CLINICAL TRIALS
A DYNAMIC ENVIRONMENT FOR CLINICAL TRIALS
With world-class research capabilities, an efficient regulatory system and a strong and stable business environment, Australia is an ideal location for high-quality clinical trials.

Australia is home to some of the world’s leading scientists, physicians and healthcare professionals. It boasts world-class medical research and healthcare infrastructure, a stable socioeconomic environment, an ethnically diverse population and a strong intellectual property regime. An efficient regulatory system, including a rapid clinical trial approval system, well-established clinical trial infrastructure, experienced and well-qualified personnel and globally competitive tax incentives for research and development (R&D) investment, all help make Australia a leading destination for clinical trials.

Every year, over 1000 new clinical trials are commenced in Australia by pharmaceutical, biotechnology and medical device companies (Figure 1). In 2015, about 1,360 clinical trials commenced, representing an estimated $11 billion of direct expenditure. Of this, approximately $830 million came from commercial entities, the majority via international inbound investment. An estimated 6,900 highly skilled staff in commercial and clinical facilities across Australia are involved in conducting clinical trials.¹

Global companies benefit from streamlined processes and clinical trial protocols which are immediately globally transferable, ensuring outcomes that are reliable, highly respected and can be made readily available in other jurisdictions.

The Australian Government, in partnership with industry and other stakeholders, has introduced a number of reforms to make Australia an even more attractive place to conduct clinical trials whilst maintaining the highest quality and ethical standards. They include initiatives to improve the speed of study approvals, boost patient recruitment and standardise and reduce costs associated with clinical trials in Australia.²

All Australian Governments at both state and federal levels have demonstrated a strong commitment to supporting clinical research across Australia.

Talk to your local Austrade representative for more tailored information and advice about connecting and partnering with the Australian clinical trials industry.
Figure 1: New clinical trials for medicines (drugs) and medical devices, 2009-2015

Note: excludes ‘withdrawn’ trials and duplicate entries. Where trials had a ‘NULL’ actual start date, the anticipated start date was used. Drugs includes all ‘drug’ or ‘biological’ intervention types only (excluding any ‘device’ intervention types). Devices includes ‘device’ intervention types only (excluding any ‘drug’ or ‘biological’ intervention types). Drug & Device includes both ‘drug’ and/or ‘biological’ and ‘device’ intervention types. Other includes: ‘behavioral’, ‘procedure’, ‘genetic’, ‘radiation’, ‘dietary supplement’, (not exhaustive) and trials where no intervention type was specified.

Source: ANZCTR and ClinicalTrials.gov – combined by ANZCTR; L.E.K. analysis
For over three decades, pharmaceutical, biotechnology and medical device companies from around the world have relied on the ability of Australian clinical trial sites to deliver timely results, whilst meeting the highest quality and ethical standards.

International and local pharmaceutical, biotechnology and medical device companies conduct a full range of clinical trials in Australia, from Phase I to Phase IV (Figure 2) and across numerous therapeutic areas (Figure 3), all supported by a comprehensive range of services to the sector.

Historically, Phase III studies were the largest component of clinical trial activity in Australia. However, since 2008, Phase I activity in Australia has grown steadily, recording a 17.2 per cent growth in volume from 2012–2015, compared with 1.8 per cent globally. This reflects the advantages offered by specialised Phase I units in Australia, which have earned a reputation for superior quality assurance. In addition, Australia has a stable and streamlined regulatory environment that offers start-up times that are highly competitive compared with other countries. It is also an indication of the increasingly important role Australia plays in developing new therapeutic products for the global market.

As an example, collaboration between global pharmaceutical companies and Australian entities has enabled the development and distribution of ground-breaking Australian discoveries such as Gardasil®, a vaccine against human papillomavirus, which is helping protect millions of women around the world from cervical cancer, as well as Relenza®, the first effective drug for treating all strains of influenza, as well as the catalyst for a new class of antiviral agents, neuraminidase inhibitors.
The global medical device and pharmaceutical industry and non-industry bodies all conduct a full range of clinical trials in Australia, from first-in-human (Phase I) trials to post-market studies (Phase IV).

### Industry-sponsored trials*

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<td>IV</td>
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<td>Other</td>
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* Industry-sponsored trials totalled 1,305.

### Non-industry sponsored trials

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<td>IV</td>
<td>9%</td>
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<tr>
<td>Other</td>
<td>72%**</td>
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** Non-industry sponsored trials totalled 2,697. The majority of these trials are in areas that do not follow the phase paradigm, such as trials involving non-biological procedures or methods of care, clinical practice improvements or preventative care.
In early phase clinical trials Australia is 28 per cent cheaper than the US before tax incentives, and 60 per cent cheaper after tax incentives.\textsuperscript{7}
INTRODUCTION

INDUSTRY OVERVIEW

INDUSTRY STRENGTHS

COMPANIES AND CAPABILITIES

FURTHER INFORMATION

Figure 3a: Australian Clinical Trials By Therapy Area & Sponsor Type

- Oncology
- CNS
- Infectious Disease
- Metabolic Disorders
- Cardiovascular

Trial Count

Figure 3b: Clinical Trials for the Top Five Indications by Phase in Australia

- Pain
- Non-Small Cell Lung Cancer
- Type 2 Diabetes
- Solid Tumours
- Hepatitis C

Trial Count

Scope (provided by Global Data)
- *observational, interventional or expanded-access trials/studies on human-related therapeutics
- *trials recorded started between January 1 2012 and December 31 2016
- *trials include those with locations in Australia, including multi-national studies.
WHAT MAKES AUSTRALIA AN IDEAL DESTINATION FOR CLINICAL TRIALS?

✓ Quality medical research infrastructure and a skilled workforce
✓ Key opinion leaders across most therapeutic areas
✓ A world-class healthcare system
✓ Attractive research & development (R&D) tax incentives for clinical trials
✓ A fast, pragmatic regulatory pathway
✓ Clinical data which complies with the highest international standards
✓ Strong capability in manufacturing of products to be trialled
✓ A strong intellectual property system
✓ A national focus on continuous improvement through government reform and policy innovation
✓ An ethnically diverse, English-speaking population
✓ Proximity to Asia
✓ Establishment by the Australian Government of the Medical Research Future Fund to support research projects and infrastructure in Australia
The Australian Government invests around $3 billion each year on supporting medical research projects and building and enhancing Australia’s medical research infrastructure. The major recipients of this funding include:

- public hospitals
- public universities
- independent medical research institutes.

**National Health and Medical Research Council**

The National Health and Medical Research Council (NHMRC) is the Australian Government’s main funding body for medical research. It functions similarly to the National Institute of Health (NIH) in the United States or the National Institute for Health Research (NIHR) in the United Kingdom. Like the NIH and the NIHR, the NHMRC helps to boost and constantly improve the nation’s medical research capabilities through diverse funding schemes and rigorous peer review of research applications.

The main beneficiaries of NHMRC funding, through independent investigator-driven research, are Australian hospitals, universities and medical research institutes. As a result of this sustained investment, these organisations are among the best in the world.

In addition to funding research, NHMRC also works with stakeholders to develop and implement national policies in fields such as research ethics, science training and public health.
Figure 4: Australia is a leader in health and medical R&D

TOTAL AUSTRALIAN RESEARCH & DEVELOPMENT SPEND
$33 BILLION

WORLD’S TOP FIVE IN BIOTECHNOLOGY INNOVATION

140 ASX-LISTED LIFE SCIENCES COMPANIES

232,213 PEOPLE EMPLOYED IN THE AUSTRALIAN LIFE SCIENCES SECTOR

MORE THAN $50 BILLION MARKET CAPITALISATION
Medical Research Future Fund (MRFF)

In 2014, the Australian Government announced the establishment of the $20 billion Medical Research Future Fund (MRFF) to provide a sustainable source of funding for medical research over the medium to longer term. The MRFF is designed to deliver a major additional injection of funds into the health and medical research sector.

The MRFF offers the opportunity to strategically fund research and address national priorities in a cohesive and coordinated way. It complements existing medical research and innovation funding to improve health outcomes by distributing new funding in more diverse ways supporting stronger partnerships between researchers, healthcare professionals, governments and the community. MRFF funding is intended to complement the work of the National Health and Medical Research Council, the Commonwealth Science Council and the Australian Government’s National Innovation and Science Agenda, including the Biomedical Translation Fund.16

Independent medical research institutes

Australia has more than 50 independent medical research institutes. Many of these institutes operate in close partnership with universities and teaching hospitals, providing a direct interface between laboratory-based research and clinical practice.

Independent medical research institutes in Australia receive the majority of their funding via competitive government grants for research projects, with other funding through state government infrastructure support, competitive grants from foundations and trusts, commercialisation collaborations and contracts and public donations.19

Universities

Clinical research is a focus for many of Australia’s more than 40 universities, many of which are associated with advanced teaching hospitals. These hospitals are among the most active and sought-after clinical trial sites in Australia.27

Each year, the Australian Government provides around $2 billion to universities to support their research and training activities, and this is complemented by additional research funding from the private sector, non-profit organisations and state and territory governments.16

Biobanks

Biobanks are becoming an increasingly important tool for medical research. Among their other roles, they give pharmaceutical and biotechnology companies the opportunity to conduct in-vitro, proof-of-concept type studies before they commit to large-scale clinical trials.

Australia has numerous biobanks, including cancer and brain banks, which are maintained under the strictest ethical and scientific protocols. Many of these collections include biological specimens with matching blood and patient records, providing a resource for organisations seeking to discover and validate new biomarkers.21

MTPConnect

MedTech and Pharma Growth Centre (MTPConnect) is a not-for-profit organisation which aims to accelerate the rate of growth of the medical technologies, biotechnologies and pharmaceuticals sector to achieve greater commercialisation and establish Australia as an Asia Pacific hub for MTP companies. It was formed in November 2015 as part of the Australian Government’s A$250 million Industry Growth Centres Initiative.22
MINIMISING REGULATORY BURDENS

For over two decades, Australia’s Clinical Trial Notification (CTN) scheme has been a global benchmark for best practice in reducing the regulatory burden on clinical trial sponsors. The majority of commercially sponsored clinical trials conducted in Australia are performed under the CTN scheme. All materials relating to a proposed clinical trial, including the trial protocol, are submitted directly to institutional ethics committees by researchers at the request of the relevant sponsor. The ethics committee is solely responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device, the ethical acceptability of the trial process, and for the approval of the trial protocol. The institution at which a clinical trial will be conducted gives the final approval for the conduct of the trial at the site. Under the CTN scheme, the Therapeutic Goods Administration (TGA), the Australian equivalent of the United States Food and Drug Administration (USFDA), is simply notified of a clinical trial and does not review any data relating to it. The TGA does, however, have the authority to audit and enquire into the management of a clinical trial. The CTN scheme eliminates unnecessary duplication and saves sponsors conducting clinical trials in Australia a significant amount of time and money, which can then be allocated to, among other things, other research projects.

The ethics review process can occur in parallel with the site governance processes, generally shortening the overall trial approval timelines at an individual site level. Ethics committees are located in both the private and public sectors, with review timelines often shorter in the private sector.

PROVIDING ATTRACTIVE TAX INCENTIVES

The Australian Government’s R&D Tax Incentive gives companies with an annual aggregated turnover of less than $20 million a 43.5 per cent refundable tax credit, and companies with an annual aggregated turnover of more than $20 million a 38.5 per cent non-refundable tax credit on eligible R&D expenditure.23 The R&D Tax Incentive is specially designed to make access to tax benefits more efficient and more predictable. Unlike similar programs in other countries, there is no requirement for companies in Australia to demonstrate year-on-year growth in their R&D expenditure in order to claim a tax benefit. There is also no requirement for intellectual property from eligible R&D projects to be held in Australia. This recognises the inherent value of the research and development process itself, regardless of the eventual ‘location’ of ownership of the resulting intellectual property.

Above all, the R&D Tax Incentive provides a globally competitive incentive for both home-grown and foreign-owned companies to conduct R&D activities in Australia. In fact, a recent report by global accounting firm KPMG placed Australia among the top ten most competitive locations for R&D investment.24

Eligibility of clinical trials for the R&D Tax Incentive

To be eligible, a clinical trial must meet the definition of a ‘core’ R&D activity or a ‘supporting’ R&D activity under Australian law.25 An eligible claim must have at least one ‘core’ R&D activity, which must be an experimental activity that meets certain criteria. In general, while there are some exclusions to eligible core and supporting activities, activities conducted in early stage development or clinical trials (Phase 0/I, II and III) undertaken in Australia are likely to meet the criteria for eligibility. Phase IV clinical trials are not eligible as core R&D activities if they are being carried out to meet regulatory requirements, or are for other purposes. However, where trials are being carried out as experiments for the purpose of resolving further scientific unknowns, and eligibility requirements are met, Phase IV clinical trials may be eligible. For example, testing the interaction of a developed drug with an existing commercial drug is an example of an activity that may be eligible.
The Australian Government, in partnership with state and territory governments, industry and other stakeholders, has initiated a series of reforms to further reduce study start-up times, boost patient recruitment and standardise clinical trial costs. These reforms are designed to make Australia an even more attractive place to conduct clinical trials.

Important initiatives include:

**National Mutual Acceptance**

The National Mutual Acceptance (NMA) scheme enables mutual acceptance of scientific and ethical reviews for multicentre clinical trials. The introduction of the NMA is a phased process. Five of the eight Australian states and territories, which together account for 90 per cent of clinical trial activity in Australia, currently participate in the system.

**Standardising clinical trial costs**

In 2015 the Australian Government developed a standard table of costs in order to help sponsors to reliably predict the cost of conducting clinical trials in Australia and significantly reduce the time taken to negotiate contracts with individual sites.

**Raising consumer awareness**

The Australian Government has developed a comprehensive, easy-to-use website, [australianclinicaltrials.gov.au](http://australianclinicaltrials.gov.au), to enable consumer access to information about clinical trials being conducted in Australia. Among other things, visitors can search for relevant clinical trials and learn more about the risks and benefits of participating.

Additionally, the Government, in partnership with the Consumer Health Forum of Australia – the national peak body representing the interests of Australian healthcare consumers – has published the Consumer Guide to Clinical Trials, which is also designed to help patients and volunteers understand why, how and when to participate in clinical trials.

Both these resources are part of a range of initiatives to boost patient recruitment.

[australianclinicaltrials.gov.au](http://australianclinicaltrials.gov.au) also includes a [Clinical Trials Toolkit], containing useful information and resources for conducting a clinical trial in Australia, and [Search for an Australian Clinical Trials Site] which enables sponsors to find and contact over 180 Australian clinical trial sites.

**Boosting skills**

The Australian Government has developed nationally accredited education and training courses for investigators and site personnel who prepare clinical trial applications and oversee the process for their approval.

This initiative is aimed at building and enhancing the skills of those on the front line of clinical trial activity in Australia, enabling them to adopt a more efficient and a more nationally consistent approach to research governance.
PROTECTING VALUABLE INTELLECTUAL PROPERTY

Australia has one of the strongest and most stable intellectual property systems in the world. Australia’s intellectual property system currently ranks as the 12th most secure in the world (out of 128 countries), making it comparable to intellectual property systems in Hong Kong and Canada, and just ahead of the systems in the United Kingdom, United States and Germany.26

Some of the major strengths of the Australian intellectual property system include:

**Broadly defined patentable subject matter**

In Australia, patents are available for a wide range of therapeutic inventions such as new active ingredients, new formulations, isolated forms of (therapeutically useful) natural products and new methods of treatment.

**Patent term extensions**

In compliance with Article 33 of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights, Australia grants (standard) patent owners 20 years of protection. However, since 1999, Australia has also granted owners of patents covering pharmaceutical substances the right to seek patent term restoration, called an ‘extension of term’. This is the right to apply for up to five years of patent term extension to compensate for the process of obtaining regulatory approval, in order to achieve an effective patent life of up to 15 years from the date of first entry of a new pharmaceutical substance on the Australian Register of Therapeutic Goods.

**Data exclusivity**

In addition to patent protection, Australia also provides five years data exclusivity to new pharmaceutical products. Australian data exclusivity laws prevent competitors from relying on proprietary safety and efficacy data for five years, beginning from the date of a new medicine or vaccine’s first inclusion on the Australian Register of Therapeutic Goods.

**Innovation patents**

In Australia, an innovation patent lasts up to eight years – compared to 20 years for standard patents – and is designed to protect inventions that do not meet the inventive threshold required for standard patents. An innovation patent is a relatively quick and inexpensive way to obtain intellectual property protection for a new medical device or pharmaceutical substance, method or process.
Australia has benefited from 26 consecutive years of economic growth. The country’s economic growth rate is forecast to be the highest among major advanced economies over the next five years.28

The success of the pharmaceutical, biotechnology and medical device industries in Australia has been built on a number of factors, not least of which is the fact that the country is currently one of the largest markets in the world for prescription medicines, medical devices and other health services and technologies. Moreover, Australia is predicted to remain among the world’s top 20 markets for these products for years to come.29

Australia is also one of the few countries in the world with a comprehensive national strategy specifically focused on medicines. In this strategy, the National Medicines Policy (NMP), the term ‘medicine’ encompasses prescription and non-prescription medicines, including complementary medicine products.

The overall aim of the NMP is to meet medication and service related needs, so that both optimal health outcomes and economic objectives are achieved.

The main benefit of the NMP is that all partners – including the Australian Government, industry, the broader healthcare sector and healthcare consumers – share the responsibility to various degrees for achieving each of these objectives. This approach strengthens Australia’s ability to provide a stable and investor-friendly business environment. The NMP is a key indicator of the Government’s commitment to provide companies with a viable operating environment in Australia.

Australia provides one of the most stable and predictable business operating environments in the world. The World Bank currently ranks Australia in the top 15 of 190 countries in the world in terms of ease of doing business.27
Maintaining a Vibrant Industry

Australia’s tradition of excellence in medical research has made it a key player in global healthcare. It has attracted billions in global investment in research and development over the past 10 years, and collaborations between global pharmaceutical companies and Australian entities have enabled the development and distribution of groundbreaking Australian discoveries.

Pharmaceutical, biotechnology and medical device industries have a long and proud history in Australia, stretching back more than a century. Today, over 1000 companies across the three sectors operate in Australia. Together, they employ more than 70,000 highly-skilled Australians, and generate more than $5 billion in exports each year, including around $3 billion in pharmaceutical exports alone.

They deliver medicines, vaccines, medical devices and other health technologies that millions in Australia and around the world use every day to live longer, healthier and more productive lives.

Medicines and vaccines are Australia’s largest manufactured export. China and the United States are the biggest markets, followed by New Zealand, South Korea and the United Kingdom.

![Fig 5: Top Industry Sponsors for Australian Clinical Trials](chart.png)

Scope (provided by GlobalData) between January 1, 2012 and December 31, 2016.
LuinaBio excels in contract manufacturing

Case Study
For 20 years LuinaBio has provided development and production services to clients based in America, Asia, Australia and Europe. Clients include biopharmaceutical development companies, research institutes, veterinary drug companies and universities.

LuinaBio performs GMP manufacture of:
- recombinant proteins and vaccines
- live Biotherapeutics
- human and veterinary products
- material for pre-clinical, clinical and market
- aerobic and strictly anaerobic microorganisms.

More specifically LuinaBio carries out microbial aerobic and anaerobic fermentation, cell banking, vaccine production, process development, analytical services and stability studies.

Recent projects include:
- recombinant protein from E.coli for a Phase III trial in the US under IND
- fully anaerobic GMP production and lyophilisation of over 10 bacterial strains
- recombinant protein from E.coli conjugated to a carbohydrate for a Phase II in the US under IND and Phase II/III trial in the EU
- fermentation sourced semisynthetic carbohydrate for a Phase III clinical trial in Asia
- whole cell killed vaccine for a Phase II trial in the US and Australia under IND.

LuinaBio recently helped a US-based company develop a number of new anaerobic bacterial strains for their microbiome projects. This involved both developing and producing their bacteria in fully anaerobic conditions. Following success in the initial project LuinaBio have been asked to carry out a larger scale development project by the same company, and are looking at producing some of the initial strains for Phase II.

luinabio.com.au
Linear’s knowledge and recruiting networks offer clients maximum efficiency

Case study

Australian clinical trials company Linear is contributing to medical breakthroughs via a technologically focussed early-phase research facility of 32 beds based in Perth, Western Australia. Linear specialises in first-in-human, clinical pharmacology, glucose clamp, oncology, hybrid HV + patient and first-in-patient trials. Linear’s extensive network of key opinion leaders and unique ability to recruit patients across Western Australia create distinct advantages for patient recruitment.

Linear actively invests in clinical education with a dedicated oncology fellow and rotating junior doctors, as well as embracing eSource to output live data and enable fast close-out.

In a recent project, Linear guided a South San Francisco biotech company through the Australian trial framework for a hybrid HV + renal patient trial. From the outset, Linear was able to devise innovative solutions for efficient IP manufacture and import to enable fast start-up. Linear’s open collaboration with the trial sponsor included reviewing protocol and IB, providing advice on ethics committee requirements, logistical efficiencies as well as medical review. Engaging a key opinion leader in nephrology, Clinical Professor Mark Thomas, Linear reviewed the renal patient population, facilitating efficient recruitment whilst maintaining robust quality and ensuring patient safety.

This careful work resulted in study approval within five weeks of submission and first dose within seven days of drug receipt. The study will be used to open an FDA IND for future Phase II development. The client company commented ‘your team really impressed us with your collaborative, knowledgeable approach as we were working through the logistics and challenges for the trial’.

linear.org.au
Novotech expertise makes expedited timelines possible

Case study

Novotech is Australia’s largest independent contract research organisation. Operating in eleven Asia-Pacific countries, Novotech’s services span the full spectrum of clinical drug development.

When South Korean oncology biotechnology company PharmAbcine completed a successful domestic phase I study for the treatment of metastatic/refractory solid tumour, they were keen to progress into Phase II. PharmAbcine engaged Novotech to help them benefit from Australia’s supportive regulatory and rapid clinical trial environment.

Novotech provided initial phase II protocol review and medical writing services to ensure both the primary endpoints were clear and the data collected would also meet South Korean regulatory requirements.

Novotech worked with PharmAbcine to secure prompt HREC approval and manage site initiations. Strong Principal Investigator (PI) and site relations allowed PharmAbcine to accelerate feasibility activities, further expediting timelines.

Novotech’s oncology team established a competitive recruitment environment between trial sites, resulting in full recruitment of one cohort within just four weeks of site initiation and overall recruitment closing two weeks early.

The TGA’s Special Access Scheme was initiated for one patient who showed positive results during the trial, allowing further treatment to be approved.

Throughout PharmAbcine’s phase II study, Novotech provided full clinical trial management and monitoring, including medical writing services, PI and site liaison, clinical trial supply management, recruitment for complicated inclusion/exclusion criteria, project and data management.

‘Novotech not only efficiently guided us through the Australian regulatory process to deliver the trial quickly, their in-depth knowledge of South Korea’s regulatory environment meant we could use the resulting trial data for both regulatory processes. This was of great benefit to our business and development timelines.’

Head of Clinical Development, PharmAbcine Inc.

novotech-cro.com
Nucleus Network: a leader in early-phase studies

Case study

Nucleus Network is Australia’s largest early-phase clinical research centre. Specialising in first-in-human studies, it conducts approximately 50 phase I clinical trials annually, including 20-15 first-in-human trials, totalling 500 Phase I clinical trials in over 13 years. It is co-located with a major tertiary teaching hospital (Alfred Hospital) and research institutes at the prestigious Alfred Medical Research & Education Precinct (AMREP) in Melbourne, which houses 2,000–3,000 medical professionals and researchers.

Located in a 2200 square metre facility, Nucleus Network’s 80-bed clinical unit offers a full suite of early phase clinical studies, including first-in-human, proof of concept, pharmacokinetic and pharmacodynamics, thorough QTc, biosimilar, ethnopharmacology (i.e. Japanese bridging studies), drug/food interaction studies, and specialty studies in pharmacodynamic markers such as Elispot, flow cytometry, cytokine analysis and allergen challenges.

Nucleus Network’s diverse customer base includes pharmaceutical companies and biotechnology companies across North America, Asia and Europe, with approximately 80 per cent of revenue from US clients. A strong track record of outstanding project delivery, robust quality systems and recognised expertise has seen Nucleus Network form ongoing successful partnerships.

Nucleus Network has:

- a large, experienced recruitment team, operating 7 days per week, and a recruitment database of over 45,000 individuals
- a laboratory team with expertise in PBMC isolation, cytokine stimulation assays, flow cytometry, sample biopsy management, and pharmacokinetic processing
- an internal pharmacy with Grade A laminar flow in a clean room rated facility and the ability to receive clinical trial material for just-in-time compounding. Nucleus Network also has a small stake in a GMP licensed facility, which enables sterile manufacturing with matching placebos, encapsulation, blinding, oral solution and suspension manufacture.

Image courtesy of Nucleus Network
Neuroscience Trials Australia facilitates testing of a new treatment option for severe epilepsy

Case study

Neuroscience Trials Australia is an Australian-based, niche contract research organisation (CRO) specialising in all aspects of neuroscience clinical research.

Therapeutic areas of expertise include epilepsy, stroke and stroke-related conditions, multiple sclerosis, Alzheimer’s disease/ cognitive disease studies, Motor Neurone Disease/ALS, mental health and associated conditions, Parkinson’s disease, spinal cord injuries, Huntington’s disease, neurosurgery, pain, neuromuscular disease and migraine.

Recently NTA delivered clinical trial services for a world first drug and device trial for the treatment of severe refractory epilepsy. The trial sponsor, Cerebral Therapeutics, has developed a complex precise medication delivery pump which administers a reformulation pharmaceutical implanted and delivered through a catheter implanted directly into the fluid around the brain.

Contracted services included project and site management, monitoring, ethics and regulatory submissions, data management and biostatistics and specialist clinical field engineer services support.

‘Neuroscience Trials Australia helped to guide our company in the setup of our subsidiary in Australia, including establishing links with world-leading clinical trial sites in Australia, approval through the local regulatory process, negotiation and establishment of local clinical trial site contracts and budgets, establishment of a specifically designed electronic data capture system and compliant regulatory monitoring management of the clinical trial process. We have worked with three sites. This first-in-humans study is in the middle of recruiting 20 patients. Neuroscience Trials Australia has been integral in successfully moving our drug development program forward from an administrative, leadership, and direct operational detailed perspective. NTA has been a critical partner to us.’

Dr Dan Abrams, Cerebral Therapeutics CEO

neurotrialsaustralia.com

Image courtesy of Neuroscience Trials Australia
CMAX combines experience and flexibility with state-of-the-art facilities

Case study
Based in Adelaide, South Australia, CMAX Clinical Research is among Australia’s most experienced clinical trials units. It has conducted over 550 studies since 1993, including over 100 first-in-human studies.

In 2016, CMAX relocated to a brand new, purpose-built facility, adjacent to the new South Australian Health and Biomedical Precinct, which provides the foundation for a cluster of organisations to deliver world-leading research. The new CMAX facility offers a central location with easy access to public transport for study participants and customers and has 50 beds, which facilitates flexibility for study scheduling and fast study start-up times.

These advantages help CMAX meet and exceed enrolment targets and offer flexibility that minimises dropouts.

An example of this was a Phase I, three-period, biosimilar study for a US pharmaceutical company, with a minimum 56 day washout between treatments. Target enrolment was 150 and CMAX enrolled 152, which meant that extra participants could be dosed at short notice. To minimise dropouts, CMAX maintained flexibility by allowing enrolled participants to be dosed in other groups, in subsequent periods, while maintaining the washout duration.

During a Phase 1 SAD/MAD study for a US pharmaceutical company, CMAX was able to add an additional cohort partway through the study, managing the ethics amendment submission to enable this. For a Chinese pharmaceutical company’s Phase 1 SAD study, CMAX was able to add an additional visit partway through the study, handling the ethics amendment submission, re-consenting four cohorts of participants and fitting in the visit as required for each cohort.

cmax.com.au
TetraQ’s bioanalytical and pharmacokinetic services help clients go global

Case study

Located at the University of Queensland, TetraQ is recognised for its R&D infrastructure, providing bioanalytical, pharmacokinetics and toxicology services to clients across North America, Europe, Asia, New Zealand and Australia.

In 2006, a biotechnology client engaged the bioanalytical capabilities of TetraQ to support development of a novel first-in-class product. Working in close collaboration, the client and TetraQ advanced the product through the development process, with TetraQ’s scientists generating key data informing each drug development stage, including pre-clinical and multiple Phase I, II and III clinical trials.

The biotechnology client said ‘TetraQ was an integral partner along the development journey, providing contract research services to an internationally recognised standard, suitable for submission to the US Food and Drug Administration (FDA). The ability to access these services within Australia, rather than having to go overseas, is a significant advantage. The infrastructure and capabilities within TetraQ are truly world-class, and are a real strategic advantage for the Australian life sciences industry.’

TetraQ scientists provided support to the client up to the time of submission of a New Drug Application with the FDA in 2015. Subsequently the client has announced a major deal with an international pharmaceutical company for licensing of the product to facilitate the entry of this important new product into use.

tetraq.com.au
Mobius Medical enables a time-critical FDA submission

Case study

Mobius Medical is a boutique contract research organisation with almost a decade of experience working predominantly with startup medical device and pharmaceutical companies. From its headquarters in Sydney and an office in Melbourne, supported by experienced staff up and down the eastern seaboard, Mobius provides clinical research expertise to enable seamless technology development from bench to patient.

In mid-2014, Mobius was commissioned by a US startup client to initiate an early feasibility trial of its interventional cardiology device at 3 Australian sites. Timing was critical as the client had scheduled a pre-submission meeting with the US Food & Drug Administration (FDA) for July 2014, only one month after the sites were selected.

In September 2014, the client undertook site initiation visits at two of the three sites. The first in-human implantation of the device was performed at the Sydney site that November.

With its Australian trial initiated and enrolling patients, the client submitted its investigational device exemption (IDE) application. During the review process, the client was able to supply the FDA with ongoing clinical progress reports from the Australian sites managed by Mobius, and obtained IDE approval just over three months later.

Now in its third year, the early feasibility study has evolved into a combined CE Mark and IDE pivotal trial, enrolled at 19 centres across the US, Europe and Australia – a true success story for a global R&D and commercialisation strategy that began in Australia. The Sydney site is the second highest enrolling centre globally, with the Brisbane site the third highest.

mobiusmedical.com.au
George Clinical’s global experience and connections overcome trial challenges

Case study

George Clinical (GC) is a leading independent clinical research organisation (CRO) based in the Asia-Pacific region. It has staff in thirteen countries, including US and European operations. Headquartered in Sydney alongside its parent company, The George Institute for Global Health, GC provides a full range of high-quality clinical trial services to biopharmaceutical, medical device and diagnostic customers, for all trial phases.

GC collaborated with a mid-sized global pharmaceutical company to conduct a randomised trial in China comparing pain relief medication for patients with moderate to severe chronic cancer pain. GC was responsible for project management and monitoring across nearly 30 sites in China, with an enrolment goal of nearly 300 patients.

Several challenges initially threatened project commencement prior to GC’s involvement, including issues with patient exclusion criteria in the trial protocol and a number of sites that were insufficiently resourced. GC’s Project Manager liaised closely with investigators and sponsors to update the protocol and to replace unsuitable sites with others identified through the Principal Investigator’s network, as well as GC’s and the sponsor’s databases.

To ensure project timelines were still achievable, the project manager prepared work plans and additional strategies to promote recruitment, including a monthly newsletter, incentives for top enrolling sites and interim project forums. GC maintained close communication with the sponsor to identify any issues and provide solutions early.

Despite the initial challenges, the GC project team achieved exceptional metrics. The first patient entered the trial within three months of the contract’s signature, the first 50 per cent of patients within several months, and the remainder within eight months. The last patient entered the trial three months ahead of schedule.

gorgeclinical.com
Five Corners helps a new device find its way to market

Case study

Five Corners is a boutique Clinical Research Organisation (CRO) based in Artarmon, NSW. Its clients are US and European-based manufacturers and Australian and New Zealand manufacturers and distributors. Five Corners collaborates with international CROs for clinical research services and also provides regulatory consulting services, field clinical engineering, quality management system development, implementation and auditing, manuscript development, distributor profiling, reimbursement consulting and clinical training.

The UroLift prostatic retractor was developed by a US incubator company, Neotract Inc, in 2004 to bridge the gap between palliative medications and the complications associated with surgical treatments.

Having selected Australia for their first-in-human study in 2005, Neotract approached Five Corners as a partner because of their experience and knowledge in urological clinical research, particularly early concept devices.

Using multiple modalities and clinicians, the Five Corners team helped engineers determine the best way for permanent UroLift® transprostatic tissue retractors to reshape the prostate and reduce obstruction.

Over the next several years, the device and technique were improved, and a series of clinical trials across Australia showed that patients experienced meaningful improvement in symptoms and quality of life, whilst avoiding sexual dysfunction or surgical complications. A multinational randomised study was conducted in 2011 to validate these promising results and all primary endpoints were met.

The UroLift system was awarded the 2011 Medical Design Excellence Award by the MDDI (Medical Device and Diagnostic Industry). Now listed on the Australian Register of Therapeutic Goods and reimbursed on the Prostheses List, the UroLift is considered the gold standard for minimally invasive prostate treatment.

fivecorners.com.au
Southern Star Research’s experience and networks are an advantage for clients

Case study

Southern Star Research is an Australian-owned clinical research organisation (CRO) with a reputation for delivering full-service clinical trials to the highest levels of quality. Its staff have on average 16 years industry experience and are located in Australia and New Zealand. Southern Star Research has a diverse client profile, ranging from large multinational pharmaceutical companies to small biotechnology and medical device start-ups. The company also supports academic, investigator-initiated and government agency studies.

The benefits of Australia’s streamlined Clinical Trial Notification (CTN) system and the R&D Tax Incentive, along with the well-established and very experienced clinical research industry, made Australia an attractive location choice for a US biotechnology company that was looking to commence a Phase II endocrinology study. Southern Star Research’s demonstrated expertise made it an ideal partner to support the project.

By leveraging its well-established and strong working relationships with sites, fostered over many years of successfully working together, Southern Star Research was able to initiate 16 sites in Australia in just 10 weeks from the date of finalisation of the study’s clinical protocol. This included all ethics committee submissions and approvals, along with site initiation visits. This allowed the patient recruitment period to be maximised, ensuring all study milestones were achieved beyond the client’s expectations.

SouthernStarResearch.com
AMGEN

A testimonial provided in support of Australian clinical trial capabilities

Amgen has conducted clinical trials in Australia for more than 25 years, and rates Australia as one of the top medical study locations outside the United States. One of the world’s largest biotechnology companies, Amgen partners with Australian research institutes and investigators, taking advantage of leading-edge biotechnology research for the benefit of patients.

Through its significant clinical presence, Amgen Australia conducts on average two first-in-human studies every year, and almost half of its clinical trial activity is in early phase research (Phase I and II). In 2014, Amgen conducted 71 different studies at 374 sites across Australia and New Zealand, involving 1791 patients.

Amgen Australia invests around $30-35 million in local research and development annually, which represents around 13 per cent of its sales.

The company reaps the benefits of accessing Australia’s wide range of scientific talent and Australia’s medical infrastructure.
BRISTOL-MYERS SQUIBB

A testimonial provided in support of Australian clinical trial capabilities

Bristol-Myers Squibb’s mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. In Australia the company has continued to advance its early to late stage pipeline, with investment in all phases of clinical trials, in our key areas of oncology, virology, immunoscience, cardiovascular disease and fibrotic diseases.

During 2014, these programs represented millions of dollars in R&D investment by the company in Australia, a significant increase over the previous year.

Australian clinical trial sites have recently played a key role in the development of our new investigational immuno-oncology agents, with over 300 Australian patients participating in clinical trials for a variety of cancers.

This type of successful clinical development effort in Australia is only achievable because of Australia’s world class researchers and health care professionals, high quality research infrastructure, efficient clinical trials regulatory environment and high standards of good clinical practice.
A testimonial provided in support of Australian clinical trial capabilities

In recent years GSK has successfully partnered with a number of excellent research centres in Australia, who assisted with the clinical development of new medicines for the treatment of cancers, including melanoma.

World-leading medical clinician-scientists provided valuable input to the clinical development protocols, which led to the efficient execution of a number of early-phase (first-in-patient) trials.

These studies were highly complex, and relied on Australia’s first-class medical infrastructure and significant medical expertise.

The discipline for delivery of high quality research was outstanding. With careful planning and the necessary expertise, and an unrelenting focus on quality and patient care, the studies were efficiently approved and executed, which is a must for early-phase clinical development.

Ready access to cutting edge technologies, such as biomarker research and analysis, was instrumental in the efficient identification of a patient population who could potentially benefit from targeted therapies.

The seminal results of these trials have been recognised globally; Australian experts are lead authors on key publications, and have presented at international conferences.
NOVARTIS

A testimonial provided in support of Australian clinical trial capabilities

Novartis undertakes trials across a wide range of therapeutic areas, including blood cancer, central nervous system disorders, skin disorders and ophthalmic conditions, and invests approximately $30 million per year in clinical trials in Australia.

According to an independent analysis of clinicaltrials.gov registrations in 2014, Novartis was the industry’s largest investor in clinical trials across Australia – including local, investigator initiated and international trials.

High research and quality standards (especially early phase capability), comparable costs, timely trial approval and reliable patient recruitment make Australia an attractive destination to conduct clinical trials.

The VIPER study was a Novartis sponsored trial, designed and conducted in Australia. It focused on blood pressure management in a primary care setting, and encompassed almost every corner of Australia: approximately 120 surgeries, 260 general practitioners (GPs) and 3700 patients participated. The study evaluated whether a more structured approach to hypertension management, implemented in a ‘real world’ GP setting, helped patients meet their target levels. The results revealed that VIPER patients, who had a more structured approach to managing disease, were 25% more likely to achieve their ideal blood pressure goal.

VIPER showed that in the GP setting, and with existing Pharmaceutical Benefits Scheme (PBS) reimbursed drugs (that is, not requiring additional money to be spent on the PBS) 25% more patients can meet their individual goals. The key is a more active role in disease management. This finding, reported in the BMJ, has had global impact.

As one participating GP with over 18 years’ experience said, “GPs are at the grassroots of blood pressure management, and their ability to successfully manage blood pressure has potentially massive impacts on overall health”.

VIPER
The following table provides some examples of companies and their capabilities.

Contact your local Austrade representative for assistance connecting with the Australian businesses that best suit your requirements.

austrade.gov.au
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<th>Investigator-initiated trials</th>
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This table provides some examples of organisations and their capabilities, and is not an exhaustive list. Contact your local Austrade representative for assistance connecting with the Australian businesses that best suit your requirements.

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REFERENCES

2. Ibid.
3. Ibid.
6. Ibid.
8. Data provided on request by GlobalData, December 2017. globadata.com
12. Ibid.
13. Ibid.
14. Ibid.
15. Ibid.
25. Note. For a majority of Australian R&D projects, where R&D activities are carried out overseas because they cannot be conducted in Australia, these overseas activities may also attract a tax offset. Less than 50% of the expenditure must be overseas, and prior approval (and an Overseas Finding) must be obtained before overseas expenditure can be claimed.
32. Department of Foreign Affairs and Trade, Canberra, 2017, Composition of Trade (Australia)
33. Data provided on request by GlobalData, December 2017. globadata.com
ABOUT AUSTRADE

The Australian Trade and Investment Commission – Austrade – contributes to Australia’s economic prosperity by helping Australian businesses, education institutions, tourism operators, governments and citizens as they:

• develop international markets
• win productive foreign direct investment
• promote international education
• strengthen Australia’s tourism industry
• seek consular and passport services.

Austrade helps companies around the world to identify and take up investment opportunities in Australia as well as to source Australian goods and services.

Our assistance includes:

• providing insight on Australian capabilities
• identifying potential investment projects and strategic alliance partners
• helping you to identify and contact Australian suppliers.

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