Australia has a strong and active regenerative medicine eco-system with internationally recognised basic and translational research, clinical trials framework and clinical centres. Over 15 cellular therapy companies focused on product development and infrastructure support. More than 25 ongoing clinical trials in the research area.

**Australian Clinical Trials Eco-System Allows for Rapid Recruitment of Patients**

Streamlined Clinical Development Pathway

- No local study requirement for BLA and Good Manufacturing Practice (GMP) manufacturing licenses, which include collection.
- BLA or Advanced Therapy Medicinal Product (ATMP) data is usually sufficient for TGA filing, allowing for potential parallel filings as well as circumventing the requirement for local patients.
- There is also mutual recognition of GMP with the EU.
- If patient recruitment is required, Australia has historically demonstrated rapid recruitment in cellular therapies.
- Low risk, single-language and stable test market for global deployment modeling.
- Large enough market locally to test deployment at scale yet small enough to enable real time fine-tuning without compromising patient safety or therapy.
- Bolstered by established, experienced clinical centres with needle-to-needle supply chain support.

**Regenerative Medicine Milestones**

- **1986** 2nd ever peripheral blood apheresis and stem cell transplant
- **1987** First unrelated cord blood transplant
- **1992** Demonstration of value of G-CSF in stem cell mobilisation
- **1996** Establishment of the Australian Stem Cell Centre
- **1998** First human embryonic stem cell line created involving Australians
- **2002** Introduction of Commonwealth legislation to enable use of human embryos in research; establishment of New South Wales (NSW) Stem Cell Network
- **2003** Peter MacCallum Cancer Centre commence CAR-T clinical trials
- **2004** First Australian human embryonic cell line
- **2005** Australian scientists generate Australia’s first human induced pluripotent stem cell (iPSC) lines (following 2007 discovery from Japan); establishment of the Australian Regenerative Medicine Institute (ARMI)
- **2006** World’s first clinical trial of an allogeneic iPSC-derived cell therapy product undertaken by an Australian company; first commercial CAR-T trial patient treated outside North America
- **2006** First iPSC clinical trials undertaken in Australia; first commercial CAR-T trial
- **2007** World’s first clinical trial of an allogeneic iPSC-derived cell therapy product undertaken by an Australian company; world-first surgery implanting 3-D printed shinbone in Australia
- **2008** Establishment of Stem Cells Australia
- **2014** 2008 Common wealth legislation to enable use of human embryos in research; establishment of NSW Stem Cell Network
- **2015** First Australian human embryonic cell line
- **2016** Peter MacCallum Cancer Centre commence CAR-T clinical trials
- **2017** World’s first clinical trial of an allogeneic iPSC-derived cell therapy product undertaken by an Australian company; world-first surgery implanting 3-D printed shinbone in Australia

**Cells and Stem Cells**

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Universities and institutions-based researchers are funded by the Australian Government agencies such as the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC). Ethical oversight of medical research involving human subjects and materials is overseen by more than 200 Human Research Ethics Committees (HRECs) with expected standards set-out in the National Statement on Ethical Conduct in Human Research and the Human Research Ethics Committees (NHMRC) Code of Practice.

The Australian regenerative medicine sector spans the whole field from tissue engineering through to stem cell therapy to gene and immuno-therapies. There are multiple GMP manufacturing facilities spread across multiple cities in Australia that can support the development of these technologies.

Therapeutics for patients usually require large numbers of cells. These cells are usually sourced from bone marrow or adipose tissue and often require transformation to become the desired type of cell. In Australia, various companies and research institutions are working on converting induced pluripotent stem cells (iPSCs) into cells that can be widely used in clinics.

Companies such as CellThera, which is a joint venture between Murdoch Childrens Research Institute and The Florey Institute of Neuroscience and Mental Health with Eliza Hall Institute, the Victor Chang Research Institute, and Industrial Research Organisation (CSIRO), the Walter and Eliza Hall Institute, and Flinders University will ensure that the right cells can be used for regenerative medicine.

The ARMC was established through a $153 million joint venture between Monash University and the Victorian Government. ARM is working on developing cGMP validated bioprocess technologies that can be transferred to industry. The Biomedical Translation Fund, the Medical Research Future Fund, and the Future Industries/ Sector Growth Program are funded by the Australian Government.

In September 2017, Australian surgeons performed a world-first surgery to implant a titanium-printed heel bone, printed using CSIRO’s Arcam 3-D printer, into a patient.

This demonstrates the transition of a 3-D printing technology to a medical application. Other technologies such as 3-D printing and organ printing are already in use, such as in the field of tissue engineering.

PolyNovo Biomaterials produces and sells NovoSorb, a US Food and Drug Administration (FDA)-approved temporary lattice inserted ahead of eventual skin grafts for patients with skin burns. Originally developed by CSIRO and the lattice works to encourage the regrowth of normal skin cells.

The Clinical Trials and Regenerative Medicine Ecosystem in Australia enables local companies or international company subsidiaries to obtain significant and important first-in-human data quickly and easily.

In addition to time zone and cultural advantages, strong and long trade and investment relationships have been fostered with countries in Asia. Regenerative Medicine-specific country-level agreements exist between Australia and Japan as well as Korea.

The research and development (R&D) tax incentive, which allows for a 38.5 - 43.5% tax refund or offset.