AUSTRALIAN CLINICAL TRIALS ECO-SYSTEM ALLOWS FOR RAPID RECRUITMENT OF PATIENTS

The regulatory pathways in Australia allow for immediate leverage of Investigational New Drug (IND)/Biologics License Application (BLA) to accelerate a global roll-out.

- This is supported by the presence of a Biologics framework (2011)
- The Therapeutic Goods Administration (TGA) administers pathways such as the Rapid (14 days) Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes providing timelines through which ‘unapproved therapeutic goods’ may be lawfully supplied for solely experimental purposes in humans.
- The application for CTN or CTX depends on the sponsor as well as the outcome of reviews by the Human Research Ethics Committee (HREC).
- The CTN process allows for products with US IND or EU Common Technical Document (CTD) approval to bypass further regulatory assessment in Australia.

- 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 modelling.
- 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.

OVER 30 CELLULAR THERAPY OR REGENERATIVE MEDICINE COMPANIES with a market capitalisation of over $3 BILLION

MORE THAN 30 ONGOING CLINICAL TRIALS in the research area.

More than 45 RESEARCH CENTRES across Australia

Several focussed only on stem cell and regenerative medicine.

AUSTRALIAN CLINICAL TRIALS ECO-SYSTEM ALLOWS FOR RAPID RECRUITMENT OF PATIENTS

The regulatory pathways in Australia allow for immediate leverage of Investigational New Drug (IND)/Biologics License Application (BLA) to accelerate a global roll-out.

- This is supported by the presence of a Biologics framework (2011)
- The Therapeutic Goods Administration (TGA) administers pathways such as the Rapid (14 days) Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes providing timelines through which ‘unapproved therapeutic goods’ may be lawfully supplied for solely experimental purposes in humans.
- The application for CTN or CTX depends on the sponsor as well as the outcome of reviews by the Human Research Ethics Committee (HREC).
- The CTN process allows for products with US IND or EU Common Technical Document (CTD) approval to bypass further regulatory assessment in Australia.

- 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 modelling.
- 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.

AUSTRALIAN CLINICAL TRIALS ECO-SYSTEM ALLOWS FOR RAPID RECRUITMENT OF PATIENTS

The regulatory pathways in Australia allow for immediate leverage of Investigational New Drug (IND)/Biologics License Application (BLA) to accelerate a global roll-out.

- This is supported by the presence of a Biologics framework (2011)
- The Therapeutic Goods Administration (TGA) administers pathways such as the Rapid (14 days) Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes providing timelines through which ‘unapproved therapeutic goods’ may be lawfully supplied for solely experimental purposes in humans.
- The application for CTN or CTX depends on the sponsor as well as the outcome of reviews by the Human Research Ethics Committee (HREC).
- The CTN process allows for products with US IND or EU Common Technical Document (CTD) approval to bypass further regulatory assessment in Australia.

- 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 modelling.
- 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.
Thriving Regenerative Medicine Industry Sector

The Australian regenerative medicine sector spans the whole field from tissue engineering through to stem cell therapy to gene and immuno-therapies.

- Cynda Therapeutics and Filliphs (Japan) have announced a license agreement (valued at $43 million) by which Filliphs has the exclusive, royalty-free, right to commercialise and market Cynda lead candidate, CYT-001, for the treatment of graft-versus-host disease (cGVHD).
- Perth-based regenerative medicine company, Orthosolv, has announced successful full results from the use of their CellGraft membrane, used as a scaffold for the regeneration of tendons in shoulder rotator cuff injuries. Following successful approval in Europe (EAC mark), Orthosolv is seeking approval for CellGraft from the TGA and the FDA.
- The Murdoch Children's Research Institute announced a collaboration with Organovo, a US-based company pioneering the development of 3D printed tissues. Using the Organovo proprietary approach for modelling human osteoarthritic joints that have widespread cartilage loss.
- Following successful registration with the FDA and TGA, NovoSorb has also entered the market with severe burns. Following successful registration with the FDA and TGA, Polynovo Biomaterials has announced successful trial results from the use of their temporary lattice inserted ahead of skin grafts for patients of tendons in shoulder rotator cuff injuries. Following successful registration with the FDA and TGA, Orthocell has announced successful trial results from the use of their Orthocell Acell scaffold for the treatment of graft-versus-host disease (cGVHD).
- The Peter MacCallum Cancer Centre in Victoria announced seeking approval for CelGro from the TGA and the FDA. Cynata's lead candidate, CYP-001, for the treatment of graft-versus-host disease (cGVHD) has announced successful trial results from the use of their CypaResin scaffold for the treatment of graft-versus-host disease (cGVHD).

The Australian regenerative medicine sector spans the whole field from tissue engineering through to stem cell therapy to gene and immuno-therapies.

- Cynda Therapeutics and Filliphs (Japan) have announced a license agreement (valued at $43 million) by which Filliphs has the exclusive, royalty-free, right to commercialise and market Cynda lead candidate, CYT-001, for the treatment of graft-versus-host disease (cGVHD).
- Perth-based regenerative medicine company, Orthosolv, has announced successful full results from the use of their CellGraft membrane, used as a scaffold for the regeneration of tendons in shoulder rotator cuff injuries. Following successful approval in Europe (EAC mark), Orthosolv is seeking approval for CellGraft from the TGA and the FDA.
- The Murdoch Children's Research Institute announced a collaboration with Organovo, a US-based company pioneering the development of 3D printed tissues. Using the Organovo proprietary approach for modelling human osteoarthritic joints that have widespread cartilage loss.
- Following successful registration with the FDA and TGA, NovoSorb has also entered the market with severe burns. Following successful registration with the FDA and TGA, Polynovo Biomaterials has announced successful trial results from the use of their temporary lattice inserted ahead of skin grafts for patients of tendons in shoulder rotator cuff injuries. Following successful registration with the FDA and TGA, Orthocell has announced successful trial results from the use of their Orthocell Acell scaffold for the treatment of graft-versus-host disease (cGVHD).
- The Peter MacCallum Cancer Centre in Victoria announced seeking approval for CelGro from the TGA and the FDA. Cynata's lead candidate, CYP-001, for the treatment of graft-versus-host disease (cGVHD) has announced successful trial results from the use of their CypaResin scaffold for the treatment of graft-versus-host disease (cGVHD).

2019 CCRM and BiCortice sign MOU

The signing of the MOU brings together leaders in drug, biologics, regenerative medicine and medical technology development to pave a stable and cost-effective commercialisation pathway for the Australian regenerative medicine sector.

CCRM Australia is the Australian Hub of the highly successful Centre for Commercialization of Regenerative Medicine in Canada (CCRM)

Established as a not for profit with a national focus, CCRM Australia’s mission is to address bottlenecks in the translation and commercialisation of regenerative medicine discoveries in Australia—many of which have the potential to cure some of the most devastating and costly diseases in the world today.

CCRM Australia’s commercially focused solutions enable businesses and research partners to achieve their commercialisation objectives by providing customised country, market and industry specific support. To date, CCRM Australia has collaborated with researchers to advance their regenerative medicine technologies, evaluated and supported promising technologies to seek investment funding, facilitated commercialisation training and worked with international biotechnology companies to set up their clinical trials in Australia. CCRM Australia continues to do so, while providing access to resources and expertise from other CCRM Hubs around the world.

Benefits of Partnering with Australia

2019 THE AUSTRALIAN GOVERNMENT announces $80 MILLION towards the development of a dedicated CAR-T Cell Therapy Innovation facility at the Peter MacCallum Cancer Centre in Victoria. The Peter Mac will also contribute $25 MILLION to create the Centre for Excellence in Cellular Immunotherapy which will be one of the first dedicated cell therapies treatment facilities of its kind, in the world.

ACCESS TO ASIA

Companies based in Australia can gain easier access to Asia, which contains more than 850 million potential patients.

In addition to time zone and cultural advantages and trading 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. Geographically, supply and logistics can reach most regions in Asia as well as potentially the EU and the west coast of the US.

The clinical trials and regenerative medicine eco-system in Australia enables local companies or companies to set up their clinical trials in Asia and work with international biotechnology companies to set up their clinical trials in Australia. CCRM Australia continues to do so, while providing access to resources and expertise from other CCRM Hubs around the world.

State Government Support for Stem Cell Research

- The NSW and Victorian government have provided funding towards the development of Stem Cell Nuclear Transfer (SCNT) technology.
- The Victorian government formed links with the California Institute of Regenerative Medicine (CIRM) to establish collaborations between research groups based in California and Victoria.
- The Western Australia- and Queensland governments have invested significantly in the sector via funding and collaboration with universities and medical research institutes.

$100 MILLION IN FUNDING TOWARDS THE AUSTRALIAN STEM CELL CENTRE

The Australian Regenerative Medicine Institute (ARM) was established through a $153 million joint venture between Monash University and the Victorian Government.

Curing the Most Devastating Diseases

The Australian regenerative medicine sector has the potential to cure some of the most devastating and costly diseases in the world today.

- The Western Australia and Queensland governments have invested significantly in the sector via funding and collaboration with universities and medical research institutes.
- The Victorian government formed links with the California Institute of Regenerative Medicine (CIRM) to establish collaborations between research groups based in California and Victoria.
- The NSW and Victorian government have provided funding towards the development of Stem Cell Nuclear Transfer (SCNT) technology.

The clinical trials and regenerative medicine eco-system in Australia enables local companies or international company subsidiaries to obtain significant and important first in human data quickly and easily.

Thriving Regenerative Medicine Industry Sector

The Australian regenerative medicine sector spans the whole field from tissue engineering through to stem cell therapy to gene and immuno-therapies.

- Cynda Therapeutics and Filliphs (Japan) have announced a license agreement (valued at $43 million) by which Filliphs has acquired the exclusive, royalty-free, right to commercialise and market Cynda lead candidate, CYT-001, for the treatment of graft-versus-host disease (cGVHD).
- Perth-based regenerative medicine company, Orthosolv, has announced successful full results from the use of their CellGraft membrane, used as a scaffold for the regeneration of tendons in shoulder rotator cuff injuries. Following successful approval in Europe (EAC mark), Orthosolv is seeking approval for CellGraft from the TGA and the FDA.
- The Murdoch Children’s Research Institute announced a collaboration with Organovo, a US-based company pioneering the development of 3D printed tissues. Using the Organovo proprietary approach for modelling human osteoarthritic joints that have widespread cartilage loss.
- Following successful registration with the FDA and TGA, NovoSorb has also entered the market with severe burns. Following successful registration with the FDA and TGA, Polynovo Biomaterials has announced successful trial results from the use of their temporary lattice inserted ahead of skin grafts for patients of tendons in shoulder rotator cuff injuries. Following successful registration with the FDA and TGA, Orthocell has announced successful trial results from the use of their Orthocell Acell scaffold for the treatment of graft-versus-host disease (cGVHD).
- The Peter MacCallum Cancer Centre in Victoria announced seeking approval for CelGro from the TGA and the FDA. Cynata’s lead candidate, CYP-001, for the treatment of graft-versus-host disease (cGVHD) has announced successful trial results from the use of their CypaResin scaffold for the treatment of graft-versus-host disease (cGVHD).