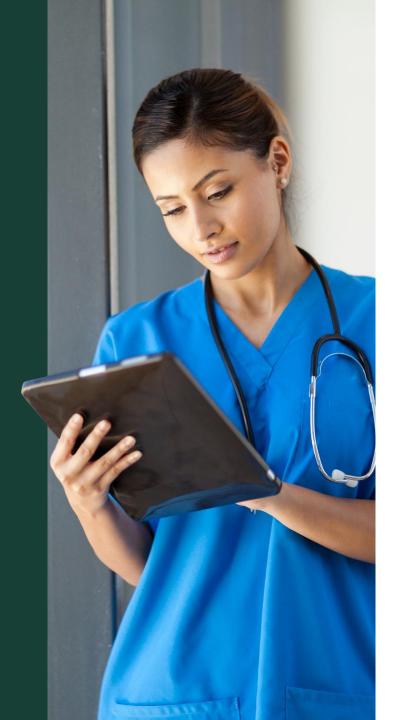


Quality. Speed. Cost.

Australia is an ideal location for conducting clinical trials





Sophisticated health and medical research and environment



Quality transferable data



Cost-efficient



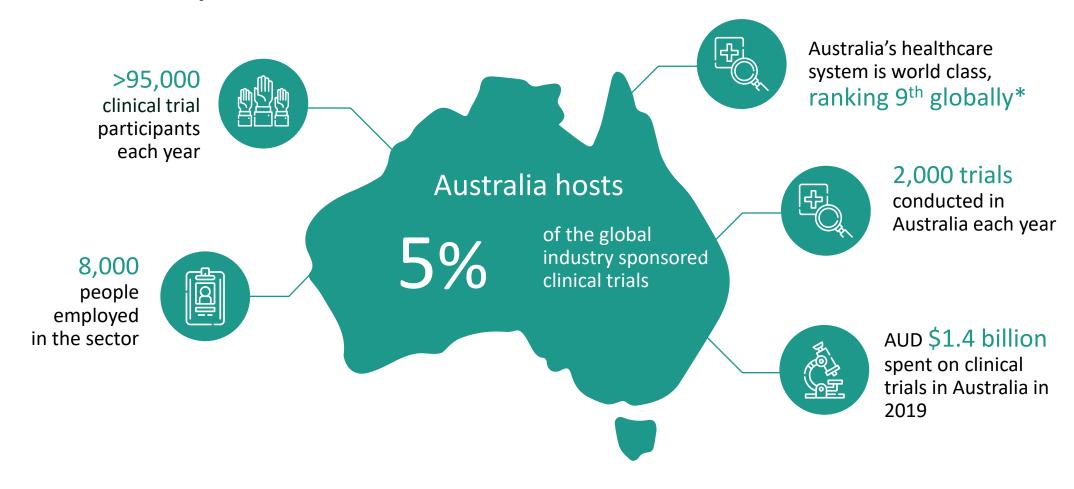
Rapid approvals and robust regulatory framework



An ethnically diverse patient population

Clinical trials

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





Whole-of-government support for clinical trials



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

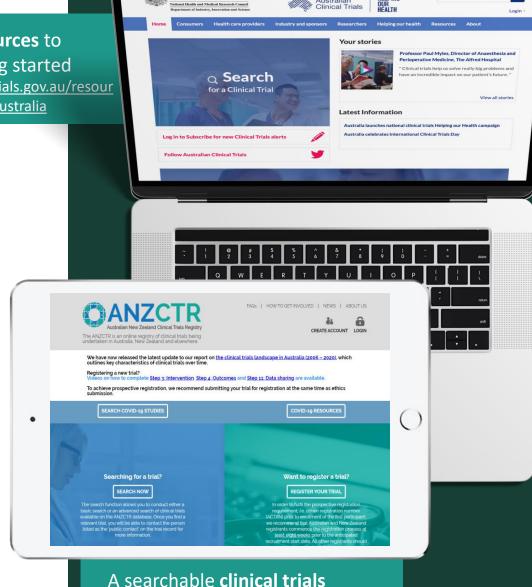
Whole-of-government support for clinical trials

National resources to support getting started australianclinicaltrials.gov.au/resour ces-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 provides
- Support services



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)

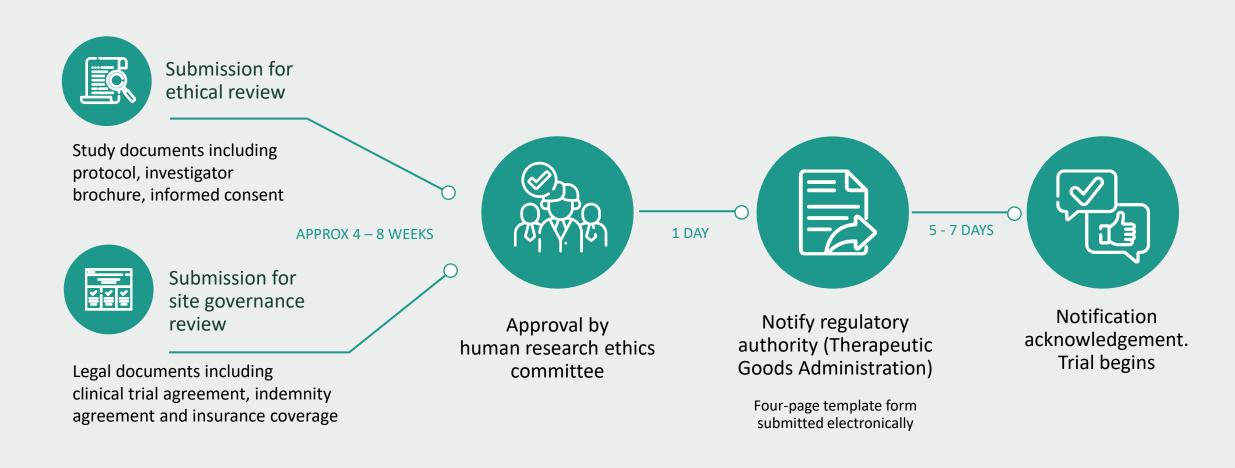


Clinical trials conducted in Australia do not require US FDA Investigational New Drug (IND) application approval



Speed

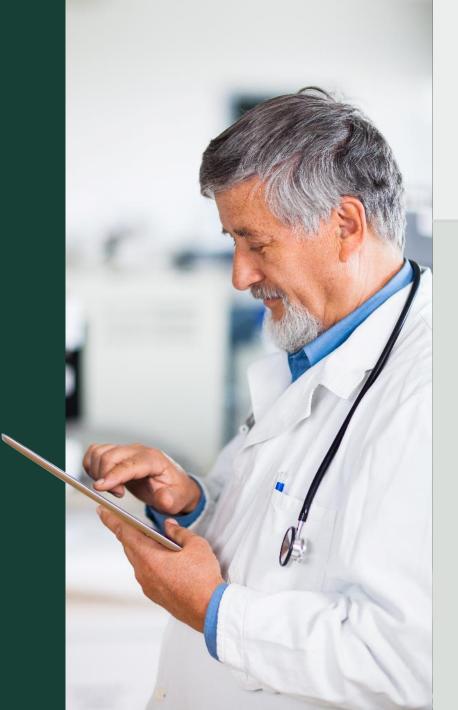
Streamlined clinical trials notification scheme





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

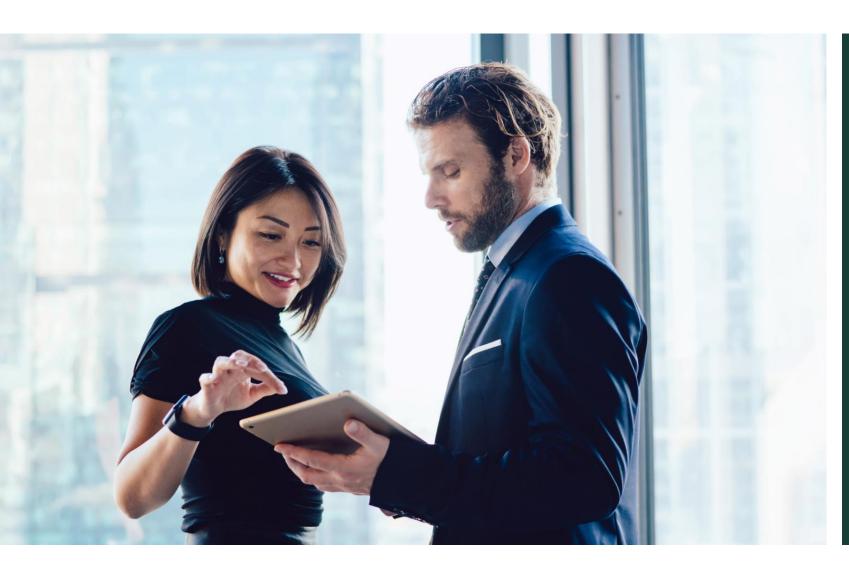


Companies with an annual aggregated turnover of more than A\$20 million receive a non-refundable tax offset and depends on intensity of the R&D expenditure as a proportion of total expenditure for the year.

- 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%.

Cost-effective



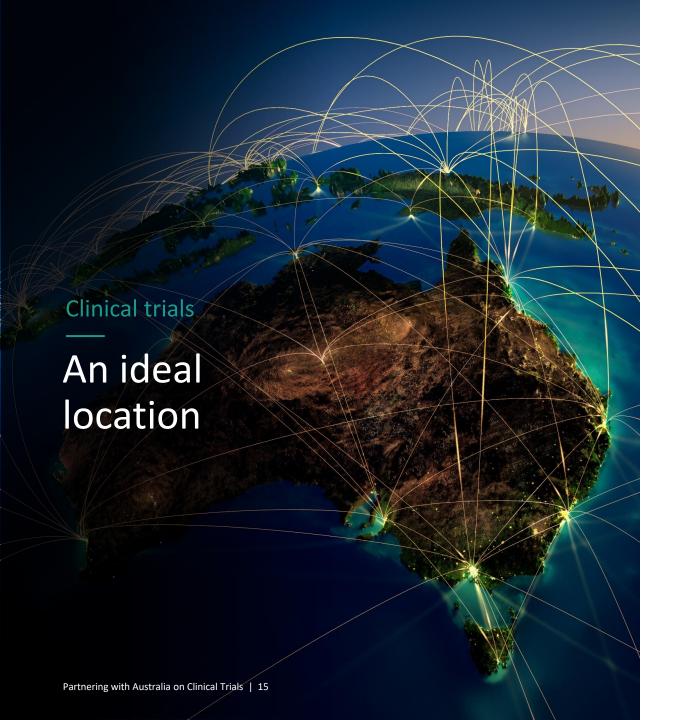
Reports show Australia is

28%

cheaper than the US before tax incentives, and

60%

cheaper after tax incentives, for early-phase clinical trials





Strong economic & cultural ties with Asia supported by Free Trade Agreements



Seasonal differences



Investigators, clinical networks and trial facilities of a global standing



Use of digital expertise and analytics in patient recruitment



Globally recognised key opinion leaders in major therapeutic areas



An ethnically diverse population



Contract manufacturing capabilities to support clinical trials

Find out more

AusBiotech

ausbiotech.org

Australian Clinical Trials

australianclinicaltrials.gov.au

Australian Clinical Trial Handbook

tga.gov.au/publication/australian-clinicaltrial-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

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

National Statement

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



Clinical Trials

Australia's
R&D response to COVID19 global pandemic



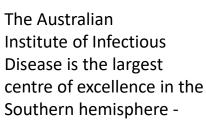
7 COVID vaccine candidates being trialed in Australia



200+ Covid-related research studies being conducted throughout Australia



Clinical trial activity resumed mid 2020, thanks to Australian governments and MTP sector COVID response



\$650 million project

Breakthrough and Innovation Funds by State and Federal governments





How Austrade can help



info@austrade.gov.au | austrade.gov.au



Australia and Expo 2025



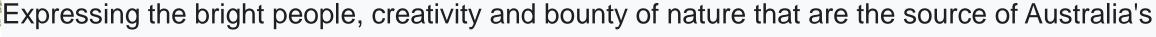
1988年のブリスベン万博 Brisbane Expo 1988





Partnering with Australia on Clinical Trials | 20









AUSTRALIA'S THEME

「Chasing the Sun — 太陽の大地へ」

オーストラリアのエネルギーの源である、明るい人びと、創造性、自然の恵みを表現。

Representing the optimistic people, creativity and boundless nature that are the source of Australia's energy



Visitor **Experience**

ユニークな没入型アドベンチャー

Unique visitor experience through Australian land, sky and sea country



