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CLINICAL TRIALS

A DYNAMIC ENVIRONMENT FOR CLINICAL TRIALS
INTRODUCTION

Australia is regarded as one of the best places in the world to conduct 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 socio-economic environment, an ethnically diverse population and a strong intellectual property regime. An efficient regulatory system, including a rapid clinical trials approval system, a strong mechanism of support services and globally competitive tax incentives for research and development (R&D) investment, all help make Australia one of the leading destinations for clinical trials.

Every year, around 1000 new clinical trials are commenced in Australia by pharmaceutical, biotechnology and medical device companies (Figure 1), representing a $1 billion investment.¹ The world’s top 10 pharmaceutical companies alone invest around $200 million each year in clinical trials in Australia.²

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

The Australian Government, in partnership with industry and other stakeholders, is implementing a series of reforms to further reduce study start-up times, boost patient recruitment and develop a standard list of costs for clinical trials. These reforms will make Australia an even more attractive place to conduct clinical trials, whilst maintaining the highest quality and ethical standards.

Figure 1 New Clinical Trials (Medicines, Medical Devices), 2007-2013.³
Every year, around 1000 new clinical trials are commenced in Australia by pharmaceutical, biotechnology and medical device companies.
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 accounted for most of the clinical trial activity in Australia. However, since 2008, there has also been a significant increase in Phase I activity. To some extent this reflects global trends in clinical trial activity, but it is also a reflection of Australia’s capabilities in early-phase clinical research, as well as an indication of the increasingly important role Australia plays in developing new products for the global market.

Already, for 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®, a new type of antiviral drug used to treat influenza.

**Number of New Clinical Trials**

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<thead>
<tr>
<th>Category</th>
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<tr>
<td>Cardio-Vascular &amp; Blood Disorders (excl. Cancer)</td>
<td>78</td>
</tr>
<tr>
<td>Lung &amp; Respiratory Conditions (incl. Cancers, Asthma, etc.)</td>
<td>58</td>
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<tr>
<td>Skin Disorders (incl. Cancers)</td>
<td>56</td>
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<tr>
<td>Mental Health &amp; CNS Disorders (excl. Cancer)</td>
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</tr>
<tr>
<td>Breast Cancer</td>
<td>50</td>
</tr>
<tr>
<td>Musculo-Skeletal Disorders (incl. Autoimmune Disorders)</td>
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<tr>
<td>Other Infectious Diseases</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Ophthalmic Conditions</td>
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<tr>
<td>Brain Cancer</td>
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</tr>
<tr>
<td>Cancer of the Female Reproductive Organs</td>
<td>15</td>
</tr>
<tr>
<td>Renal &amp; Urinary Tract Disorders</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
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**Figure 2 New Clinical Trials (Medicines), 2013.**

The global pharmaceuticals industry conducts a full range of clinical trials in Australia, from first-in-human (Phase I) trials to post-market studies (Phase IV).
WHAT MAKES AUSTRALIA AN IDEAL DESTINATION FOR CLINICAL TRIALS?

✓ Quality medical research infrastructure and a skilled workforce
✓ 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
✓ 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
BUILDING AND SUSTAINING WORLD-CLASS MEDICAL RESEARCH 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 (Figure 4). It is similar in its functions 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 a diversity of 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, which, as a result of sustained investment, 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.
Universities
Clinical research is a focus for many of Australia’s more than 40 universities, some of which have advanced teaching hospitals connected to them. These hospitals are among the most active and sought-after clinical trial sites in Australia.9 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.10

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, and help provide a direct interface between laboratory-based research and clinical practice. As well as tapping into philanthropic money, independent medical research institutes in Australia are eligible for competitive government grants. They are also supported by more than $600 million a year from the Australian Government, and by millions more from the private sector, non-profit organisations and state and territory governments.

Clinical Trial Networks
There are currently more than 50 clinical trial networks operating in Australia. These networks are led by highly experienced clinicians and can facilitate access to both patients and ‘trial-ready’ infrastructure.

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.11
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 after it has received site approval, and does not review any data relating to it. The TGA does 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.

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 45 per cent refundable tax credit, and companies with an annual aggregated turnover of more than $20 million a 40 per cent non-refundable tax credit on eligible R&D expenditure. The R&D Tax Incentive is specially designed to make access to tax benefits more efficient and more predictable.

Unlike similar programmes 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, notwithstanding 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.

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. 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 they 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 industry and other stakeholders, is now in the process of implementing a series of reforms to further reduce study start-up times, boost patient recruitment and standardise clinical trial costs. These reforms will make Australia an even more attractive place to conduct clinical trials.

Important initiatives include:

**National Mutual Acceptance Programme**

The National Mutual Acceptance (NMA) programme enables mutual acceptance of scientific and ethical reviews for multicentre clinical trials. The introduction of the NMA is a phased process. Four 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**

The Australian Government is developing a list of standard costs associated with conducting clinical trials in Australia. The aim of the project, which is scheduled to be completed by the end of 2015, is to help sponsors to reliably predict the cost of conducting clinical trials in Australia and significantly reduce the time it takes them to negotiate contracts with individual sites.

**Raising Consumer Awareness**

The Australian Government has developed a comprehensive, easy-to-use website 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. australianclinicaltrials.gov.au

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, again, is designed to help patients and volunteers understand why, how and when to participate in clinical trials.

Both australianclinicaltrials.gov.au and the “Consumer Guide to Clinical Trials” are part of a range of initiatives to boost patient recruitment.

**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. According to the International Property Rights Index, Australia’s intellectual property system currently ranks as the 11th most secure in the world (out of 142 countries), making it comparable to intellectual property systems in Germany, Japan and the United Kingdom, and more secure than systems in countries like Belgium, France, Taiwan, and Israel.16

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.
PROVIDING A STABLE OPERATING ENVIRONMENT

Australia provides one of the most stable and predictable business operating environments in the world. The World Bank consistently ranks Australia among the top 10 countries in the world in terms of “ease of doing business”. 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 at least the next decade.

Australia is also one of the few countries in the world that has a comprehensive national strategy in relation to medicines in particular. The strategy is known as the National Medicines Policy (NMP), where the term “medicine” includes prescription and non-prescription medicines, including complementary healthcare 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.
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 (Figure 7) use every day to live longer, healthier and more productive lives.

Figure 7 Australian pharmaceutical export destinations, 2011-2013, $Million

Medicines and vaccines are Australia’s largest manufactured export. China is the biggest market, followed by South Korea, Taiwan and New Zealand. Recent bilateral free trade agreements with China, South Korea and Japan will make it more competitive for manufacturers in Australia to export pharmaceutical products there.
Manufacturing active pharmaceutical ingredients for clinical trials

Case Study: IDT Australia

Successful pharmaceutical companies rely on new products to keep them ahead of the competition, but developing and bringing them to market on-time and on-budget requires knowledge, competence and a proven track record. IDT helps fast-track products from research and development, through to clinical trials. With over 35 years’ experience, IDT has developed more than 115 products for customers including 9 of the top 10 pharmaceutical companies worldwide.

IDT specialise in developing and manufacturing complex, highly potent drugs, beta-lactam antibiotics and cytotoxic products at their Melbourne manufacturing campus. In addition, IDT CMAX is a 50-bed clinical trial unit currently located at the Royal Adelaide Hospital, South Australia.

IDT CMAX specialises in first-in-human studies, and has conducted over 75 to date. In 2016 IDT CMAX will relocate to purpose-built premises adjacent to the new South Australian Health and Biomedical Precinct. This will be the largest health precinct in the southern hemisphere, and provide the foundation for a cluster of organisations to deliver world-leading research and clinical service delivery. Centrally located, with easy access to public transport for study participants and customers, the new facility will continue to offer 50 beds, allowing flexibility for study scheduling and fast study startup times.

Most recently IDT helped a United States biotechnology company efficiently conduct a Phase I trial of their product. They chose IDT to conduct active pharmaceutical ingredient (API), finished dosage form, and early proof of concept clinical work. IDT helped to manufacture the API and formulate the drug product, which was then put into Phase I clinical trials at IDT CMAX. This biotechnology company was able to access the R&D tax incentive tax credit, and quickly start the trial process using the CTN scheme, without needing to secure a United States Investigational New Drug (IND) filing, saving both time and money.

Image courtesy of IDT
Realising the benefits of conducting clinical trials in Australia

**Case Study: Linear Clinical Research**

Linear Clinical Research Ltd is a dedicated early phase research organisation, co-located within Sir Charles Gairdner Hospital, a major tertiary hospital in Perth, Western Australia. With a purpose-built 32 bed facility, Linear specialises in early phase studies, with expertise in first-into-human and first-into-patient studies. Utilising the streamlined regulatory process that Australia offers, along with a database of 10,500 participants and an extensive network of sub-specialists, Linear can initiate and complete early phase studies efficiently, whilst ensuring participant safety and high quality data output.

Principia Biopharma Inc, based in San Francisco (USA), specialises in the development of novel small molecule medicines, benefitting patients with autoimmune diseases and cancer. Linear has extensive experience servicing the US biotechnology and pharmaceutical industry, and met with Principia to confirm the efficiencies that Australia offers for conducting clinical research.

Importantly for Principia, clinical trial conduct in Australia does not require US Food and Drug Administration Investigational New Drug (FDA IND) application approval. However, the data output from studies conducted in Australia can be used to support international regulatory applications, including an FDA IND submission.

Linear provided services to recruit participants, conduct the clinical trial, and provide guidance on protocol design, adaptation and mid-trial amendments within Australia’s regulatory environment. Principia successfully completed a first-in-human, single ascending dose/multiple ascending dose clinical study for a small molecule candidate through Linear in late 2014, with the data to be used for FDA regulatory submission.

Dr Steve Gourlay, Chief Medical Officer, Principia Biopharma Inc commented “Linear was an outstanding partner for our Phase I program – always professional and willing to go the extra mile.”

Image courtesy of Linear Clinical Research
A contract research organisation delivers ahead of schedule

Case Study: Novotech Australia

Novotech is Australia’s largest independent contract research organisation. With operations in 12 countries in Asia-Pacific, Novotech’s services extend across the full spectrum of clinical drug development.

In 2014, 39 per cent of adults worldwide were overweight, and 13 per cent were obese. Based on their regional experience, Novotech were appointed by a US biotechnology company to investigate the effects of a new treatment for obesity on weight reduction and safety in patients.

Novotech was engaged to deliver a multi-center adaptive design Phase I/II program and a full suite of services - from clinical through to vendor management, data management and biometrics services.

The study required rapid commencement, with sites pre-selected by the sponsor. Furthermore, during the study there were numerous challenges, including multiple protocol amendments required by the Human Research Ethics Committee (HREC), safety review committee recommendations and changes in the investigational product strength.

To meet these timelines, Novotech developed a competitive recruitment strategy that identified and supported dedicated sites to achieve rapid recruitment timelines. High-performing sites that engaged in the program were allocated a higher percentage of the overall enrolment target. Through unified collaboration between Novotech’s clinical, regulatory, data management, biometrics teams and stakeholders, all key study milestones were achieved ahead of schedule.

This outcome resulted in the sponsor securing investor funding for further clinical development of this product, and pursuing growth initiatives. In addition to these achievements, the sponsor has since retained Novotech for a second Phase II study.
Conducting biosimilar clinical trials

Case Study: Nucleus Network

Nucleus Network is a dedicated Phase I clinical trials organisation located in Melbourne, Australia. It undertakes approximately 50 clinical trials a year, including up to 15 first-in-human studies, at its dedicated Phase I unit located within the Alfred Medical Research Education Precinct at Melbourne’s Alfred Hospital. The unit contains 50 beds and incorporates state-of-the-art subject monitoring to ensure volunteer safety and comfort. Nucleus Network is experienced in delivering adaptive clinical trial protocol designs, and has good access to patient populations through co-location with one of the state’s major tertiary teaching hospitals.

Nucleus Network’s international client base is attracted to Australia’s streamlined regulatory framework, and fast approval timelines for clinical trials. Typical timeframes for a Phase I clinical trial, from submission of Protocol and Investigators Brochure, to clinical trial approval, is 4 to 5 weeks. This pathway has proven to be an attractive and successful model for clients, who have been able to enter Phase I clinical trials sooner than originally forecast, and with quality data that is acceptable to the US Food and Drug Administration (FDA) and European Medicines Evaluation Agency (EMEA). Nucleus Network has a number of preferred provider relationships with both pharmaceutical and biotechnology companies.

Nucleus Network offers a full suite of early phase clinical studies, including first-in-human; proof of concept; pharmacokinetic and pharmacodynamic; thorough QTC; bioequivalence; drug/food interaction studies, as well as specialty studies incorporating a range of pharmacodynamic markers such as Elispot, Flow Cytometry, Cytokine analysis and allergen challenges.

In 2014 Nucleus conducted a biosimilar clinical trial for a large biotechnology company. Incorporating an ethno-pharmacology component, Nucleus conducted the trial with a cohort of 30 healthy Japanese subjects. After successful completion of the trial, the same sponsor has now awarded a second biosimilar study to Nucleus.
Bioanalytical and pharmacokinetic services in Australia

Case Study: TetraQ

Located at The University of Queensland, TetraQ is recognised for its quality accredited R&D infrastructure, knowledge and capabilities, and has clients across North America, Europe, Asia, New Zealand and Australia.

In 2006, a biotechnology client engaged the bioanalytical and pharmacokinetic capabilities of TetraQ, a National Association of Testing Authorities (NATA GLP/ISO17025) accredited facility. Working in close collaboration, the client and TetraQ advanced a new therapeutic product, 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 acknowledged that "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."

In 2014, TetraQ scientists continued to work on the client's New Drug Application for the FDA. With the assistance of TetraQ, this biotechnology company is moving forward with commercialisation of its asset, and improving human health globally.
Australian expertise made accessible by the R&D Tax Incentive

Case Study: George Clinical

Patients with heart failure are reported to have lower levels of hydrogen sulphide, even though sulphur is available naturally in the diet. Sulfagenix Inc., a United States biotechnology company, developed a novel compound, SG1002, identified as a potential treatment for heart failure as it increases blood levels of hydrogen sulphide.

After considering locations around the world, Sulfagenix selected Australia for its first-in-human trial because of its simple regulatory process and outstanding cardiovascular clinicians. Sulfagenix Australia Pty Ltd was established for the purpose of developing SG1002 for the global market. The company was also able to access the Australian research and development (R&D) tax incentive programme, which significantly reduced their cost of development.

George Clinical was responsible for study management, clinical monitoring, medical monitoring, statistical analysis and medical writing. The Phase I trial in healthy volunteers and heart failure patients was conducted in an Australian Phase I unit.

The study was completed successfully in 2014. The product was well tolerated and there is encouraging data suggesting a benefit to heart failure subjects. Sulfagenix is now planning a small Phase IIa study in Australia.

Established by The George Institute for Global Health (ranked among the top 10 research institutions in the world for scientific impact), George Clinical is a full service contract research organization (CRO) that designs and manages large-scale clinical trials both for the Institute and for biopharmaceutical organizations. Headquartered in Sydney, Australia, George Clinical has offices in the Asia Pacific, Europe and the United States.
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.

Image courtesy of Bristol-Myers Squibb
GSK

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.

Image courtesy of GSK
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 grass-roots of blood pressure management, and their ability to successfully manage blood pressure has potentially massive impacts on overall health”.

Image courtesy of Novartis
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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.

austrade.gov.au
The Department of Industry and Science’s Single Business Service is streamlining the way businesses access industry information, grants and services by putting their needs first – reducing red tape and providing quality, consistent services at the lowest possible cost.

business.gov.au offers simple and convenient access to all of the government information, forms and services you need, including the R&D Tax Incentive. It is a whole-of-government service providing essential information on planning, starting and growing your business.

National Health and Medical Research Council (NHMRC) is Australia’s leading expert body for:
• supporting health and medical research
• developing health advice for the Australian community, health professionals and governments
• providing advice on ethical behaviour in health care and in the conduct of health and medical research.

While the pharmaceutical and biotechnology industries are major sponsors of clinical trials in Australia, there are also many that are sponsored by either collaborative research groups, institutions such as universities or hospitals, or even individual health professionals. NHMRC often funds these latter types of ‘public-good’ trials.

As an initiative of the Australian Government, NHMRC, together with other key stakeholders, is working to achieve a nationally consistent approach to the way that clinical trials are conducted, by streamlining the ethics review and governance process, promoting education and training, and making it easier for potential participants to enrol in clinical trials. The Australian Clinical Trial website provides comprehensive and up-to-date information for consumers, health care providers, researchers and sponsors and also enables potential participants to register their interest in being part of a clinical trial.

australianclinicaltrials.gov.au

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices. The TGA administers the Therapeutic Goods Act 1989, applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary. The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

www.tga.gov.au

AusBiotech is Australia’s biotechnology industry organisation, working on behalf of members for almost 30 years to provide representation and services to promote the global growth of Australian biotechnology. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial sectors.

AusBiotech is dedicated to the development, growth and prosperity of the Australian biotechnology industry, by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

ausbiotech.org
The Australian Clinical Trials Alliance (ACTA) has been established as a national mechanism to support and represent the networks of clinician researchers that conduct investigator-initiated or ‘public-good’ clinical trials within the Australian health system. The ACTA community currently incorporates more than 60 clinical trials networks, clinical trial coordinating centres and clinical quality registries around Australia. Collectively, these collaborations represent more than 10,000 senior doctors, nurses, allied health professionals and career researchers. They cover a broad range of disease groups and clinical disciplines and extend well into regional and rural areas, representing a large proportion of the public-good clinical research conducted in Australia each year.

clinicaltrialsalliance.org.au

Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to Australian patients. Medicines Australia’s members are responsible for the discovery, research, development and commercialisation of up to 86% of prescription medicines currently available on the Pharmaceutical Benefits Scheme (PBS), by value. Last year, the industry generated over $34 billion in exports, and invested over $1 billion in research and development (R&D).

medicinesaustralia.com.au

REFERENCES

3. Therapeutic Goods Administration, Canberra, 2014, Half-Yearly Performance Report, Jul-Dec 2013. Note: Figures do not include clinical trials conducted outside the “CTN scheme”, such as low-risk, non-interventional trials.
11. Specimen Central LLC, Minneapolis, 2015, Global Directory of Biobanks, Tissue Banks and Biorepositories.
12. Note: There is a $100m expenditure threshold on the concessional rate of tax offset for eligible R&D. The Australian Government has announced its intention to reduce the tax offset rates to 43.5 and 38.5 per cent respectively, subject to legislation.
15. 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.
21. Department of Foreign Affairs and Trade, Canberra, 2013, Composition of Trade (Australia).
The Australian Trade 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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E  info@austrade.gov.au