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Australia is an attractive destination for conducting clinical trials. Australia’s clinical trials industry is sustained by a strong economy, supportive Government, and highly skilled workforce.

Conducting clinical trials in Australia provides a gateway to strategically expand into Asian markets due to its growing economic ties and geographic proximity to the Asia Pacific region.

**Why Australia for clinical trials**

**Thriving medical research industry**

Australia has a thriving medical research industry, with 50 pharmaceutical companies, 400 biotechnology companies and 500 medical technology companies. Over 100 of these are listed on the Australian Stock Exchange.

Australia is in the top 10 countries worldwide for the number of clinical trials conducted in the last decade, with:

- more than 10,000 trials conducted
- over 5 million participants enrolled
- 33% of trials recruiting from multiple countries
- 45% of trials involve industry.

**Supportive Government and regulatory environment**

The Australian Government offers significant tax incentives for R&D expenses, strong intellectual property protections, and streamlined and customs duty-free importation of clinical trial kits and placebos.

Australia has a supportive regulatory environment for clinical trials. No IND or regulatory approval is required to commence clinical trials. Australian data is accepted by multiple regulators worldwide, including the European Medicines Evaluation Agency, US Food and Drug Administration, China Food and Drug Administration and other regulators worldwide.

**Smart workforce**

Australia is home to world-class medical research institutions and universities that work in a culture of collaboration, supporting researchers and health professionals recognised as global key opinion leaders in major therapeutic areas.

**Strong economy and business outlook**

- 5th largest economy in the Asia Pacific region
- 14th largest economy in the world
- 28 years of consecutive economic growth
- 2.7% annual GDP growth projected over the next five years, the highest among major advanced countries
- 11th globally for business environment outlook for the next five years
- Ranked top 20 countries for ease of doing business by the World Bank
- Ranked 1st for scientific research in terms of productivity and impact in Asia-Pacific
- 5th in the world in biotechnology capability
- 1st for scientific research in terms of productivity and impact in Asia-Pacific
- 8th largest producer of most-cited scientific publications in OECD nations
- 9th for proportion of the population with tertiary qualifications globally
New South Wales has the capabilities and strengths to facilitate fast, high quality and cost-effective clinical trials from approval to completion. NSW has natural strengths that support a thriving clinical trial sector, including a large and diverse population, strong market and highly networked health system.

**Australia’s largest market and population**

New South Wales is home to one third of the Australian population. The State has a primarily English speaking, ethnically diverse population, with 17.9% of the NSW demographic being born in non-English speaking countries, predominantly Asia.

NSW is Australia’s best performing economy. The State’s economy is larger than Malaysia, Singapore and Hong Kong. Over half of Australia’s medtech companies are headquartered in NSW.

**Sophisticated and highly networked health system**

The NSW public health system is the largest healthcare system in Australia and one of the largest in the world. The health system is highly networked, with 228 public hospitals and over 200 private hospitals serving metropolitan, regional and rural/remote populations.

Integrated into the health system are statewide clinical networks, research hubs and overarching health translation centres that facilitate innovation within the system. NSW has the biggest Cerner footprint in the world, with the majority of the State’s medical records now electronic.

**World-class facilities and expertise**

The State’s mature research ecosystem connects local health districts, medical research institutes, universities and clinical trial networks to provide centres of excellence in genomics, proteomics, biobanking and early phase clinical trials.

NSW has the most highly skilled workforce in Australia and is home to three of Australia’s top five highest ranked research universities. Contributing to a promising market is NSW’s innovative culture, with a large percentage of Australian start-ups founded in NSW.

NSW researchers are globally recognised key opinion leaders in oncology, neuroscience, cardiovascular medicine, and medical devices.

**Home to 8.0 million people, more than Singapore and Hong Kong**

The State is Australia’s largest economy: A$600 billion

$25.1 billion health system budget (expenditure 2018-19).

80% of the State’s medical records are electronic.

3 of Australia’s top 5 highest ranked research universities based in NSW.

44% of Australian start-ups founded in NSW.
NSW clinical trial statistics

• 30% of clinical trials in Australia are conducted at NSW centres, including 30% of early phase trials.
• Clinical trials can access the entire NSW public health system and patient population with a single ethics application.
• Specialist ethics review providers assess early phase clinical trials within 20 days.
• Over 90% of clinical trials are approved within 60 days.
• Over 90% of clinical trials authorised (contracts signed) within 30 days.

Fast and efficient start-up

NSW has leveraged Australia’s single ethics review system to ensure clinical trials are fast to start.

Efficient start-up of trials is a key performance indicator for NSW hospitals. This translates to more than 90% approval of clinical trials within 60 days of application, and contracts signed within 30 days.

Across the State, 15 Human Research Ethics Committees are certified by the National Health and Medical Research Council to review clinical trials. Two specialist Human Research Ethics Committees have been appointed by the NSW Government for the expedited review of early phase clinical trials. Rapid resolution of issues is supported by our Clinical Trials Triage service.

High quality delivery

Clinical trials in Australia are conducted under the oversight of the national regulatory authority, the Therapeutic Goods Administration (TGA). This rapid and robust regulatory system means trials can commence within a week of notification to the TGA – no IND is required.

Data from trials conducted in Australia can be used to support international regulatory applications, including the US Food and Drug Administration, European Medicines Evaluation Agency and the Chinese Food and Drug Administration. Our ethnically diverse population also supports the collection of demographically-driven data.

To ensure the high quality of Phase I and First-in-Human clinical trials, the NSW Government has also implemented a quality recognition scheme certifying the capability of all sites conducting early phase clinical trials.

Cost competitive

Australia is up to 60% more competitive for clinical trials under the R&D Tax Incentive scheme. A standardised cost schedule for support services provides transparency and accountability to sites’ costs.

There are many local and international contract research organisations (CROs) based in Sydney to support your clinical development program – whatever your size and requirements:

• Five Corners
• George Clinical
• IQVIA
• Mobius Medical
• Southern Star Research

Business advisory capabilities can support access to funding, benefits such as the R&D Tax Incentive, and the local market.

Australia has the 8th most efficient healthcare system worldwide

Two specialist HRECs to expedite review of early phase clinical trials within 20 days.

56% of Australians indicate they are willing to participate in a clinical trial

Early phase clinical trials in Australia are 28% cheaper than the US, increasing to 60% with tax incentives for eligible companies
Capability highlights

Data linkage and analytics

NSW has internationally recognised data linkage and data analytics capability. Around half a billion linked records from health and other administrative data sets are released annually for research and policy purposes, supporting feasibility studies, longitudinal follow up for clinical trials for regulatory approvals, post-market surveillance and more.

- HealthStats NSW is an interactive, web-based application provided by the NSW Government that allows users to access data and tailor reports on health status, health inequalities and the determinants of health, major causes of disease and injury.
- The Centre for Health Record Linkage (CHeReL) links data on hospitalisations, emergency department presentations, births, cancer registrations and deaths. CHeReL maintains a record linkage system that protects privacy, and can offer advice on the design and cost of linkage studies.
- Secure Analytics for Population Health Research and Intelligence (SAPHaRi) provides data in an analytic-and-reporting ready system to teams within NSW Health to drive innovation in NSW healthcare, policy and planning.
- The Secure Unified Research Environment (SURE) is a secure computing environment that allows researchers to remotely analyse linked health data. SURE strengthens Australia’s capacity for national and international large-scale research collaborations.

Genomics and proteomics

The NSW Government has made a long term commitment to ensure the potential benefits of genomics and proteomics are incorporated into the NSW health system effectively and efficiently. The NSW Health Genomics Strategy positions NSW Health at the forefront of genomic technology in healthcare, both nationally and internationally.

- ProCan aims to identify the type and quantity of proteins in around 70,000 cancer biopsies, and create a freely accessible database of this information, plus genomic, patient treatment and disease progression data. It will identify therapeutic targets, biomarkers associated with disease prognoses and facilitate rapid matching of patients to treatments with the highest likelihood of success.
- The Genomic Cancer Medicine Program uses genomics to improve the understanding, early detection, prevention and management of cancer. The program includes Molecular Screening and Therapeutics (MoST), which provides patients with access to targeted clinical trials based on the specific genomic features of their cancer.
- The Zero Childhood Cancer program brings together all major Australian clinical and research groups working in childhood cancer to offer Australia’s first ever personalised medicine program for children with high-risk or relapsed cancer.

Cell and gene therapy

NSW has strong clinical implementation structures in place for cell and gene therapy research, with statewide governance structures that incorporate executives, policymakers, researchers, clinicians, manufacturing, industry and consumers.

NSW has made significant contributions to this field globally through the development of novel technologies and their clinical implementation, for example the development of a new vector technology currently being tested in five separate academic and commercial trials globally, and lead participation in world-first trials of therapies for a number of genetic diseases, infections and cancers, including providing the first patients outside of North America with gene therapy for spinal muscular atrophy.

- Key opinion leaders involved in viral vector development including some of the most elite global vector technology for targeting liver disease, and multiple international clinical trials for cell and gene therapies.
- Advanced cell and gene therapy manufacturing facilities, including GMP licensed facilities and early phase research facilities. NSW manufacturing facilities provide a tertiary training program for GMP lab staff.

Health economic analysis

Health economics research is a core strength of the NSW research environment. Capability in this area is supported by key NSW research groups that provide dedicated services and facilities to support high quality research.

- The Health Research Economics group at the Hunter Medical Research Institute fosters the integration of economic principles and techniques into health research. The group supports researchers to design and implement economic evaluations, conduct cost studies, cost-effectiveness and cost-benefit modelling, and assess research impact and more.
- Macquarie University’s Centre for the Health Economy delivers innovative health economics research including choice modelling, econometrics, economic evaluation, health technology assessment and policy analysis. The Centre provides training in health economics for professionals and researchers.
- The Centre for Health Economics Research and Evaluation is an international leader in health economics, health services and health policy research. Based at the University of Technology Sydney, the Cancer Research Economics Support Team was established at the Centre to support oncology clinical trials. The Centre is developing resources to assist clinical trial groups to include health and pharmaco-economic analyses into trial protocols and build health economics capacity.
Case study: NSW Health Statewide Biobank

Biospecimen banking is a growing enterprise which has become essential to health science research and personalised medicine. To support this, the NSW Government invested A$12 million to develop the NSW Health Statewide Biobank which was launched in November 2017.

NSW’s Statewide Biobank is the largest biobank in the Southern Hemisphere and has capacity to collect, process and store three million human biospecimens. Stringent standard operating procedures, large-scale robotics, and fully automated barcode tracking systems ensure biospecimens are optimally stored and retrieved.

The state-of-the-art facility is the first and largest of its kind in Australia and unlocks a new model of biobanking, tapping into 200+ collection centres and 60+ laboratories of NSW Health Pathology, to enable projects and collaboration throughout NSW. The Statewide Biobank supports a broad range of population, precision and translational research aiming to deliver long-term health benefits for the people of Australia and globally.

Collections are supported by a robust, opt-in consent framework

The NSW Health Statewide Biobank Consent Toolkit provides standards on informing and consenting participants. It ensures high ethical standards are met while improving sample and data availability and enabling truly informed consent.

With robust consent, the Statewide Biobank works with the Centre for Health Record Linkage (CHeReL) to annotate and enrich biospecimens with routinely collected administrative health datasets. Data linkage transforms biospecimens into a powerful resource for health and medical research. Researchers can undertake detailed, high-quality, longitudinal studies that integrate genetics, phenotype, health service use and lifestyle.

Strategic collections accessible to international researchers

Strategic collections supported by NSW Health range from population cohorts (see 45 and Up Study below) to novel cohorts (e.g. psychiatric disorders, autoimmune disease, Kawasaki disease). Bona fide researchers with ethically approved proposals can request access to specimens and linked data. Researchers must return results to enhance the story each biospecimen can tell, contributing further to future research.

45 & Up Study is the largest study of ageing in the Southern Hemisphere

NSW Health supports the Sax Institute to deliver the 45 and Up Study, a cohort of more than 250,000 people, the largest ongoing study of healthy ageing in the Southern Hemisphere. Participants have consented to their survey answers being linked to information sources such as hospital, pharmaceutical and general practice records. A subset of these participants has also consented to donating biospecimens to the Statewide Biobank.

By following such a large cohort over the long term, we are creating a world-class resource to boost our understanding of ageing in the genetically and culturally diverse Australian population.

www.biobank.health.nsw.gov.au
Case study: Scientia Clinical Research

Scientia Clinical Research is a not-for-profit early phase clinical trial company fully owned by the University of New South Wales. Scientia operates a 30-bed Phase I unit co-located within the Prince of Wales Hospital, a tertiary teaching hospital offering a full range of clinical specialities.

Scientia conducts approximately 30-35 clinical trials per year, including 10-15 First Time In Human (FTIH) single and multiple dose studies, food effect studies, drug interaction studies, ethnopharmacology studies (Japanese, Chinese, Korean), biosimilar studies, formulation studies and specialty studies incorporating a range of pharmacodynamic markers such as Flow Cytometry and Cytokine analysis. These studies are being performed in healthy volunteers as well as specialist patient populations such as oncology, haematology, Parkinson’s disease, diabetes, NASH and liver & lung fibrosis.

The majority of Scientia’s sponsors are multinational pharmaceutical and biotechnology companies from the US, China, Europe and South East Asia.

Scientia has access to Japanese, Chinese and Korean volunteers and conducts 3-4 ethnopharmacology studies a year. Scientia has staff fluent in Japanese and Chinese.

Scientia is able to manufacture finished product (investigational product) from active pharmaceutical ingredients and manage investigational product importation, receipt and labelling. These services have provided significant time and cost savings to our Sponsors.

A proven track record

Scientia Clinical Research has recent experience assisting a Chinese biotech, with no experience in Australia, to conduct an FTIH oncology study. Scientia were able to provide rapid approval through experienced ethics committees, utilising external toxicology & immunology review in parallel to ethics review. The trial was conducted in an experienced phase I facility and experienced sites. Numerous other FTIH oncology studies are now ongoing through Scientia.

Scientia worked with a large US biotech wanting to conduct a FTIH biological study with study specific biomarker assays. Scientia were able to facilitate local conduct of cytokine stimulation assay under CO2 incubation, based on sponsor trained and validated methodology to provide the customer with vital information about the stability of samples for use as a biomarker.

A large US biotech approached Scientia wanting to establish proof of concept for a product before finalising product formulation. Scientia were able to navigate limited availability of manufacture, and requirements for a special patient population to complete a proof of principle study, conducted to GCP and GMP standards.

For all these customers, Scientia delivered rapid study start up, and rapid dose escalation decisions through fast data turn around. Working with Scientia allowed these customers to reduce direct and indirect costs, to accelerate their development plans through subsequent regulatory filing in international markets including the US and China.

The Cancer Institute NSW is the cancer control agency for NSW. The Cancer Institute NSW collects and uses the latest cancer data, information and evidence to drive improvements in cancer outcomes and is the largest funder of cancer research in the State. At the core of this is a translational cancer research program to bring ground-breaking research to improve the lives of people with cancer.

Seven Translational Cancer Research Centres were established in 2011 to help accelerate the translation of research from the laboratory bench and bringing it to the hospital bedside. They have different focuses, but they are all built on common foundations: leadership, governance, research strategy, collaboration, and capacity-building for sustainability.

These centres are actually networks, which bring together research, clinical training, education and service delivery. The network comprises 70 leading research and clinical institutions and almost 1,000 cancer researchers from across NSW. The connections cancer researchers are making bridge administrative and institutional boundaries, fostering collaboration across the State and working together to reduce the impact of cancer.

Creating the right structure to help cancer research reach the people who need it most

Associate Professor Caroline Ford has seen the impact in her own work. A member of the Translational Cancer Research Network, linking leading research and clinical centres in south-east Sydney, it has spurred her study ‘HSA Biobank – from the lab to clinical trial’. Together with her team at the University of New South Wales’ Lowy Cancer Research Centre, they are working to improve outcomes for women with ovarian cancer.

Ovarian cancer ranks sixth in cancer deaths among women in NSW. Risk increases with age, with most cases diagnosed in women aged 50 years and over. There is currently no early detection test for ovarian cancer, and the symptoms are not unique.

A/Prof Ford’s team are using the Network’s flagship Health Science Alliance Biobank to support research into the role of two genes implicated in ovarian and endometrial cancer - ROR-1 and ROR-2.

Using the Biobank has been revolutionary for the study, changing the approach from individual researchers or tumour types. Previously, researchers were individually collecting their own samples for research. With the Biobank, everyone with cancer at a hospital is asked if they want to have one of their blocks banked.

A/Prof Ford aims to find new drug targets for women with ovarian cancer by understanding the molecular changes underpinning individual subtypes of the disease, and is now set to take her research through to a potential clinical trial. The trial will be a collaboration with Professor Thomas Kipps from the University of California, San Diego and pharmaceutical company Oncentra Therapeutics.

The Health Science Alliance Biobank was established through the Translational Cancer Research Network as a joint initiative of the University of New South Wales, South Eastern Sydney Local Health District and NSW Health Pathology.

It truly embodies the mission of the Translational Cancer Research Program, connecting diverse research institutions to deliver real results for people with cancer.

www.cancer.nsw.gov.au
Case study: Okogen

Okogen is a specialty biotechnology company focused on developing therapeutics for ocular diseases. Founded in the US, Okogen created a NSW-based subsidiary to deliver the Phase II clinical trials of their lead development candidate, a broad-spectrum antiviral to treat viral conjunctivitis.

Establishing a presence in NSW has allowed Okogen to take advantage of world class physician researchers, a flexible but robust regulatory environment and significant government financial support.

Working through a NSW-based subsidiary has allowed Okogen to access the Australian R&D tax incentive and apply for significant government support. In 2018, Okogen received A$13 million in funding from Australia’s Medical Research Commercialisation Fund to advance the ongoing development of the company’s lead development candidate, OKG-0301.

The Medical Research Commercialisation Fund supports the development and commercialisation of early stage biomedical discoveries originating from member research organisations, providing both capital and expertise to guide the successful development of new therapies. It is the largest life science investment fund in Australia, with over A$700 million under management.

In 2019, Okogen opened recruitment for the multi-centre Phase II study to test the efficacy and safety of OKG-0301 against adenoviral conjunctivitis (the RUBY trial). The RUBY trial is being conducted entirely within Australia and is currently recruiting to seven sites across the country, including three metropolitan and regional sites in NSW.

Access to world class physician researchers in NSW has been key to effectively establishing this trial in Australia. Okogen teamed up with Professor Stephanie Watson, Save Sight Institute, University of Sydney as the coordinating principle investigator for the RUBY trial. Professor Watson is an ophthalmic surgeon and an international leader in ophthalmic research and innovation.

Conducting this trial in NSW will enable Okogen to use the data to support international regulatory applications for OKG-0301, including the US Food and Drug Administration and European Medicines Evaluation Agency.

Doing business in NSW has allowed Okogen to bring this treatment closer to market efficiently and cost-effectively, while upholding a robustness and quality of delivery recognised globally.

www.okogen.com
www.rubytrial.com.au
Case study: George Clinical

George Clinical is a leading global clinical research organisation founded in Asia-Pacific driven by scientific expertise and operational excellence. With 20 years of experience and more than 300 staff managing 38 geographical locations throughout the USA, Asia-Pacific region and Europe, George Clinical provides the full range of clinical trial services to biopharmaceutical, medical device, and diagnostic customers, for all trial phases, registration and post-marketing trials.

George Clinical’s operational staff have a wealth of experience conducting clinical research trials globally - particularly across the Asia-Pacific region. George Clinical’s management team is drawn from large pharmaceutical companies and global contract research organisations. The team’s experience spans a number of major therapeutic areas and all phases of clinical research.

An example of George Clinical’s success includes a recent clinical trial program in which George Clinical worked with a biopharmaceutical company developing a novel therapeutic agent. The study was conducted in Australia, however the results impact children with certain types of epilepsy all over the world.

The studies were performed in two rare genetic neurological disorders in which children have epileptic seizures that are refractory to medications. George Clinical’s role in the program encompassed end to end management of the studies and the investigative sites, medical monitoring and safety reporting.

George Clinical provided expert guidance to the sponsor with regards to the complex consent procedure that is required for pediatric patient populations. George Clinical engaged dedicated investigators who were willing to invest the time required to build confidence in patients to participate in these studies, and this was a critical success factor.

George Clinical also collaborated with indication specific support networks to effectively engage and educate the patients, and provided operational design elements that placed patient comfort front and centre.

The studies were successfully recruited by George Clinical, delivering high data quality which led to the approval of the new product by the FDA.

www.georgeclinical.com
Case study: Southern Star Research

Southern Star Research is a leading Australian, privately owned, full service Contract Research Organisation (CRO). Headquartered in Sydney and supporting regional staff throughout the region, Southern Star Research specialises in providing a highly specialised clinical research service for biotechnology, pharmaceutical and medical device clinical trials in the region. In particular, Southern Star Research has exceptionally strong early phase clinical trial expertise.

Southern Star Research share their Client’s vision to promote and advance healthcare to patients. Working with Southern Star Research doesn’t simply mean you are collaborating with an Australian CRO – it means you’re working with a regional partner who takes time to understand your product, is able to work productively with trial sites and investigators and has a strong track record of exceeding project milestones.

Southern Star Research’s goal is to help their Clients successfully complete their clinical trial ahead of time and budget, accelerate their Clients’ clinical development programme and deliver value for their Clients.

Southern Star Research have a wealth of experience

Southern Star Research’s experience is wide and varied across both study phase and therapeutic area, built through a diverse client profile, ranging from large multinational pharmaceutical companies to small biotechnology and medical device start-ups. Along with this, Southern Star Research also supports academic, investigator initiated and real world data studies.

Southern Star Research has assembled one of the most experienced clinical research teams in the Asia Pacific region and aims to consistently provide a team of clinical research professionals that have extensive experience and a wealth of clinical trial knowledge that no other Australian CRO can match.

Southern Star Research can also provide smooth and seamless global coverage for your clinical program. By undertaking your early phase research with Southern Star Research, you take advantage of the Australian clinical trial ecosystem and with their network of quality focused CROs based in Europe, North America, South America and Asia, Southern Star Research can help you expand the global reach of your trial.

Southern Star Research is a full service CRO

Southern Star Research is a registered Research Service Provider under the Australian Government R&D Tax Incentive program. The majority of the Southern Star Research team are based in Australia and are able to support the following aspects of the clinical trial process:

• Clinical Operations including Study Feasibility, Project Management and Monitoring;
• Biometrics including Data Management and Biostatistics;
• Medical Monitoring and Local Safety Reporting;
• Vendor Qualification and Management;
• Medical Writing including Protocol Development, Investigator Brochure, Regulatory Submissions and Clinical Study Report;
• General Clinical Research Consulting and Quality Assurance; and
• Local study Sponsorship.

www.southernstarresearch.com.au
Case study: IQVIA

IQVIA offers full-service clinical development solutions.

IQVIA has structured the team to be based in Australia for our customers wanting to maximize the advantage of the R&D Tax Incentive. Our dedicated teams have the global experience, with deep therapeutic knowledge and robust infrastructure to effectively guide your study to the next milestone.

Early and late phase expertise

IQVIA has staff with specific early phase and late phase experience to address the nuances of different phases of development and can grow with you as your pipeline matures. We power our clinical solutions through the dynamic integration of data, technology, analytics and deep expertise in therapeutics and clinical operations to help you discover a better and faster path to success. You can trust IQVIA to plan and deliver your trial with quality, speed and efficiency.

Our extensive early phase experience enables us to guide your compound through the intricacies inherent in dose-finding, safety and proof-of-concept studies in a healthy or patient population, particularly in oncology.

• We’ve run hundreds of dose-escalation and dose expansion trials, ensuring we understand the speed and flexibility required for effective cohort management.

• We look beyond first-in-human milestone, and are active in a range of adaptive, basket and umbrella designs, and are fluent in the implementation of mid-study registrational amendments.

• Our global capabilities allow for international expansion to support timely accrual of rare or competitive indications.

• We’re actively working with cutting-edge targeted small molecules as well as immunotherapies such as CAR-T, autologous vaccines, ADCs and oncolytic viruses.

Additionally, we have specialized Phase I/II project teams, preferred site relationships, and standardized database structures and reporting tools, to quickly move your product safely to the next stages of development.

We work closely with sites in New South Wales and have many partner sites who help us deliver fast start up of your study. An example of this is a phase I oncology study in a target therapy in solid tumors. This study enrolled 25 patients in 5 sites: 4 sites in New South Wales and 1 in Victoria. Rationale for the sites selected in New South Wales:

• Key Opinion Leaders who actively engaged with the Sponsor and IQVIA

• Proven track record with best in class start up timelines, recruitment and quality in dose-escalation phase I studies

• Highly qualified site staff

IQVIA Partnering with Sponsors & Sites

- Final Protocol to HREC Submission ≤ 10 days
- HREC Approval ≤ 23 days
- HREC Approval to First Patient In ≤ 59 days
- First Patient In to Last Patient In ≤ 207 days
Case study: The National Health and Medical Research Council Clinical Trials Centre

The National Health and Medical Research Council Clinical Trials Centre (NHMRC CTC) was established in 1988 to promote high-quality clinical trials research to improve healthcare and patient outcomes for Australians, as well as the global community.

Over the 30 years since its inception, the CTC has grown to host over 200 staff, who collaborate with over 1,000 national and international researchers and organisations. Our team includes experts in oncology, cardiology, diabetes, translational medicine, health economics and evidence integration, as well as in trial design and biostatistics. The CTC is also home to the Australian New Zealand Clinical Trials Registry and the Biostatistics Collaboration of Australia, and continues to educate the next generation of researchers and clinicians.

As our Director, Professor John Simes says, ‘Australia has the opinion leaders, the intellectual resources, and the capability to design and analyse studies and undertake translational clinical research from discovery to practice of the highest global standard’. The CTC plays a key role in driving and managing trial activity, both nationally and internationally.

Together with our collaborators, we have conducted over 200 trials that have made real differences to patients’ lives world-wide. Our work has helped to reduce illness and mortality and improve the quality of life of people with cancer, cardiovascular disease and diabetes, and improve the care of premature babies.

Saving premature babies’ lives

The Australian Placental Transfusion Study (APTS) aimed to determine whether immediate or delayed cord clamping was better for premature babies in both the short and the long term. This study, the largest ever randomised controlled trial of delayed cord clamping in premature babies, was led by Professor William Tarnow-Mordi, Head of Neonatal and Perinatal Research at the CTC, and involved leading obstetricians, gynaecologists and neonatologists across Australia.

The study involved researchers across 25 hospitals in seven countries, and enrolled over 1,600 women who had pre-term babies and was successful in demonstrating that delayed clamping could reduce the number of fatalities among premature babies before 36 weeks.

These results have already changed clinical practice in the management of premature births, and have the potential to save the lives of thousands of premature babies around the world.

The APTS trial was awarded ‘Clinical Trial of the Year’ by Federal Health Minister, Greg Hunt MP, and the Australian Clinical Trials Alliance in May 2018. Studies like APTS demonstrate the value of close collaboration between researchers, academics and clinicians to solve clinical problems and allow the rapid translation of these solutions into clinical practice.

www.ctc.usyd.edu.au
How we can help

NSW Government can help you establish your clinical trials in NSW and assist you to grow your business.

The NSW Investment Concierge team can assist by:
- coordinating your enquiries
- connecting you to the right people across the State
- giving you insight on the State’s capabilities relevant to your business
- linking you to the Clinical Trials Triage service
- providing free and confidential advice on doing business in NSW.

Contact us

The NSW Government’s dedicated Investment Concierge team can connect you to experts across all levels of government, hospitals, research, commercialisation and service providers to help you to innovate and grow your business.

T: +61 2 8222 4888
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