Insight Brief

Clinical Development of Cell and Gene Therapy (CAGT) Products in Australia

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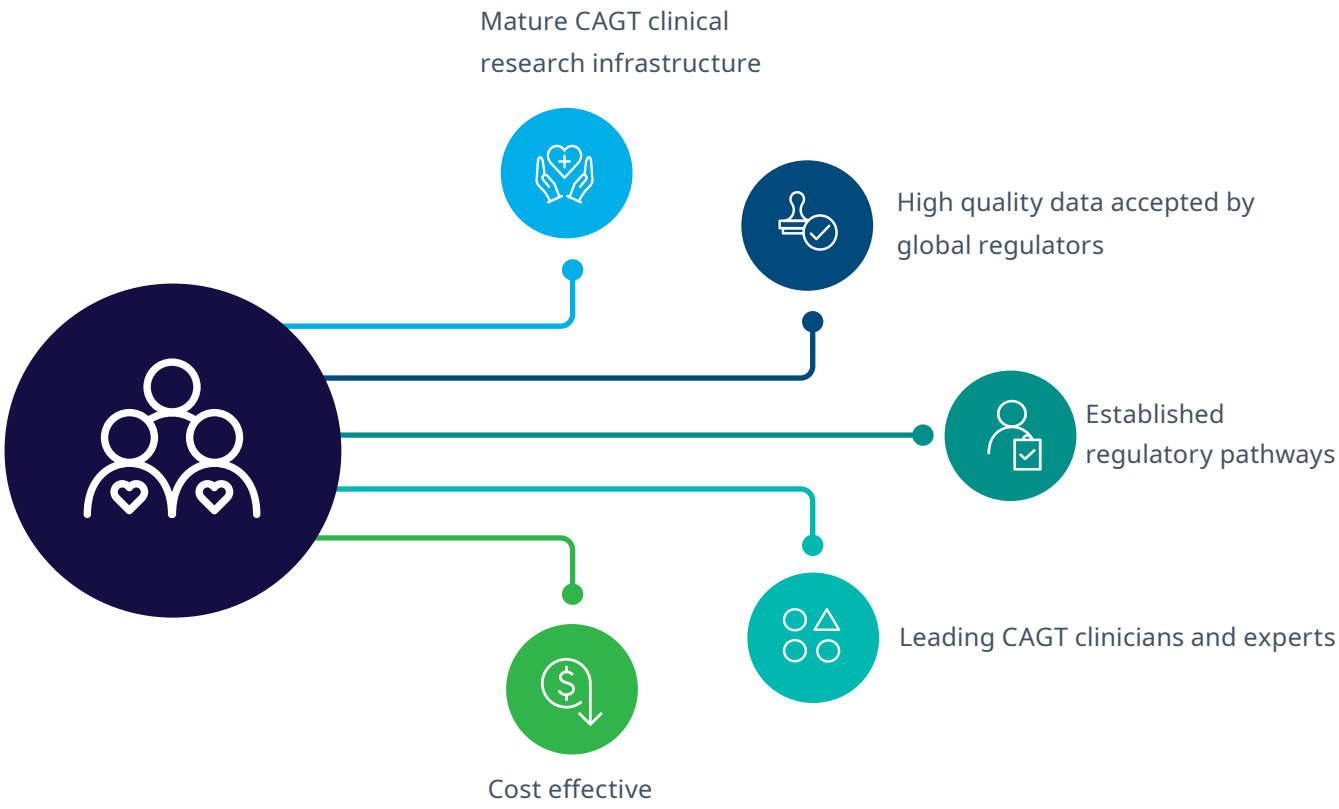
Why Australia for CAGT trials?



Australia, with its established regulatory framework and expertise, sets a "gold standard" for running CAGT trials

Speed of delivery with **simple regulatory** framework

Rapid start up, fast approvals

- CTN scheme (No IND application required) for eligible trials
- Minimal documents required: IB/Protocol/PICF

Cost effective

- Meaningfully less expensive than conducting trials in U.S.
- R&D tax incentive: Up to **43.5%** tax refund
- Favorable AUD exchange rate
- **30-40%** less expensive investigator grants compared to U.S.

Access to advisory board and contracted IBC

Local excellence, global strategy

Quality

Quality data generated in Australia is acceptable to international regulatory agencies to support applications, including U.S. FDA and EMA

World leading investigators and KOLs

CTN: Clinical Trial Notification, IND: Investigational New Drug, IB: Investigator Brochure, PICF: Participant Information and Consent Form, IBC: Institutional Biosafety Committee, FDA: Food and Drug Administration, EMA: European Medicines Agency, KOL: Key Opinion Leader

Mature R&D ecosystem

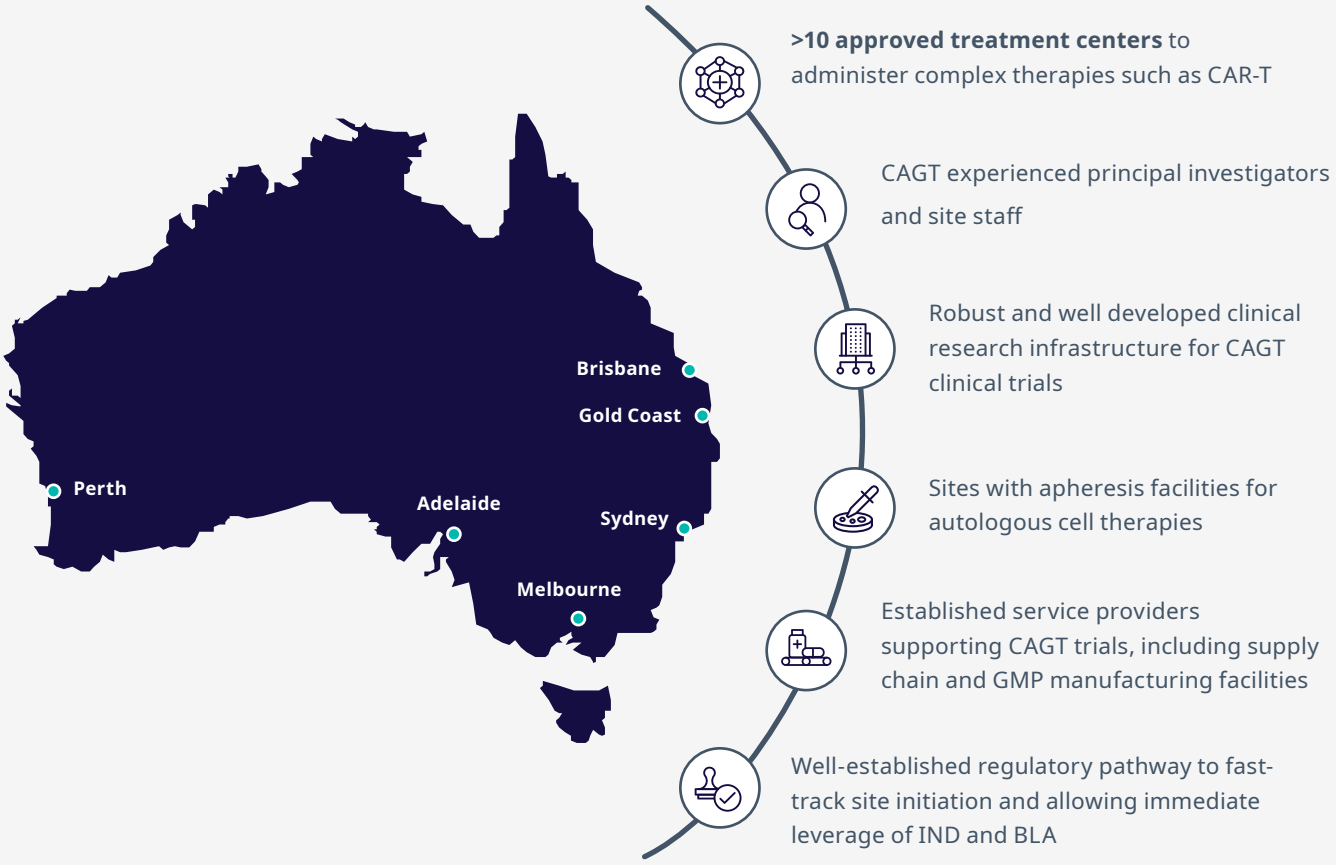
The landscape

Over **160** ongoing industry CAGT trials in Australia

Top CAGT indications

- Oncology (non Hodgkins lymphoma, solid tumour, melanoma)
- Autoimmune diseases
- Cardiovascular

Australia healthcare system



GMP: Good Manufacturing Practice, BLA: Biologics License Application

CDMO partners

Australia is home to several established and capable Contract Development and Manufacturing Organization (CDMO) offering end-to-end support for drug development and manufacturing, including advanced therapies.

Established and favorable regulatory pathway in Australia

1 Australia has established regulatory pathways for CAGT clinical trials. Most of these trials benefit from a fast regulatory start-up process, particularly when classified under prescription medicine. Common submission routes include:

- Simple CTN (Clinical Trial Notification)
- Investigator's Brochure (IB)
- Protocol-only submissions

	EX-VIVO PRODUCTS	IN-VIVO PRODUCTS
Regulatory pathway	Class 4 biologics	Prescription medicine
Guidelines	Australian Regulatory Guidelines for Biologicals (ARGB)	Australian Regulatory Guidelines for Prescription Medicines (ARGPM)

Timeline: ~7 — 10 days

Clinical Trial Notification (CTN)

- A notification scheme is used for clinical trial submissions
- TGA does not evaluate clinical trial data submitted under this scheme
- Instead, the data is reviewed and approved by the Human Research Ethics Committee (HREC) before submission to the TGA

Timeline: ~6 months

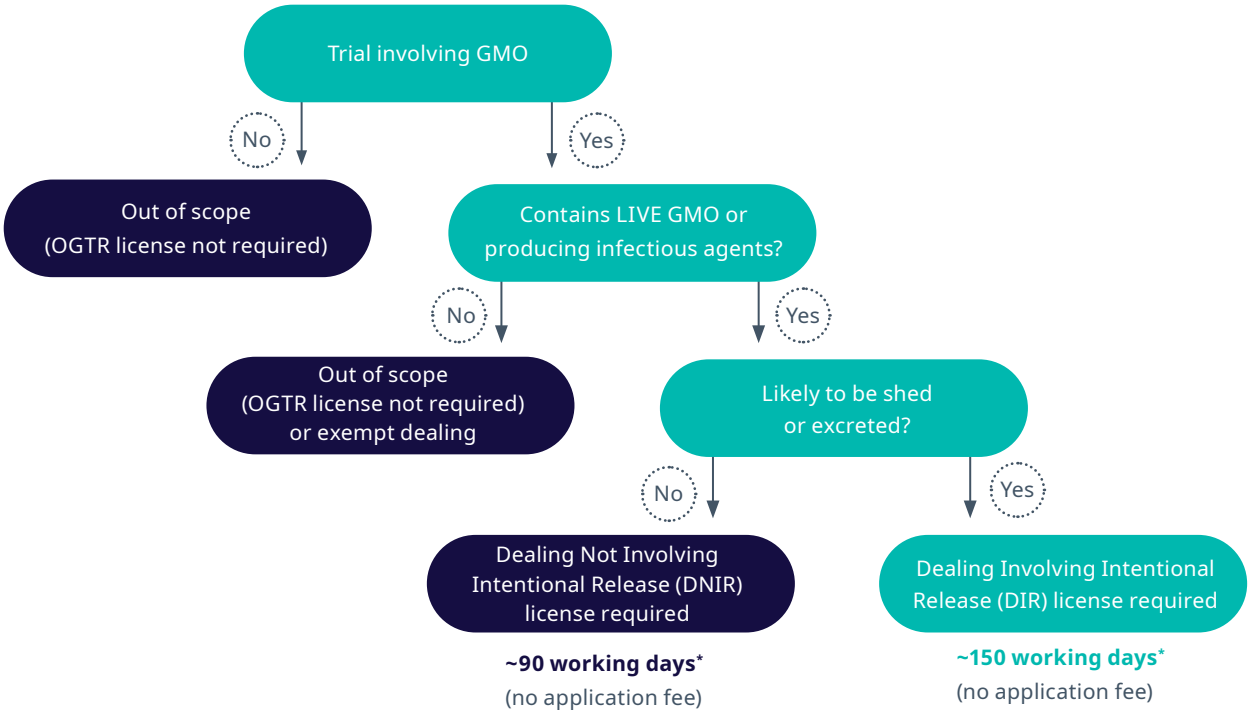
Clinical Trial Approval (CTA)

- Involves an evaluation process before a clinical trial begins
- Reviews relevant but limited to scientific data. This may include pre-clinical and early clinical data
- TGA's focus is on product safety
- HREC's responsibility:
  - » Reviewing scientific and ethical aspects of the proposed trial protocol
  - » Approving the conduct of the clinical trial

2 Any biological or prescription medicine involving GMOs may require the review of Institutional Biosafety Committee (IBC) and licence from the Office of the Gene Technology Regulator (OGTR). IQVIA is well-equipped to support this process, leveraging its extensive experience to ensure full compliance and smooth trial initiation.

2 types of OGTR licence:

- Dealings involving intentional release (DIR) into the environment;
- Dealings not involving intentional release (DNIR)



KEY INFORMATION TO BE INCLUDED IN APPLICATION FOR GMO LICENSE:

1. Description of proposed activities involving GMO
2. Description of proposed facilities
3. Compliance to relevant standards and guidelines
4. Endorsement by IBC (Institutional Biosafety Committee)

*GMO license application can be submitted to OGTR at the same time as submission to HREC and if TGA (if CTA is required).

License holder require to be accredited under the Gene Technology (GT) act.

IQVIA, the leading CRO in Australia

Supporting CAGT products from pre-clinical to post marketing

CAGT focused team

- CAGT Center of Excellence offering medical and scientific expertise to support clinical trials in Australia
- CAGT Study Management Team (SMT) specializing in the operationalization of CAGT trials in Australia
- IQVIA AdBoard providing timely feedback on protocols to strengthen trial readiness

Site network

- Australian sites supporting smarter trial planning
- **2 prime sites** and **14 partner sites** delivering reliable performance across recruitment, retention, speed, and quality. A dedicated site relationship manager providing close support to ensure quick issue resolution and smoother collaboration
- Vendor network accredited for complex logistics including depot and transportation chain for CAR-T storage and transport in Australia

Global reach, local impact

- IQVIA's local footprint with global capabilities allow sponsors to seamlessly integrate new countries as part of a Multi-Regional Development Plan for CAGT investigational products

Local presence

- Largest CRO in Australia and New Zealand with over 1100 employees
- Low turnaround of staff bringing stability to your trials

Market access and policy shaping

- IQVIA's consulting team to navigate Australia's complex market access and policy environment
- End-to-end strategy for CAGT: Commercialization, policy shaping, stakeholder engagement, and Health Technology Assessment (HTA) expertise

IQVIA global footprint

Top CAGT therapeutic areas

Therapy type

KEY MODALITIES:

1. Gene-modified cell therapies (CAR-T, CAR-NK, TCR-T, CAR-M, HSC and other)
2. Non-gene modified cell therapies (Mesenchymal stem cell therapies)
3. RNA therapeutics (siRNA, ASO, mRNA)

CVRM: Cardiovascular, Renal & Metabolic, Tx: Therapy

IQVIA has participated in the clinical development of 17 approved CAGT products (20%)

Gene therapies	Cell therapies and tissue engineering	RNA therapeutics
7/30 (23%) including in-vivo and ex-vivo	**5/37 (14%)**	**5/19 (26%)** including two full programs

Ready to expand your trial to Australia?

Navigating the complexity of clinical trials and market access in Australia demands deep local knowledge and regulatory expertise. IQVIA combines broad CAGT expertise, robust site networks and innovative technologies to help drive your trials with precision and confidence.

Contact IQVIA today: bryce.davies2@iqvia.com

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