The Future of Clinical Trials

New South Wales, Australia

NSW GOVERNMENT


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Why Australia for clinical trials

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.

Strong economy and business outlook

5th largest economy in the **Asia Pacific** region

28 years of **consecutive economic growth**

2.7% annual GDP growth projected over the next five years, the highest among major advanced countries

14th largest economy in the world

Ranked **11th globally for business environment outlook** for the next five years

Ranked **top 20 countries for ease of doing business** by the World Bank

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 Investigational New Drug (IND) Application 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 institutes and universities that work in a culture of collaboration, supporting researchers and health professionals recognised as global key opinion leaders in major therapeutic areas.

Ranked **1st for scientific research** in terms of productivity and impact in Asia-Pacific

5th in the world in biotechnology capability

8th largest producer of most-cited scientific publications in OECD nations

9th for proportion of the population with tertiary qualifications globally


Cryo-
Gloves

Why NSW for clinical trials

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.

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

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

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 one of the biggest electronic medical records footprints in the world.

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

80% of the State's **medical records are 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.

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

44% of Australian start-ups founded in NSW

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.

Australia has the **8th most efficient healthcare system worldwide**

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

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 Application 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 60% more cost-competitive for clinical trials under the R&D Tax Incentive scheme.

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

clincaltrialsNSW can assist you to find the right partner to deliver your clinical trial - clinicaltrialsNSW@health.nsw.gov.au

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

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

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.

Capability highlights

Data linkage and analytics

NSW has internationally recognised data linkage and data analytics capability that supports value-based care and high quality research. Around a billion anonymised, linked records from health and other 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.

- The Centre for Health Record Linkage (CHeReL) links data from multiple sources, including hospitals, emergency departments and non-admitted settings. The data includes information on births and deaths and a range of medical diseases and conditions and is done using methods which minimise the risks to individual privacy.
- Comprehensive e-research advisory services are available to support access to linked and unlinked health data and provide technical services that enable high quality research.
- NSW Health is accelerating the roll-out of electronic medical records and integrated clinical information systems that will enhance patient, provider and research access to digital health.
- HealthStats NSW is an interactive, web-based application that allows users to access thousands of open data sets and tailor reports.
- 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. Highlights include 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. This has seen the first patients outside of North America be treated 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. The NSW Biolink service will provide streamlined and timely researcher access to a longitudinal linked data asset. This service will enable the transformation of 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.

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 ethno-pharmacology 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.

www.scientiaclinicalresearch.com.au


T12S
Mortara
DELL
DELL

Case study: Cancer Institute NSW's Translational Cancer Research Centres

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 Oncternal 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

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
- providing free and confidential advice on doing business in NSW.
- More information on clinical trials in NSW can be found at www.medicalresearch.nsw.gov.au/clinicaltrialsnsw and by emailing clinicaltrialsNSW@health.nsw.gov.au

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.

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