



Australian Government

Australian Trade and Investment Commission

Why Australia

for Clinical Trials

AUSTRALIA





Australian Government









Australian Trade and Investment Commission

Who we are - Austrade

Austrade is the Australian Government's trade promotion and investment attraction and facilitation agency.

In cooperation with State and Territory governments, Austrade provides confidential assistance and services.

National coordination of Australian government investment services	Advice on Australian government programs and approval processes
Introductions to key government agencies, including the State and Territory governments	Market intelligence and investment opportunities
Information on the Australian business and regulatory environment	Identification of suitable investment locations and partners, and site visit arrangements

 ENERGY Hydrogen Renewables (Storage, Wind, Solar) Energy Tech	 RESOURCES Critical minerals Oil and gas Bulk commodities Resources Tech
 CIRCULAR ECONOMY Waste Processing (E-Waste, Plastic, Building Materials) Waste to Energy	 DIGITECH Fintech Cyber security Enterprise technology Immersive technology Edtech
 INFRASTRUCTURE Civic & transport infrastructure Future Transport/Smart cities Tourism Infrastructure	 HEALTH INDUSTRIES Biotechnology Pharmaceuticals Medical devices Digital health
 AGRI-FOOD Advanced food & beverage processing Aquaculture Intensive horticulture Agtech	 DEFENCE & SPACE Automation & Robotics Space

A hybrid public–private healthcare system

Australia's hybrid public-private healthcare system supports a dynamic research and innovation ecosystem that attracts investment and expertise from around the world.



Universal services:

Medicare is Australia's universal health insurance scheme



Private insurance:

Health companies own 630 hospitals with 33,000 beds (1/3 the total)



Subsidised pharma:

covers 5,200 medicines



Funded research:

inc. the A\$20 billion Medical Research Future Fund and the National Health and Medical Research Council (NHMRC)



High-energy innovation:

top-ranking universities, medical precincts



Niche expertise:

oncology, neurology, tropical medicine, medical devices and diagnostics

Quality. Speed. Cost.

Australia is an ideal location for conducting clinical trials



Sophisticated health and medical research and environment



Quality transferable data



Cost-efficient

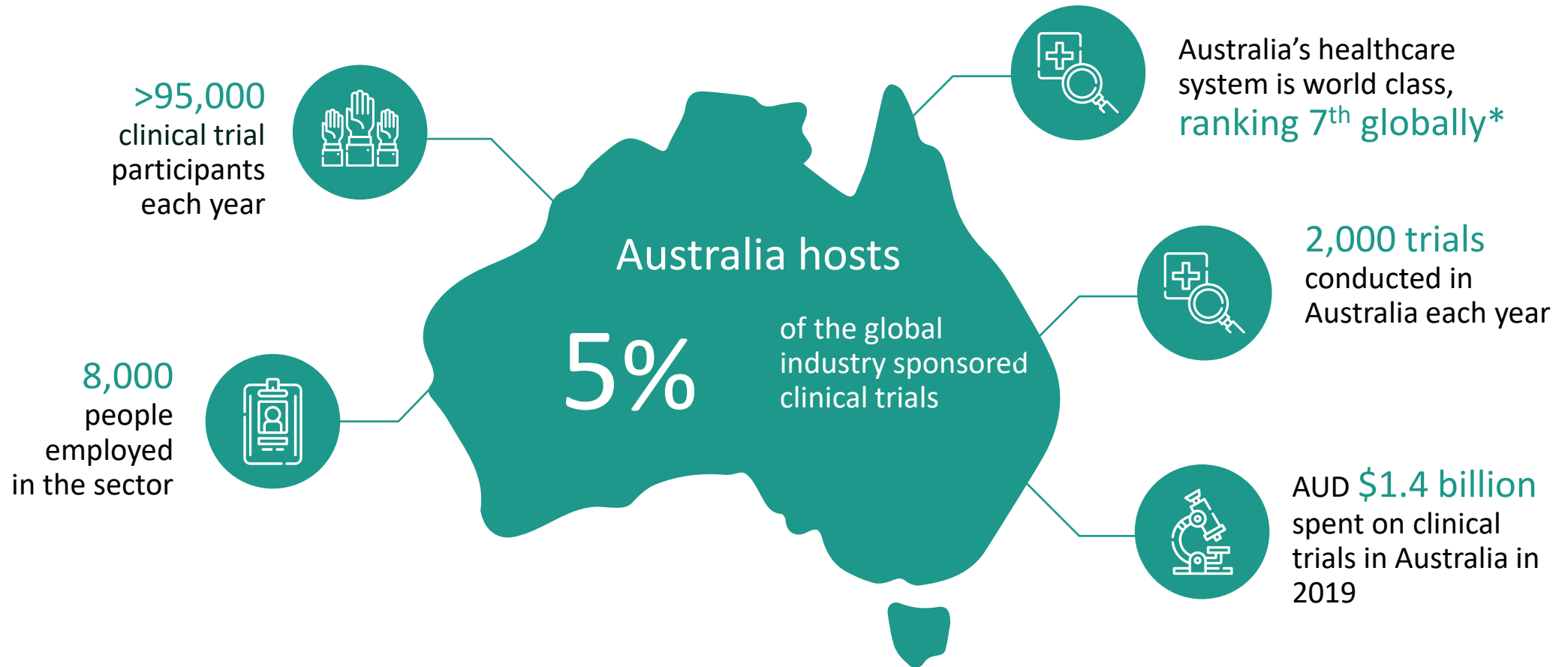


Rapid approvals and robust regulatory framework



An ethnically diverse patient population

Clinical trials are part of a robust and diverse health and medical research ecosystem in Australia



Clinical trials

Whole-of-government support for clinical trials

Strong government commitment



and national action to ensure an efficient, high-quality and vibrant clinical trials environment

A \$20 billion endowment fund



Medical Research Future Fund (MRFF) supports translational research and commercialisation

Includes \$750 million **Clinical Trials Activity Initiative** over the next 10 years

National Mutual Acceptance (NMA)



a system for mutual acceptance of scientific and ethical review for multi-centre clinical trials conducted across multiple states

Clinical trials

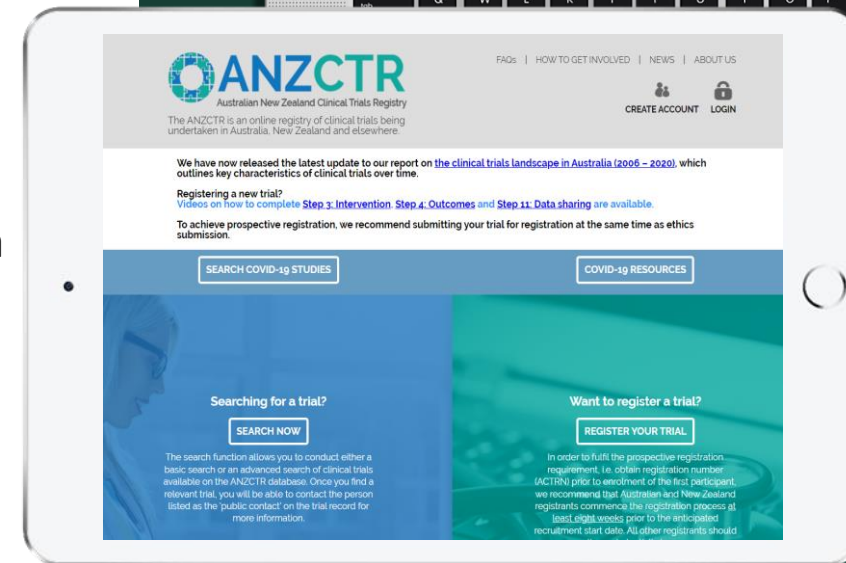
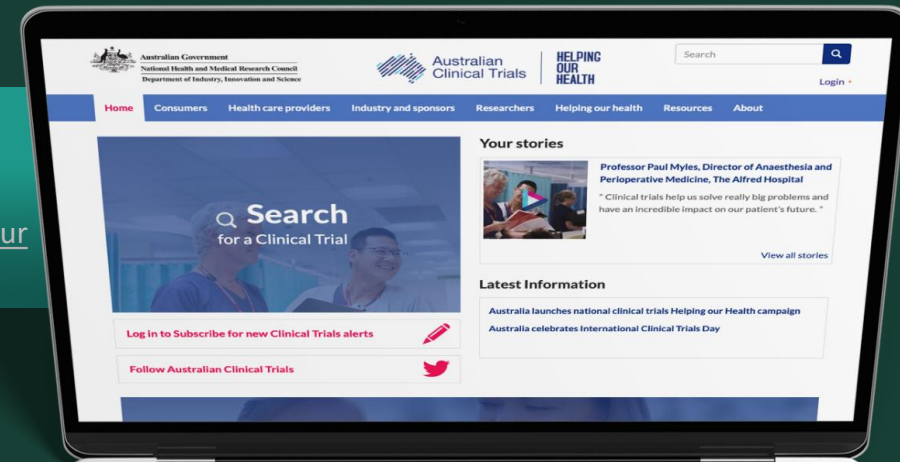
Whole-of-government support for clinical trials

National resources to support getting started
australianclinicaltrials.gov.au/resources-clinical-trials-australia

The Australian Government is strengthening and reforming the operating environment for clinical trials and research as a national priority, with the goal of making it easier for patients, researchers and sponsors to participate in and conduct trials.

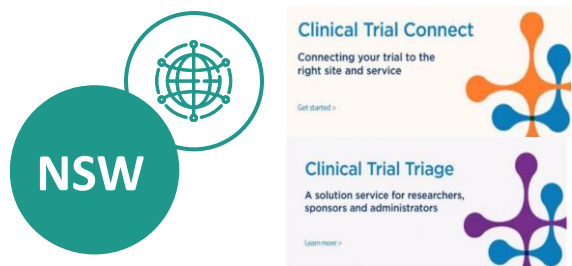
Government initiatives to support this include the:

- Proposed **National One Stop Shop** for Clinical Trials and Health Related Human Research Approvals (National One Stop Shop), a national, streamlined platform
- Proposed **National Clinical Trials Front Door**, a central access point
- **National Clinical Trials Governance Framework** a nationally consistent accreditation which embeds clinical trials into routine health service provision of health services undertaking trials



A searchable **clinical trials registry** accessible to the public
www.anzctr.org.au/TrialSearch

State government support for clinical trials



Connection to:

- Investigators and sites
- CROs, CMOs, Research Support Services
- NSW Health services eg: Biobank & Pathology
- Information and guidance on clinical trial delivery specific to Australia

Assistance with:

- Ethics & governance
- Regulatory matters
- Finance



Victorian Clinical Trials *Gateway*, provides:

- Connections to Victorian clinical trial sites, contract research organisations and professional services
- Regional advice services
- Understanding core capabilities



Queensland Clinical Trials Coordination Unit (QCTCU), services include:

- Clinical Trial Liaison Service – single point of contact for sponsors to find a site for a clinical trial, or to locate service providers
- Research Ethics and Governance Service – provides advice and direction on ethical and governance issues
- Intellectual Property and Commercialisation Service – supports translation of research



South Australian clinical trials portal, includes:

- Information on conducting clinical trials in South Australia including information for researchers, for participants and sponsors
- List of clinical trial providers
- Support services

AUSTRALIA

01.
Quality

A sophisticated medical research environment



1,342

medical technology
and pharmaceutical
companies



152

ASX-listed life sciences
companies



>58

world-class medical
research institutes



>40

universities focusing on
clinical research



>50

clinical trial networks



>50

biobanks



73,000

people employed in
research and MTP sector



Quality

Quality data from Australian clinical trials is accepted in key jurisdictions

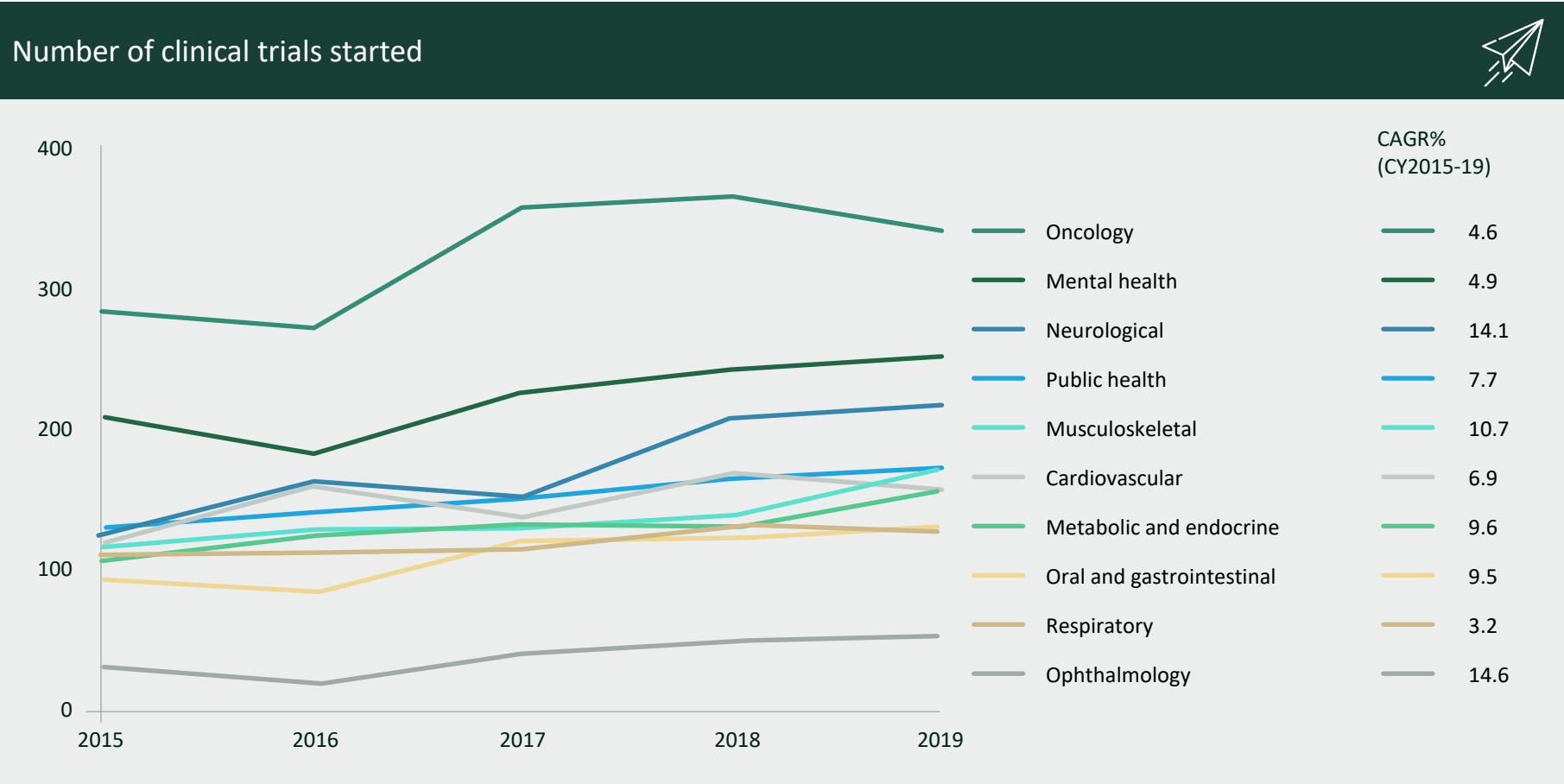


Data from studies conducted in Australia can be used to support international regulatory applications, including the US FDA and the European Medicines Agency (EMA)

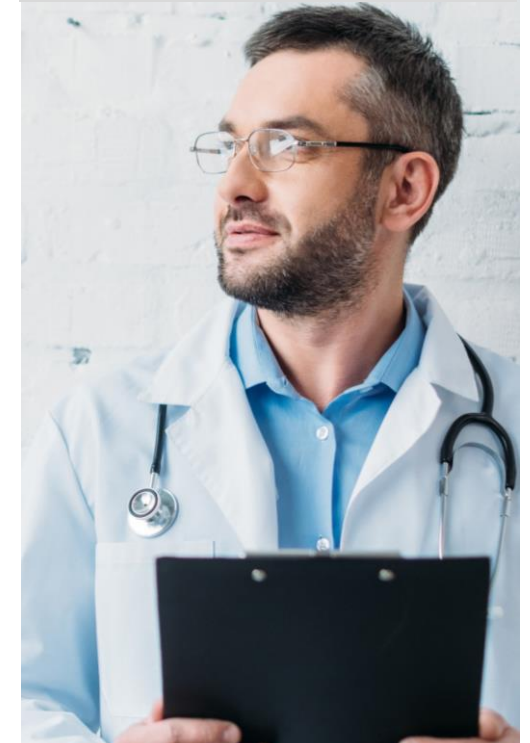


Clinical trials conducted in Australia do not require US FDA Investigational New Drug (IND) application approval

Clinical trials by therapy area in Australia CY2015-19



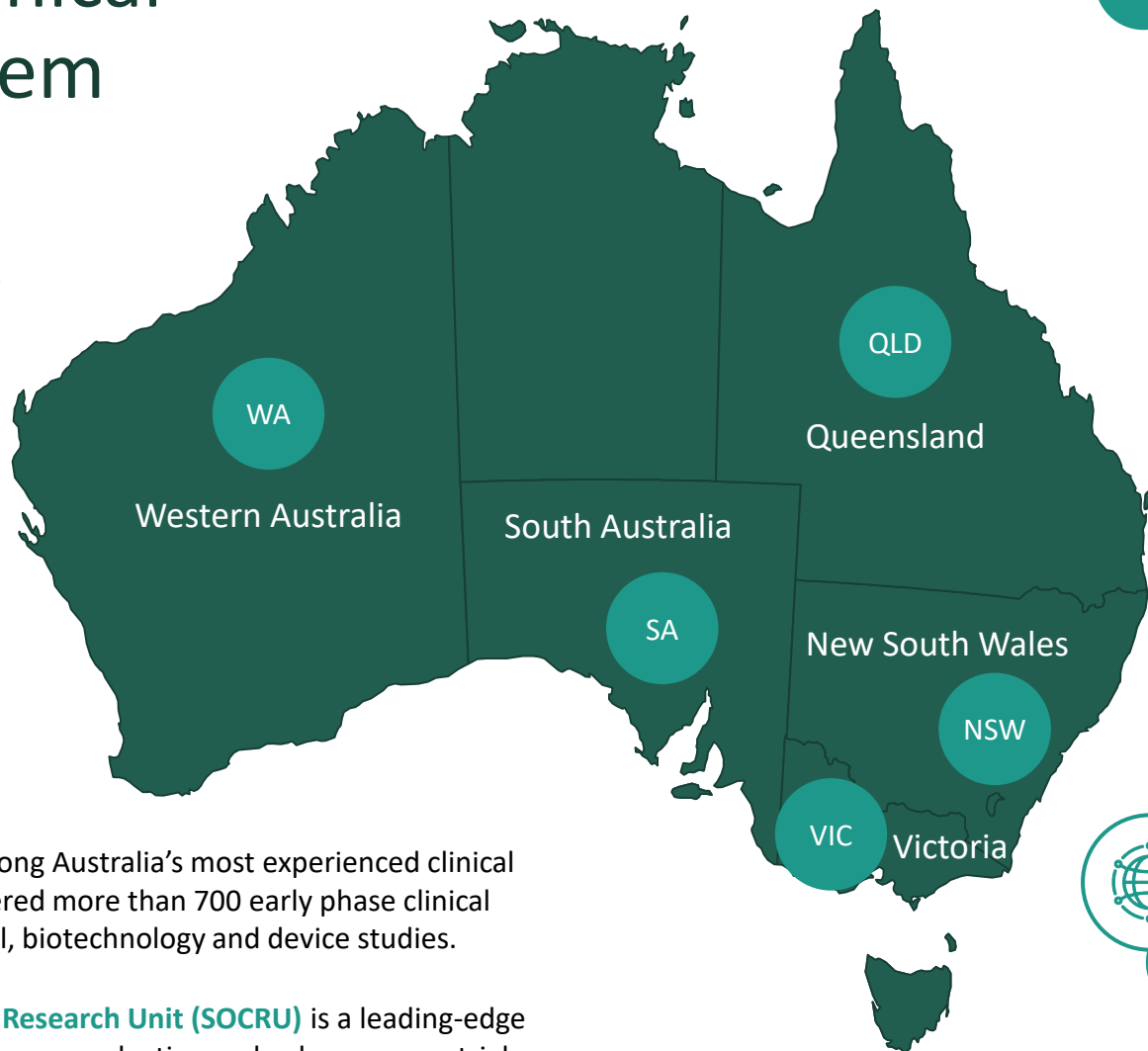
Australia host **5%** of global sponsored industry trials every year



In 2021, Australia accounted for **11%** of ongoing clinical trials investigating regenerative medicine

Quality

Australia's Clinical Trials Ecosystem



LuinaBio is a contract manufacturing organisation with GMP capabilities for manufacturing: recombinant proteins and vaccines, live Biotherapeutics, materials for pre-clinical, clinical and market, and aerobic and strictly anaerobic microorganisms

Australian Clinical Labs - Specialised Trials offers a dedicated pathology approach to Phase I-IV clinical trials, for clinical research, pharmaceutical and biotechnology clients.



NSW Health State-wide Biobank is the largest biobank in the Southern Hemisphere and has capacity to collect, process and store three million human biospecimens.

Mobius Medical is a boutique CRO with almost a decade of experience working predominantly with startup medical device and pharmaceutical companies



Melbourne Children's Trial Centre (MCTC) is a unique collaboration between the Royal Children's Hospital, Murdoch Children's Research Institute and University of Melbourne working in a wide range of indications, including cancer

Nucleus Network is Australia's largest Phase 1 clinical research organization with facilities in both the US and Australia



Linear Clinical Research has a purpose-built phase 1 facility, specialising in first-in-human, through to phase 4 clinical trials. The facility has strong connections 3 major hospitals enabling patient recruitment as well as collaboration opportunities with specialised physicians across many therapeutic areas.



CMAX Clinical Research among Australia's most experienced clinical trials units, which has delivered more than 700 early phase clinical trials, across pharmaceutical, biotechnology and device studies.

Southern Oncology Clinical Research Unit (SOCRU) is a leading-edge research facility and focusses on conducting early phase cancer trials, across a variety of interventions.

Biopharmaceutical Manufacturing

Australia is developing infrastructure for scaling biomedical product manufacturing



Specialised advanced manufacturing infrastructure

- CSIRO Advanced Biologics Manufacturing Facility
- Westmead viral vector facility
- National Biologics Facility



An established health ecosystem with end-to-end, research and clinical support capabilities.



Established advanced manufacturing infrastructure to optimise and accelerate production of complex biopharmaceuticals.



Medical product manufacturing is a key priority for Australia.

Funding initiatives are established by Commonwealth, including the National Reconstruction Fund, and State governments to strengthen Australia's manufacturing capability.

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02.
Speed



Speed

Rapid approvals and robust regulatory framework



Clinical trial process allows flexibility without compromising quality



Good Clinical Practice (GCP) standards ensure research quality

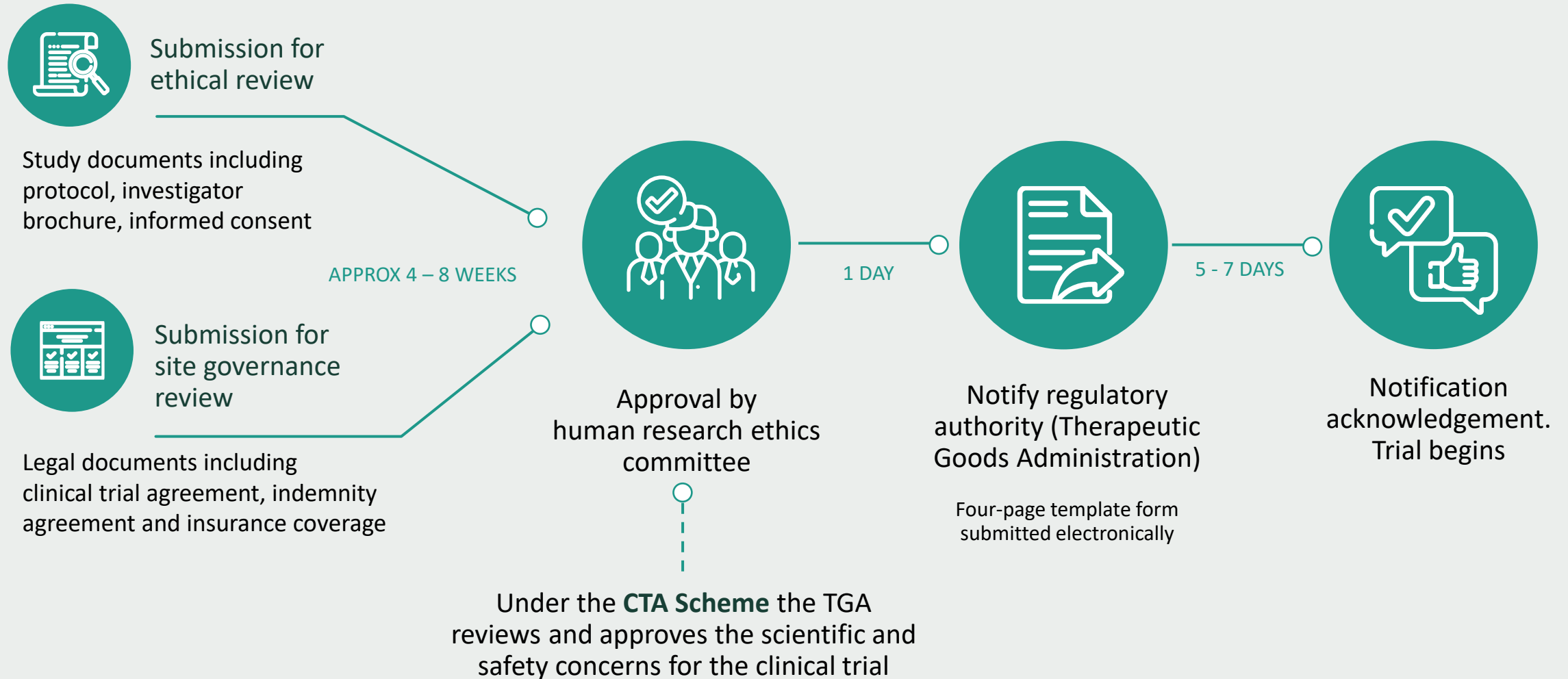


Simplification of clinical trial delivery by removing tariffs on clinical trial kits and placebos



World leading intellectual property (IP) system

Streamlined Clinical Trials Notification (CTN) Scheme



AUSTRALIA

03.
Cost-effective

Cost-effective



Reports show Australia is
28%
cheaper than
the US before tax
incentives, and
60%
cheaper after tax
incentives, for early-phase
clinical trials

Cost-effective

Favourable exchange rate and a generous R&D tax incentive boosts Australia's attractiveness



Companies with an annual aggregated turnover of less than **A\$20 million** receive a **refundable** tax offset, equal to their corporate tax rate plus an **18.5% premium**



Companies with an annual aggregated turnover of more than **A\$20 million** receive a **non-refundable** tax offset and depends on intensity of the R&D expenditure as a proportion of total expenditure for the year.

- ❑ R&D intensity up to 2% receives a tax offset equal to the company tax rate plus **8.5% premium**.
- ❑ Additional R&D intensity above 2% receives a tax offset equal to the company tax rate plus **16.5% premium**.

* Depending on turnover threshold corporate tax rate is either 25% (for small-medium businesses) or 30%.



Clinical trials

An ideal location



Investigators, clinical networks and trial facilities of a global standing



Globally recognised key opinion leaders in major therapeutic areas



Contract manufacturing capabilities to support clinical trials



Quality data recognised in key markets, such as the US and EU



An ethnically diverse population



Seasonal differences



Use of digital expertise and analytics in patient recruitment

Find out more

AusBiotech

ausbiotech.org

Australian Clinical Trials

australianclinicaltrials.gov.au

Australian Clinical Trial Handbook

tga.gov.au/publication/australian-clinical-trial-handbook

Good Clinical Practice Inspection Program

tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice

MTPConnect

mtpconnect.org.au/
[Australia's Clinical Trials Sector \(2021\)](#)

Medicines Australia

medicinesaustralia.com.au

Medical Research Future Fund

health.gov.au/our-work/medical-research-future-fund

National Statement

nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018





Australian Government

How Austrade can help



Our assistance includes



Providing insight on Australian capabilities



Identifying potential Australian service providers



Helping international companies identify potential investigators and sites

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