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Leveraging Australia's Biopharma Benefits

To get therapeutics to market faster and more affordably

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Executive Summary

Kangaroos. Quokkas. Breathtaking beaches.
Australia's been known for a lot of things, but a world-class biopharma sector hasn't been one of them—until now.

That's changing: Australia is quickly becoming the fastest and most cost-efficient destination for biopharma R&D, clinical trials, and commercialization. With lucrative R&D tax incentives, a streamlined regulatory framework, and top quality manufacturing partners, it's no wonder that Australia has established itself as a hub for the global biopharma industry.

Enterprising biopharmas will find a lot to love in Australia. These include cost effectiveness, speed, strong IP environment, internationally recognized quality standards, compatibility with US and EU frameworks, and a strong biopharma services sector. Cost effectiveness is achieved through R&D incentives, a favorable currency exchange rate, and funding opportunities that greatly reduce the burden of drug development expenses and assist companies in commercialization. Speed is ensured by simplifying the clinical trial assessment procedure and eliminating the need for an Investigational New Drug (IND) filing. Research data from clinical trials conducted in Australia are also suitable for use in other regulatory approval processes [including with the United States Food & Drug Administration (FDA) and European Medicines Agency (EMA)].

As a premium provider of contract development and manufacturing organization (CDMO) services in Australia, BioCina is at the vanguard of a new wave of therapeutic process development and manufacturing services. Based in Adelaide, it's headquartered in the only FDA-approved manufacturing facility of its kind in the country. Find out what other drug developers have already discovered: when you're considering CDMOs for your next therapeutic development project, **try Australia. Try BioCina.**

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Cost-Efficient Drug Development in Australia

Biopharmas know that drug development expenses are one of the most significant contributors to the total cost of the therapeutic development and commercialization.

But what if we told you that you could perform R&D up to 60% more cost effectively than in the US?

Australia provides generous cost-saving R&D tax incentives and access to public and private funding opportunities for biopharmas that do business here. With cost efficient drug development activities (including clinical trials) in Australia, you could be saying *"No worries, mate!"* in no time.

1.1 Tax Incentives

R&D up to 60% Cheaper Than in the US

The Australian government offers R&D tax incentives that can significantly lower costs and reduce monetary burden for biopharmas that do business in-country. In fact, a recent report suggested that R&D in Australia is 28% cheaper than in the US before tax incentives; and 60% cheaper after tax incentives![*1]

The table below summarizes the R&D tax incentives available:

Table 1: R&D Tax Incentives Offered by the Australian Government for Biopharma Companies[2]

Company Size	Small to Medium Enterprise (SME)	Large	Large
Aggregated Annual Turnover	Below $20M AUD (~13.5M USD†)	Below $50M AUD (~$33.7M USD†)	Above $50M AUD (~$33.7M USD†
Australian Corporate Income Tax (CIT)	25%	25%	30%
Premium Rate (i.e., R&D Intensity‡ up to 2%)	18.5%	8.5%	8.5%
Premium Rate (i.e., R&D Intensity over 2%)	18.5%	16.5%	16.5%
R&D tax offset (i.e., CIT + Premium Rate)	43.5%	33.5% (0-2% R&D Intensity) 41.5% (>2% R&D Intensity)	38.5% (0-2% R&D Intensity) 46.5% (>2% R&D Intensity)
Refundable	Yes	No	No

* Based on outdated R&D incentives. The rates prior to 30 June 2021 were 43.5% (refundable) for eligible entities with an aggregated turnover of less than $20 million AUD annually; and 38.5% (non-refundable) for all other eligible entities[23].

† US dollar conversion based on current conversion rates as of Dec. 27, 2022.

‡ R&D Intensity: R&D expenditure as a percentage of total expenses.

Key Features:

- A minimum floor of $20,000 AUD applies to R&D tax expenditures. However, in the case of insufficient tax liability, unused credits can be carried forward indefinitely and are refundable for SMEs.
- A ceiling of $150 million AUD applies to qualifying R&D expenditures. For notional deductions above $150 million AUD, the R&D tax offset rate is the corporate tax rate. The R&D premium does not apply.
- Unlike other similar programs in other countries, there is no requirement for companies in Australia to demonstrate year-on-year growth in their R&D expenditure.
- There is no requirement for intellectual property from eligible R&D projects to be held in Australia.

To learn more about eligibility for R&D tax offsets in Australia, visit the **Australia Taxation Office's (ATO) Website**[§].

1.2 Access to R&D Funding Opportunities

The Australian government works with biopharma companies and private-sector fund managers to support health and medical research. These funding opportunities are offered to small and large companies at various points in their products' journeys from R&D to commercialization.

Biomedical Translation Fund (BTF)

The BTF is a privately managed fund that helps developers access investment in the development and commercialization of their biomedical discoveries. The fund is comprised of capital from the Australian government ($250 million AUD) and the private sector ($251.25 million AUD). A total of $501.25 million AUD is available for biomedical companies working on therapeutic, medical, or pharmaceutical discoveries. These can be a product, process, service, technology, or procedure[3].

To view available grants and initiatives, visit the the **BTF website**[**].

MedTech and Pharma Growth Centre (MTPConnect)

MTPConnect is a not-for-profit organization that aims to accelerate the growth of the medical technology, biotechnology, and pharmaceutical (MTP) sector in Australia. It forges stronger connections between research and industry by supporting scientific and technological breakthroughs, proof-of-concept development, and commercialization through funding programs, expertise and mentoring, and other strategic initiatives. MTPConnect funds projects that address sector growth priorities, constraints, and gaps[4].

To view available grants, initiatives, and MTP sector resources, visit the **MTPConnect website**[††].

https://www.ato.gov.au/business/research-and-development-tax-incentive/eligibility-for-r-d-tax-offsets/

[**] https://business.gov.au/grants-and-programs/biomedical-translation-fund

[††] https://www.mtpconnect.org.au

Medical Research Future Fund (MRFF)

The MRFF is a $20 billion AUD research fund set up by the Australian government to provide sustainable medium- and long-term funding to the health and medical research sector. The MRFF offers grants for various research areas and outcomes, including genomics, cardiovascular health, international clinical trials support, and more[5].

To view available grants and initiatives, visit the **MRFF webpage[#]**.

National Health and Medical Research Council (NHMRC)

The NHMRC is the Australian government's main funding body for medical research. It's the Australian equivalent to the National Institute of Health (NIH) in the US and the National Institute for Health Research (NIHR) in the UK. The council works independently to boost and improve Australia's medical research capabilities through funding, peer review of research applications, and the contribution to ethical research policy in Australia. The NHMRC offers grants for clinical trials and cohort studies that contribute to improvements in public health and healthcare practice or policy[6].

To view available grants and initiatives, visit the **NHMRC website[§§]**.

[#] https://www.health.gov.au/our-work/medical-research-future-fund

[§§] https://www.nhmrc.gov.au/

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Faster Clinical Trials in Australia

Start Patient Testing for Phase I Studies in as Little as Four Weeks

A Phase I study conducted in Australia can begin in as little as four weeks. The entire Phase I trial timeline can be accelerated by as much as six to nine months, compared to a similar trial program based in the US.

You might be asking, "How is this possible?" It all starts with how Australia structures its regulatory pathways and clinical trial timeline.

Australia's Therapeutic Goods Administration (TGA) is the government authority responsible for evaluating, assessing, and monitoring products that are defined as "therapeutic goods." It is analogous to the US FDA.

In contrast to the FDA, the TGA provides a more efficient regulatory pathway through early clinical trials. The TGA streamlines the clinical trial timeline by allowing ethics committees to assess clinical trials—as opposed to assessments conducted by congested regulatory bodies—and standardize R&D costs.

Perhaps most attractive: the TGA, and therefore Australia, does not require Investigational New Drug (IND) filings prior to Phase I trials.

What's more the data output from Australian studies meets global standards and can be used to support international regulatory applications, including the FDA°.

2.1 Trials Assessed by Ethics Committees

(Not Congested Regulatory Bodies)

The TGA provides a pathway to streamline clinical trials: the Clinical Trials Notification (CTN) Scheme. The CTN is a "notification-only" process that requires the completion of an online notification form and payment of a fee prior to the use of an "unapproved" therapeutic good in a clinical trial situation.

Under the CTN framework, an ethics committee [i.e., a public or private registered Human Research Ethics Committee (HREC)] reviews:

- The scientific validity of the trial's design
- Risk versus harm
- Ethical acceptability of the trial

After the review, the HREC will approve or deny the conduct of the trials[7,8].

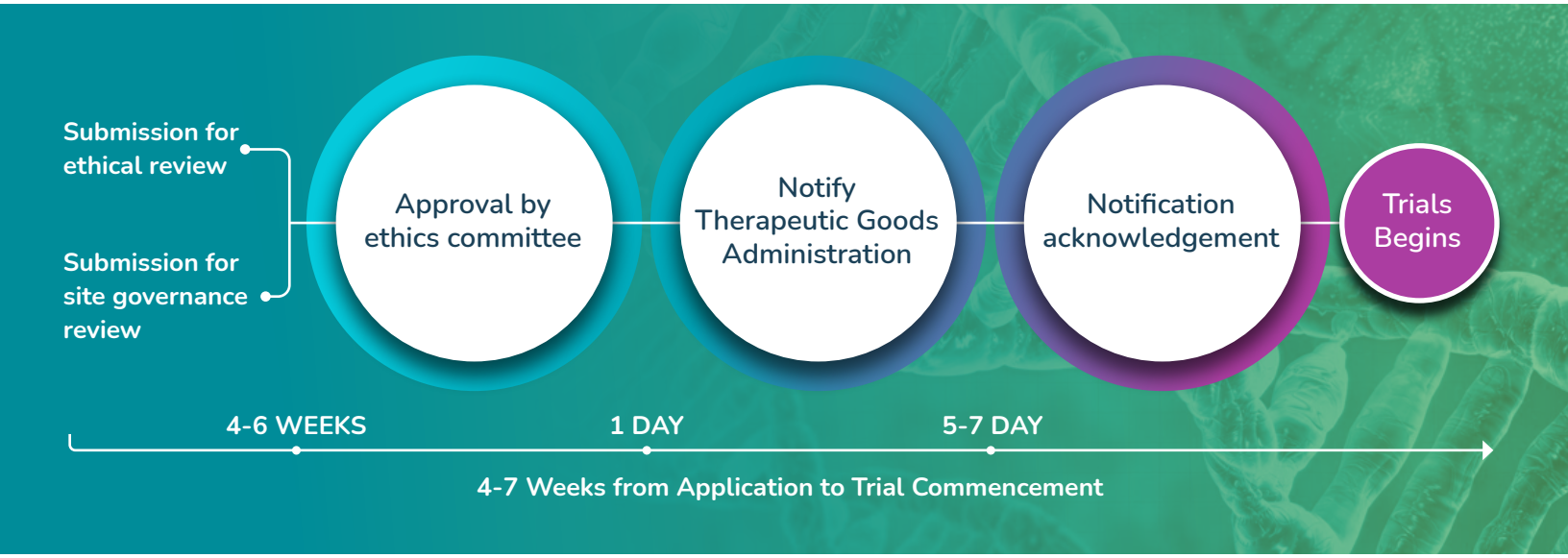
The CTN Scheme eliminates the duplication of processes and enables sponsors conducting clinical trials in Australia to save both time and money. The review process can be carried out in parallel with site governance processes, which further contributes to the shortening of trial approval timelines.

The TGA does not evaluate any data related to the clinical trial at submission. The TGA only needs to be notified of the intent to carry out a clinical trial with an "unapproved" therapeutic good.

Final approval for the trial's conduct is given by the "approving authority" (i.e., the institution or organization where the trial will be conducted) based on the advice of the HREC. The TGA does have the authority to audit and inquire into the management of a clinical trial.

It only takes an average of 4–7 weeks to reach clinical trial commencement from ethics and site governance review submissions[9].

Figure 1: Approximate Timeline for Approval of a Clinical Trial in Australia[9]



2.2 Accelerate Clinical Trials by a Month

No Investigational New Drug (IND) Requirement Contract Negotiations

In the US, the FDA allows clinical trials to commence 30 days after the submission of an Investigational New Drug (IND) application[10]. Clinical trials conducted in Australia, however, do not require an IND application approval and thus, save biopharma companies an entire month of waiting.

2.3 Standardized Costs Streamline Contract Negotiations

The Australian government has developed a standard table associated with costs to help companies reliably predict the expense of conducting clinical trials in Australia[11]. This allows companies abroad and incountry to easily assess potential costs and aid in internal decision-making processes. The standardized list also significantly reduces the time necessary to negotiate contracts with individual sites.

To see the list of standard costs, view this PDF report***.

*** https://www.ihacpa.gov.au/sites/default/files/2022-02/Determination of standard costs associated with clinical trials in Australia.pdf

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Australia Provides Compatible Quality and Regulatory Requirements

Data collected from R&D activities (including clinical trials) in Australia are compatible and acceptable for use in FDA and EMA applications[9].

In fact, the TGA closely aligns its regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible15. The technical data requirements for medicine applications in Australia are closely aligned with requirements set out in guidelines by international partner authorities, including the EU, FDA, and ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

TGA and FDA Collaboration and Shared GMP Compliance

The FDA and TGA have a cooperative agreement regarding the exchange of information on GMP inspections of human pharmaceutical facilities[16].

TGA and EMA Collaboration and Shared GMP Compliance

The EMA and TGA have a cooperative agreement regarding the exchange of information for regulatory and scientific processes. Additionally, the EU and Australia also have a mutual recognition agreement (MRA) in place on good manufacturing practice (GMP) compliance[19].

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Strong IP Protection

5 YEARS

Protection with data exclusivity for new pharmaceutical vaccines or medical products

20+ YEARS

Protection for active ingredients, new formulations, isolated forms of (therapeutically useful) natural products, and new methods of treatment.

Australia's intellectual property (IP) system is one of the strongest and most secure in the world. In fact, Australia's IP system is currently ranked as the 11th most secure in the world (out of 129 countries), putting it just ahead of the US, UK, Canada, and Germany[12].

Australia's IP system supports the biopharma industry in the following ways:

- Broadly defined patentable subject matter
- Five-year patent term extensions
- Five-year data exclusivity for new pharmaceuticals

Broadly Defined Patentable Subject Matter

A wide range of medical inventions are covered in Australia, including new active ingredients, novel formulations, isolated forms of therapeutically useful natural products, and new methods of treatments[13].

Five-Year Patent Term Extensions

In accordance with Article 33 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, Australia grants (standard) patent owners 20 years of protection.

Australia also grants patent owners of pharmaceutical substances the right to seek patent term restoration (i.e., an "extension of term")[14]. Such patent owners have the right to apply for up to five years of patent term extension as compensation for the process of obtaining regulatory approval. This allows patent owners to achieve an effective patent life of up to 15 years from the date of first entry of a new pharmaceutical substance on the Australian Register of Therapeutic Goods (ARTG)*.

Five-Year Data Exclusivity for Pharmaceuticals

Australia provides five years of data exclusivity to new pharmaceutical products. This prevents competitors from relying on proprietary safety and efficacy data for five years. This period begins from the date of the new medicine or vaccine's first inclusion on the ARTG[13]

*https://www.tga.gov.au/resources/artg

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A Top-Ranked Biopharma Sector

Australia has one of the strongest health and medical sectors in the world.

Consistent economic growth and strong government commitment to the sector has resulted in Australia becoming a premier location for biopharma R&D and commercialization activities. Since 2019, the number of biotech companies conducting R&D in Australia has grown by 40%. With new incentives and investments, from the Australian government and its private sector partners, this number is expected to increase over the next few years.

Australia has a sophisticated, world-leading health and medical research environment. With strong government support and tax incentives, the biopharma industry continues to grow.

AUSTRALIA: A History of Biopharma Development

Australia has been involved with biopharma development for decades. In fact, Australian pharmacologist Howard Florey played an enormous part in the development of penicillin, which marked the start of modern antibiotics. He shared the Nobel Prize in Physiology or Medicine in 1945 with Ernst Chain and Alexander Fleming.

A bronze bust of Lord Howard Florey by South Australian sculptor John Dowie is located in Adelaide, Australia.

Here are some facts about the state of medical and health research and commercialization in Australia[9]:

- As of 2020, 1,278 medical technology and biopharma companies operate in Australia.
- More than 68,000 people are employed in the Australian health and medical research sector.
- Over 160 MTP member companies are listed on the Australian Stock Exchange (ASX).
- Australia is home to 55 world-class medical research institutes and 40 universities that focus on clinical research.
- There are more than 50 clinical trial networks and 58 registered biobanks[†††].
- In an average year, global biopharmas will conduct more than 1,000 clinical trials in Australia.
- Australia boasts top-ranked manufacturing companies for biopharma products, including BioCina, a world-class

CDMO with the only microbial drug substance facility of its kind in Australia to be inspected by the US FDA.

National Mutual Acceptance (NMA) Across Multiple States

The National Mutual Acceptance (NMA) Scheme enables mutual acceptance of scientific and ethical reviews for multicenter clinical trials[21]. Five of the eight Australian states and territories (comprising about 90% of the clinical trial activity in Australia) currently participate in the system. The NMA Scheme currently operates in Queensland, New South Wales, Victoria, South Australia, Western Australia, and the Australian Capital Territory.

Nationally Accredited Education and Training Courses

The Australian government offers nationally accredited education and training courses for investigators and site personnel who prepare and oversee clinical trial applications[13]. This initiative builds and enhances the skills of frontline clinical trial professionals in Australia. It enables them to be more efficient and develop a nationally consistent approach to research governance.

*** https://www.ihacpa.gov.au/sites/default/files/2022-02/Determination of standard costs associated with clinical trials in Australia.pdf

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BioCina: The Trusted CDMO Partner of Global Biopharmas

Your best path to successful therapeutic process development and manufacturing is a solid partnership with a CDMO. BioCina provides high quality, cost effective microbial process development and manufacturing solutions to biopharmas worldwide. We've supported successful product approvals from the EMA, Health Canada, and more, and we're well versed in the benefits that Australia provides to biopharma organizations.

FDA-Approved Facility

BioCina owns and operates the only microbial drug substance facility of its kind in Australia to be approved by the US FDA for commercial supply to the US market. The facility was previously owned by Pfizer and exceeds all compliance and regulatory standards for GMP certification.

Speed

BioCina ensures that you can capitalize on the fast and lucrative benefits of conducting drug development and commercialization in Australia. BioCina's project management team is experienced with clinical trial requirements and understands that time is always of the essence in pharmaceutical development. Our deep knowledge and experience of managing products through the development lifecycle of pre-clinical, clinical, and commercial launch ensures that we understand the broad range of studies required and the appropriate timing for these studies.

Flexibility

Sometimes an approach needs to be changed-that's the nature of drug development. BioCina is a flexible and tenacious partner that works with you to formulate the right solution when you need it. Our approach is to develop manufacturing processes that can be scaled up to clinical and commercial levels without compromising on product quality or your timelines. We solve complex challenges and continuously improve our approach and solutions.

Collaboration

Not sure about a design or a component?
BioCina works with you to find the right solution. We bring strong project management and open communication to deliver project success.

Quality and Regulatory Compliance

It's nice to see familiar faces "Down Under." Quality and regulatory compliance should be no different! Our operations are carried out to the highest cGMP standards to ensure we meet the requirements of the most highly regulated markets globally. Work with BioCina for the quality systems and compliance you know and expect.

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Try Australia. Try BioCina.

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For more information about biocina and the benefits of working in Australia, contact us today.

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