WHY AUSTRALIA FOR CLINICAL TRIALS
Australia is an ideal location for clinical trials

**Quality. Speed. Cost.**

Sophisticated medical research environment
Rapid approvals and robust regulatory framework
Quality transferable data
Cost-efficient
An ethnically diverse patient population
Clinical trials are part of a robust and diverse health ecosystem in Australia.

- Over 5 million enrolled participants between 2006–15
- More than 1,300 trials conducted in Australia each year
- 63% of trials with industry involvement
- 7,000 people employed in the sector
- >500,000 participants each year
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**
Medical Research Future Fund (MRFF) provides better access to research infrastructure, and supports translational research and commercialisation

**National Mutual Acceptance (NMA)**
a system for mutual acceptance of scientific and ethical review for multi-centre clinical trials conducted across multiple states
Whole-of-government support for clinical trials

The Australian Government is promoting clinical trials among consumers and healthcare providers, making it easy to get involved.

National consumer campaigns to promote participation in clinical trials

A searchable clinical trials registry accessible to the public
australianclinicaltrials.gov.au
Quality

01
A sophisticated medical research environment

1,230 medical technology and pharmaceutical companies

160 ASX-listed life sciences companies

>50 world-class medical research institutes

>40 universities focusing on clinical research

>50 clinical trial networks

>50 biobanks

110,000 people employed in research and MTP sector
Data from studies conducted in Australia can be used to support international regulatory applications, including the US FDA and European Medicines Evaluation Agency (EMEA) Clinical trials conducted in Australia do not require US FDA Investigational New Drug (IND) application approval
Speed

02
Rapid approvals and robust regulatory framework

Streamlined approval system, including the CTN and CTX schemes

- Clinical trial process allows flexibility without compromising quality
- Simplification of clinical trial delivery by removing tariffs on clinical trial kits and placebos
- Effective intellectual property (IP) protection
Streamlined clinical trials notification scheme

**Submission for ethical review**

Study documents including protocol, investigator brochure, informed consent

Approx 4 - 6 weeks

Approval by human research ethics committee

**Submission for site governance review**

Legal documents including clinical trial agreement, indemnity agreement and insurance coverage

1 day

Notify regulatory authority (Therapeutic Goods Administration)

Four-page template form submitted electronically

5-7 days

Notification acknowledgement. Trial begins.
Cost-effective
Australia is **28% cheaper** than the US before tax incentives, and **60% cheaper** after tax incentives, for early-phase clinical trials.
Companies with an annual aggregated turnover of less than A$20 million receive a 43% refundable tax credit, uncapped.

Companies with an annual aggregated turnover of more than A$20 million are eligible for a non-refundable tax credit on R&D expenditure. This is 30% plus an additional percent based on intensity of R&D.
An ideal location

- Strong economic & cultural ties with Asia supported by Free Trade Agreements
- An ethnically diverse population
- Centres of excellence in cellular therapy deployment
- Globally recognised key opinion leaders in major therapeutic areas
- Multi-lingual population
- Seasonal differences
Clinical trials started in Australia by phase, 2014 –18

2,348
industry–sponsored trials started in Australia in 2014-18

1,298
non-industry–sponsored trials started in Australia in 2014-18
Australian clinical trials by therapy area and sponsor type 2014-2018

- **Trial count**: 832
- **Industry**: 832
  - Oncology: 1113
  - CNS: 374
  - Infectious diseases: 665
  - Cardiovascular: 225
  - Metabolic disorders: 153
  - Government/Institution: 149
- **Government/Institution**: 340
  - Oncology: 281
  - CNS: 145
  - Infectious diseases: 145
  - Cardiovascular: 146
  - Metabolic disorders: 325

Partnering with Australia on Clinical Trials
Top industry sponsors for Australian clinical trials

- Novartis AG: 112 trials
- Merck & Co Inc: 98 trials
- AbbVie Inc: 97 trials
- F. Hoffman-La Roche Ltd: 97 trials
- Bristol-Myers Squibb Co: 87 trials
- Johnson & Johnson: 61 trials
- Gilead Sciences Inc: 58 trials
- GlaxoSmithKline Plc: 57 trials
- Pfizer Inc: 56 trials
- Amgen Inc: 54 trials

Trial Count
Find out more

AusBiotech
ausbiotech.org

Australian Clinical Trial Handbook

Australian Clinical Trials
australianclinicaltrials.gov.au

Medical Research Future Fund
beta.health.gov.au/initiatives-and-programs/medical-research-future-fund

MTPConnect
mtpconnect.org.au/

Medicines Australia
medicinesaustralia.com.au
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

For more information on Austrade’s services and how we can help your business email at info@Austrade.gov.au or visit www.Austrade.gov.au