The state hosts world-class researchers and clinicians, leading healthcare and research infrastructure, a stable socio-political environment, robust intellectual property frameworks and a simple and efficient regulatory framework for clinical research.

Queensland provides a one-stop-shop for clinical trials by offering everything needed to design products, execute high quality clinical trials and generate robust data that is accepted in international regulatory submissions. Queensland has developed an outstanding clinical trial capability including both First-in-Human and early phase clinical trials, and our ethnically diverse population across the state facilitates patient recruitment.

The state is proud to be the home to world-class universities, hospitals, academic centres of excellence and state-of-the-art clinical trial facilities. Additionally, we have Contract Research Organisations (CROs), Good Laboratory Practice and Good Manufacturing Practice (GMP) capabilities, all essential for quality clinical trials. Teletrial capability is being developed to provide a networked approach to maximise patient recruitment.

High quality

Queensland is internationally recognised for its highly trained clinical workforce and the high-quality data produced by its experienced research teams.

Under the Therapeutic Goods Act 1989 and associated regulations, International Council for Harmonisation (ICH) or ISO Good Clinical Practice (GCP) standards are mandatory for all Australian clinical trials involving unapproved medicines or medical devices.

Australian clinical trial data is accepted by international regulatory agencies, including the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
Research governance

Applying to undertake research within Queensland Health is a two-step process, comprising ethics and governance applications. A single ethics review process means one ethics approval for many sites, saving sponsors time and money.

Research proposals are submitted directly to HRECs, who have the primary responsibility for ethical and scientific review.

To obtain regulatory approval for the commencement of a clinical trial, the TGA is notified via the CTN scheme after ethics approval. Within Queensland Health, the median time from ethics submission to governance authorisation is 103 calendar days.¹

Highly efficient

Queensland and Australia adopt a fast and pragmatic regulatory pathway for clinical trials. The regulatory framework allows rapid entry into clinical trials through streamlined processes under the Clinical Trials Notification (CTN) scheme administered by the Therapeutic Goods Administration (TGA). Queensland Health can provide advice on clinical trial approval processes including documentation and regulatory requirements to gain approval to conduct a clinical trial in Queensland (including timelines for Human Research Ethics Committees (HREC), Research Governance and TGA CTN / Clinical Trials Exemption (CTX) approval).

Research approval

Documents

• Research Protocol and Investigator Brochure
• Local sponsor provides Participant Information Sheet and Consent Form

Apply

• Submission to Human Research Ethics Committee (HREC)
• Application for Research Governance Authorisation requires submission of trial site contracts including indemnity agreements and Site specific assessment (SSA)

Approval

• Ethics approval: median average in Queensland Health is approximately 21 days on the clock (this excludes the time it takes for the Sponsor to answer HREC questions)
• Research Governance Authorisation

¹. Published data 2016
An analysis of health and medical research conducted in Queensland public hospitals (January 2011 to December 2016)
Cost effective

Every year, over 1,000 new clinical trials are commenced in Australia by pharmaceutical, biotechnology and medical device companies. Commercial sponsors take advantage of competitive clinical trial costs in Queensland and Australia. In early phase clinical trials, Australia is 28 per cent less than the US before Federal Government tax incentives and 60 per cent less after tax incentives2.

Eligible companies can also take advantage of the Australian R&D Tax Incentive with a cash refund of up to 43.5 per cent on qualifying* R&D expenditure. Other incentives include:

- **Tax Incentives for Early Stage Investors**—the Australian Tax Office offers eligible investors who purchase new shares in a qualifying early-stage innovation company the potential to access a non-refundable carry forward tax offset and modified capital gains treatment. [www.ato.gov.au/earlystageinvestors](http://www.ato.gov.au/earlystageinvestors)

- **BioMedTech Horizons**—funding through MTPConnect to support proof of concept to commercial development of biomedical and medical technologies. [www.mtpconnect.org.au/biomedtechhorizons](http://www.mtpconnect.org.au/biomedtechhorizons)

- **Biomedical Translation Fund**—provides companies with venture capital through licensed private sector fund managers to develop and commercialise biomedical discoveries in Australia.


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* Clinical research that qualifies as core R&D activities are experimental activities:

- whose outcome cannot be known or determined in advance on the basis of current knowledge, information or experience, but can only be determined by applying a systematic progression of work that:
  - is based on principles of established science
  - proceeds from hypothesis to experiment, observation and evaluation, and leads to logical conclusions
  - that are conducted for the purpose of generating new knowledge (including new knowledge in the form of new or improved materials, products, devices, processes or services).


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Life Sciences Queensland

Life Sciences Queensland Ltd (LSQ), an Australian peak industry group, represents over 170 member entities in Queensland working to assist the growth of individual firms and organisations. LSQ also builds the profile, capacity and capability of the life sciences sector to ensure long term economic, social and environmental benefits to Queensland.

The Queensland Clinical Trials Network Inc, via LSQ, assists developers of human therapeutics and devices to distribute preclinical and clinical research to the network’s ‘best-of-breed’ cluster of service providers. For a full overview of Queensland’s clinical trials capabilities, visit LSQ.

Queensland has a number of clinical trial service providers:

**TetraQ**

TetraQ at The University of Queensland is a CRO recognised for quality in preclinical and clinical testing, and technical expertise in drug development and commercialisation. TetraQ undertakes pharmacology, toxicity and bioanalytical analysis on drugs/products using animal models of human diseases. These tests are essential to validate and characterise a drug or product prior to a clinical trial.

**ERA Consulting**

ERA Consulting is an international regulatory affairs and biopharmaceutical product development consultancy. ERA Consulting can assist with preclinical services, chemistry, manufacturing and controls (CMC), advice on clinical trial design and agency interaction (TGA, FDA and EMA).

**Clinical Network Services (CNS)**

Clinical Network Services (CNS) is an intelligently integrated service group focused on product development. Headquartered in Queensland with offices in New Zealand, the United Kingdom and the US, CNS creates value for small-medium sized biotechnology companies by progressing early stage products through phase 1 and 2 clinical trials or the marketplace sooner. CNS offers a unique service where it integrates BioDesk, an expert global product development and regulatory affairs consultancy, with a committed, highly experienced Australian/New Zealand clinical services and biometrics team.

**Novotech**

Novotech is internationally recognised as the leading regional full service CRO. Novotech provides clinical development services across all clinical trial phases and therapeutic areas including feasibility assessments, ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central laboratory services, report write-up to ICH requirements, project and vendor management.

**Pharma To Market**

Pharma To Market is a leading regulatory affairs consulting company with offices in Australia, Singapore and Malaysia. They assist pharmaceutical, biotechnology, medical device and other life science companies register their products throughout the Asia-Pacific region. Their other core services include compliance, pharmacovigilance and electronic Common Technical Document publishing. Pharma To Market’s client relationships are built on trust, transparency and reliability, which they achieve through their commitment to quality and excellence.

**Q-Pharm**

Q-Pharm is a state-of-the-art early phase clinical trials company providing a broad range of high-quality services to commercial and academic clients around the world since 2002. With facilities based at the QIMR Berghofer Medical Research Institute within the Royal Brisbane and Women’s Hospital precinct in Brisbane, Q-Pharm has safely and successfully conducted more than 400 early-phase clinical trials in over 15,000 volunteers.

**Icon Group**

Icon Cancer Foundation delivers a comprehensive cancer clinical trials program across Icon Group’s network. As Australia’s largest private clinical trials provider, Icon has more than 100 clinical trials running across the Group’s day hospital network. It has a solid reputation for phase 2 and phase 3 trials due to its emphasis on safety, efficiency and capacity to recruit quickly from a broad patient base. Over the last 12 months, Icon Cancer Foundation has significantly increased its participation in phase 1 oncology clinical trials to patients who have exhausted standard lines of therapies.
The Gallipoli Medical Research Foundation (GMRF) Clinical Trials Unit focuses on phase 1 patient studies and phase 2 and 3 studies at Greenslopes Private Hospital. Since its establishment in 2005, the GMRF Clinical Trials Unit has performed over 150 trials in liver disease, oncology and respiratory illnesses. The majority of trials are sponsored by multinational pharmaceutical/biotechnology companies.

Translational Research Institute Clinical Trials Unit

The Translational Research Institute (TRI) has two Clinical Trial Units, the Clinical Research Facility co-located at the Princess Alexandra Hospital and TRI@Childrens located in the Centre for Children’s Health Research opposite the Lady Cilento Children’s Hospital. These units provide state-of-the-art specialist facilities to deliver patient centric investigator led or sponsored clinical trials across Phase 1–4 in the pharmaceutical and nutraceutical sectors. The clinical trials team at TRI have extensive experience in clinical trial management and coordination services across multiple phases of clinical research. TRI’s current clients and partners include leading top 10 pharmaceutical companies, biotechnology and clinical research organisations, hospitals, universities and research institutes.

James Cook University Clinical Trials Centre

James Cook University (JCU), through the Australian Institute of Tropical Health and Medicine and in collaboration with the Tropical Australian Academic Health Centre, conducts clinical trials that seek to improve the health and wellbeing of tropical populations, with a focus on infectious disease, chronic disease and the intersection between the two. With the capacity to conduct Phase 1–4 clinical trials and experienced trial investigators, JCU is looking to further develop clinical trial activity in the northern Queensland region.

University of the Sunshine Coast Clinical Trials Centre

The University of the Sunshine Coast Clinical Trials Centre conducts commercially sponsored clinical trials across a private network of 16 locations which includes primary care, specialist medicine, cancer centres and hospitals. Phase 1–3 drug and device trials are conducted across a broad range of therapeutic areas.

Griffith University Clinical Trial Unit

Griffith University’s Clinical Trial Unit, located in the Griffith Health Centre on the Gold Coast Campus, is situated adjacent to the Gold Coast University Hospital and is part of the Gold Coast Health and Knowledge Precinct. It is a core research facility for Griffith University and offers purpose-built, GCP aligned clinical trial facilities for Phase 1–4 clinical trials, including academic or clinical investigator initiated trials.

Wesley Medical Research Clinical Trials Centre

The Wesley Medical Research Clinical Trials Centre is located within the Wesley Hospital at Auchenflower, Brisbane. The Wesley Medical Research Clinical Trials Centre conducts investigator-led and sponsored phase 1–4 clinical trials with a focus on the safety and effectiveness of drugs, devices, treatments and preventative measures.

Coastal Digestive Health

Coastal Digestive Health is a gastroenterology clinic on the Sunshine Coast that consists of a team of paediatric and adult gastroenterologists, a hepatologist, an Inflammatory Bowel Disease nurse practitioner and allied health care practitioners. Since early 2017, Coastal Digestive Health has been increasingly involved in the management of patients in clinical trials. To date, they are one of the leading sites for phase 3 trials in inflammatory bowel disease and are amongst the best recruiting sites for two trials throughout Australia.

In addition to the clinical trial sites, specialised staff and ethics and regulatory services offered through Queensland Health, Queensland has a range of providers that support the full life cycle of industry-sponsored clinical trials.
Clinical trials are conducted at locations throughout the state

Partner with us
Queensland Health, through the Health Innovation, Investment and Research Office, is looking for opportunities to collaborate with government agencies, entrepreneurs, industry and research institutions to expand our vibrant health sector to improve the wellbeing and healthcare of Queenslanders.

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