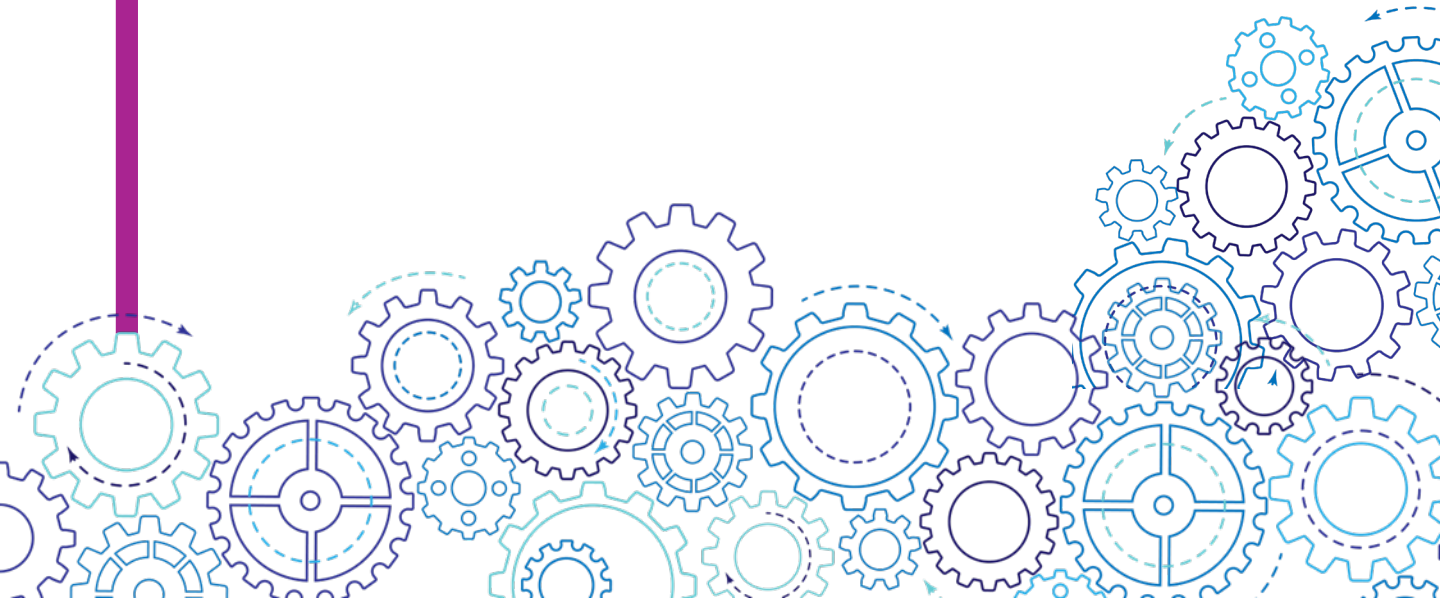


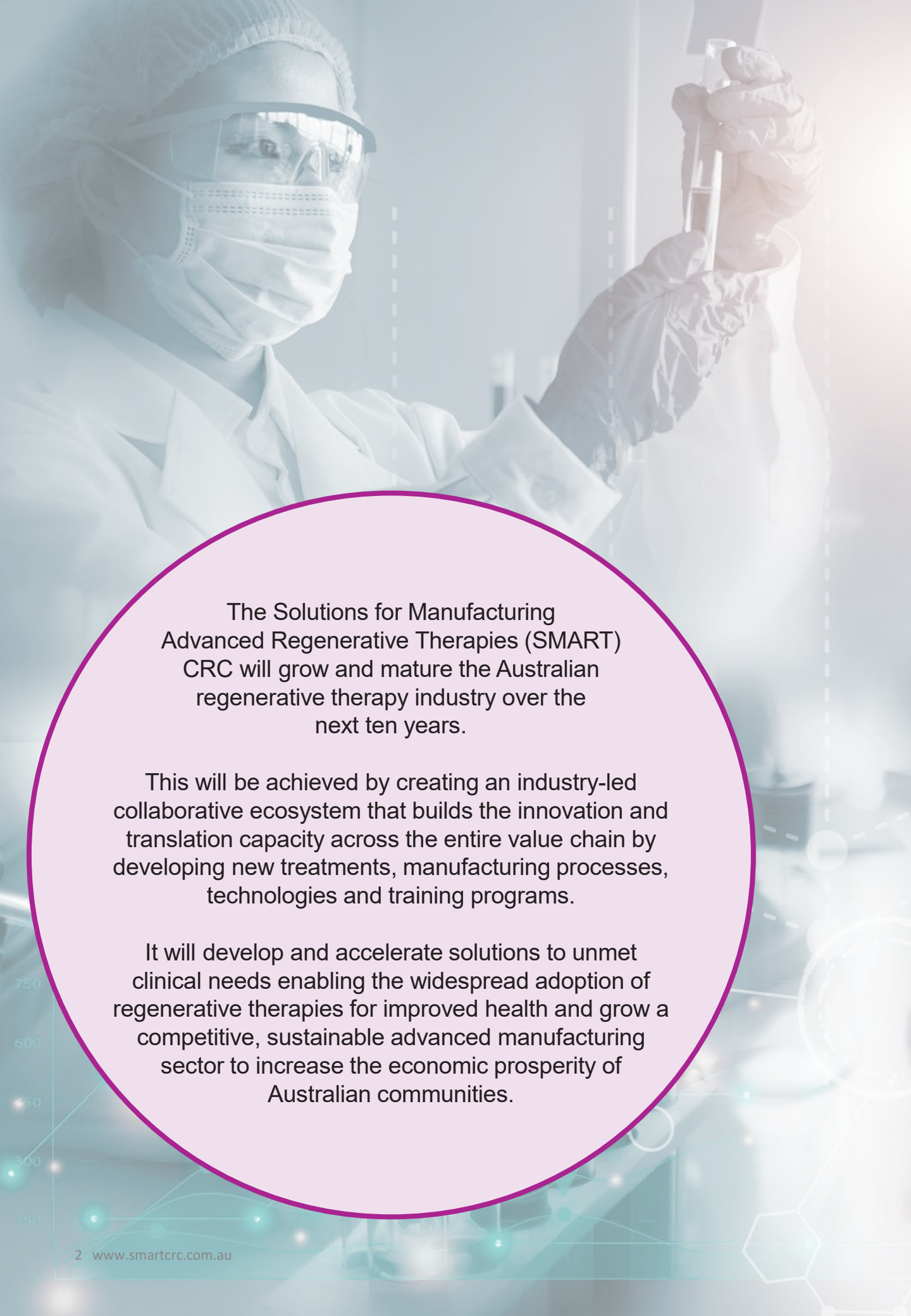


smartcra

Solutions for Manufacturing Advanced  
Regenerative Therapies

*Unlocking the Australian regenerative therapy sector*





The Solutions for Manufacturing  
Advanced Regenerative Therapies (SMART)  
CRC will grow and mature the Australian  
regenerative therapy industry over the  
next ten years.

This will be achieved by creating an industry-led collaborative ecosystem that builds the innovation and translation capacity across the entire value chain by developing new treatments, manufacturing processes, technologies and training programs.

It will develop and accelerate solutions to unmet clinical needs enabling the widespread adoption of regenerative therapies for improved health and grow a competitive, sustainable advanced manufacturing sector to increase the economic prosperity of Australian communities.

# The challenge of Australia's ageing population

Global populations are ageing; lifestyles are growing less healthy, swelling the number of chronically ill patients and increasing the burden on healthcare systems and economies worldwide.

Australian healthcare costs are estimated at 16.8% of total Government spending and are expected to rise (Department of Treasury: Australian Government, 2022).

As current therapeutic interventions primarily treat symptoms rather than the cause, the result is increasing healthcare costs that an aging population cannot afford.

Regenerative therapies offer a promising avenue to reverse this trend offering patient-specific treatments with enormous potential to cure disease and reverse damage from injury. These therapies include any combination of cell- or gene-based treatments, tissue engineering solutions or medical devices. These therapies can enhance our bodies' abilities to self-repair and even grow new tissues and organs.



# Why the SMART CRC?

Australia has a window of opportunity to become a global leader in the growing field of regenerative therapies, which is estimated to reach \$120bn by 2035 (MTPConnect, 2018). Identified as a key national priority, growing and maturing our existing strengths in this sector could unlock \$6bn in revenue for Australia and create more than 6000 jobs.

It is widely acknowledged that in order to achieve these targets, nationally addressing the critical and growing skills gap in manufacturing, building critical mass in Australia's manufacturing ecosystem, optimising Australia's contributions to the global product pipeline and tracking and guiding industry growth must be accelerated.

The SMART CRC is central to achieving this sectoral vision, to catalyse, drive and coordinate a national effort to overcome the range of existing complex barriers, enabling and guiding industry growth.

We are committed to realising this vision with the support of our academic and industry partners and other enabling organisations.



# Benefits of the CRC model

CRCs are industry-led and provide a proven mechanism to bring together industry and outstanding researchers to enable long-term sector-changing research and development.

The SMART CRC will provide benefits to partners, including:

- A single point of access to Australia's most significant hub for regenerative therapies, research capability, expertise and infrastructure.
- Collective experience, capability and capacity to significantly accelerate innovation.
- Linkages and networks to the entire regenerative therapy ecosystem, including overseas markets and partners.
- Funding certainty for up to ten years.
- Enables partners to come together to identify and overcome sectoral challenges in a coordinated and integrated way.
- Effective technology transfer mechanisms.
- Workforce development opportunities to support the sector and recruitment of highly skilled graduates.
- Recovery of up to 43% of qualifying industry partner cash contributions via the Federal Government's R&D tax rebate scheme.



# Linked to Australian Government priorities

The SMART CRC will address the [National Reconstruction Fund](#) priority areas of medical science, enabling Australia's medical manufacturing and advanced manufacturing strengths; as well as advancing the critical technology fields in the National Interest: [advanced manufacturing and materials technologies](#) and [biotechnologies](#).

The SMART CRC also fulfils key recommendations within AusBiotech's [National Cell and Gene Manufacturing Blueprint 2023](#) and [Biotechnology Blueprint 2022-2032](#).

The Centre also aligns with the [Queensland Biomedical 10-year Roadmap and Action Plan](#); the New South Wales [Future Health: Guiding the next decade of health care in NSW 2022-2032](#), the Victorian [Health and Medical Research Strategy: 2022-2032](#), the South Australian [Wellbeing SA Strategic Plan 2020-2025](#) and [Advanced Manufacturing Strategy](#) and the Western Australian [Health and Medical Research Strategy 2023-2033](#), as well as other state strategies as they come online.





## Our partners

The regenerative therapies value chain is complex, comprising a diverse array of upstream and downstream stakeholders with varying scale, sophistication and business interests. SMART CRC partners span the entire regenerative therapies value chain, including treatment developers, major manufacturing suppliers, clinical trial designers and relevant industry associations. These include governments, industry, medical providers, non-government organisations, universities and research institutes.



*In discussions with >18 organisations; logos included here upon approval.*



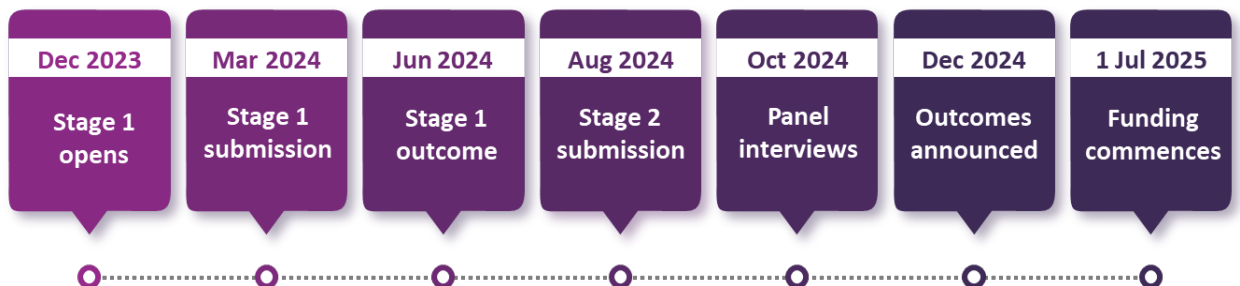
# What is a CRC?

The CRC Program, funded by the Department of Industry, Science and Resources, supports long-term (<10 years) industry-led collaborations in a consortium consisting of industry, researchers and the community to improve competitiveness, productivity and sustainability of Australian industries. Since its inception in 1990, the CRC program has committed \$4.6bn in funding to support the establishment of over 221 CRC grants.

The CRC program typically provides matching funds equal to the total **cash** contributions outlined at **Stage 1**.

Successful CRC bids are established as independent entities and are governed as incorporated companies limited by guarantee to undertake industry-led collaborations between industry, researchers and the community.

## Timeline



## SMART CRC governance

The SMART CRC will be established as a not-for-profit (NFP) company limited by a guarantee and governed by a majority independent, skills-based board.

The SMART CRC has developed a Term Sheet in consultation with its partners that further expands its governance, management and commercialisation strategy.



# Participating in the SMART CRC

The SMART CRC has three partner categories, plus the option to participate in the program under a Third-Party agreement.

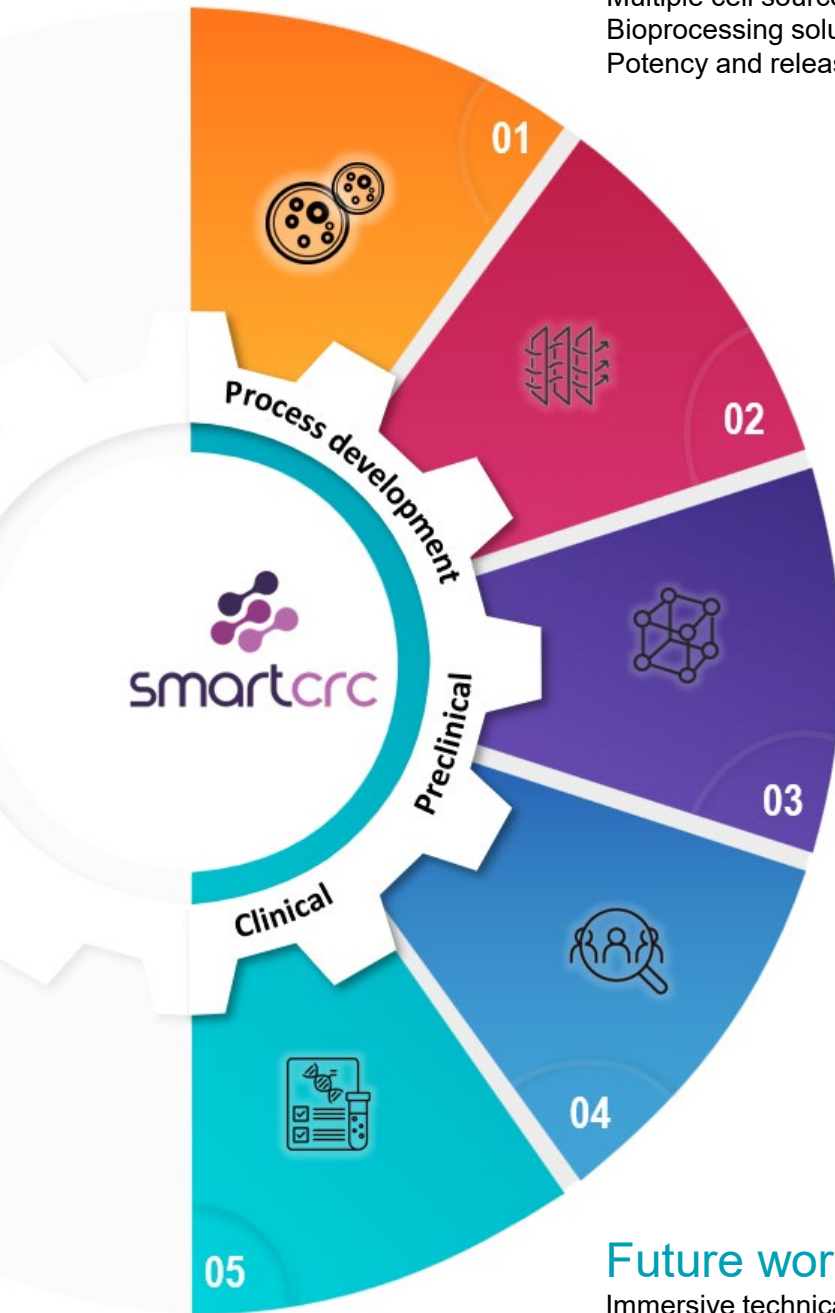
1. Core Partner	Cash contribution of \$200k and above per annum
2. Key Partner	Cash contribution of \$75k – \$199k per annum
3. Supporting Partner	Cash contribution of \$10k – \$74k per annum or a combination of <\$10k cash and a significant in-kind contribution deemed critical by the bid team
4. Third-Party	Providing only in-kind contributions

Other interested organisations will have the opportunity to engage with the CRC as Associate Members, with benefits that include invitations to attend seminars and other networking events, plus regular news updates and reports.

Category	Core	Key	Supporting	Third-Party
Consultation on program strategy	✓	-	-	-
Membership of CRC company	✓	✓	-	-
Nominate a representative to Research Program Consultative Committees	✓	✓	-	-
Opportunity for industry placements of PhD and Masters students	✓	✓	-	-
Lead and submit research projects	✓	✓	✓	-
Opportunity for co-supervision of PhD and Masters students	✓	✓	✓	-
Nominate Board members	✓	✓	✓	-
Participation in net commercialisation returns (proportional to contributions)	✓	✓	✓	-
Discounted professional training and development	✓	✓	✓	-
May be eligible for offsets under the R&D tax incentive	✓	✓	✓	-
Other benefits including participation in CRC conferences, seminars and other networking events, regular news updates and reports	✓	✓	✓	✓



# Proposed programs



## Research Program 1: Biomanufacturing

Multiple cell sources  
Bioprocessing solutions  
Potency and release assays

## Research Program 2: Bioseparation

Fluids, tissue and tissue products  
Biologics and small molecules  
Separation technologies

## Research Program 3: Biomaterials

3D-printing  
Biocompatibility  
Surfaces and coatings

## Research Program 4: Clinical enablement

Preclinical models  
Regulatory pathways  
Trial preparation, design and analysis

## Future workforce

Immersive technical experience  
Specialist commercialisation training  
Industry development program

# Proposed programs



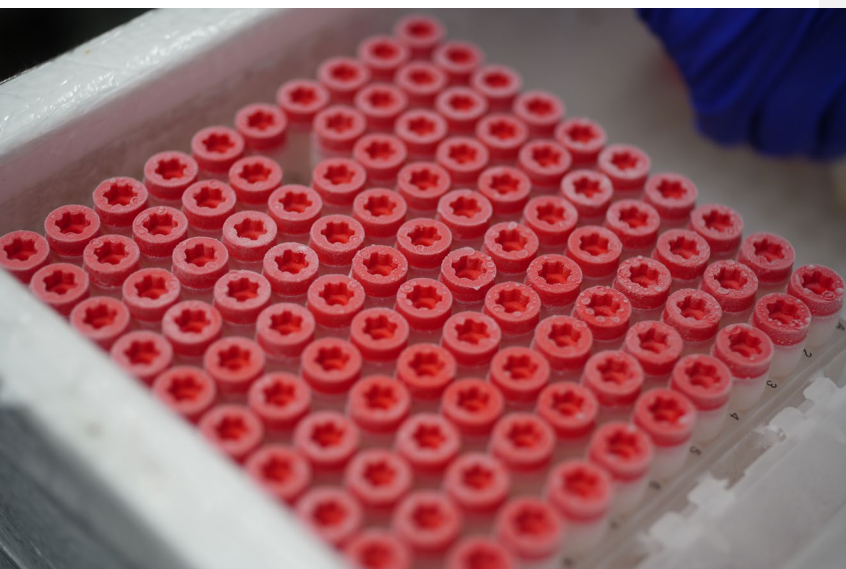
## Research Program 1: Biomanufacturing

The biomanufacturing program will address sector-wide cell therapy manufacturing challenges to develop a cost-efficient pipeline to bring new therapies to market for the benefit of Australian communities.

The program encompasses cell and cell-based therapies and will address wide-ranging industry bottlenecks in process development, bioprocess manufacturing, cryopreservation and scale-up of regenerative therapies, diagnostics, and quality assays and metrics.

### Indicative Outcomes

- Access to high-value cells, tissues and banks from screened donors
- Customised process development for cell-based therapies at scale to support commercial manufacturing
- Detailed quality management systems to facilitate regulatory acceptance
- Mechanism of action studies that underpin clinical efficacy and end use applications
- Potency and identity assays to ensure batch and product consistency
- Safety and efficacy testing to accelerate clinical translation



# Proposed programs



## Research Program 2: Bioseparation

New separation strategies are needed to achieve high-quality yield at scale and enable the extraction of more therapeutically-potent cellular and extracellular products from accessible sources.

This program will develop and optimise bioseparation technologies and platforms which overcome specificity, throughput and quality challenges. This includes separatory activities related to cells, tissues, tissue products, fluids, biologics and small molecules.

### Indicative Outcomes

- Novel surfaces and processes that increase target specificity
- Purification of regenerative compounds from bodily fluids, cells and tissues
- Separation at scale for enhanced downstream manufacturing
- Well-defined parameters for manufacturing consistency
- Pathways to commercialising purified products



# Proposed programs



## Research Program 3: Biomaterials

The biomaterials program will tackle the increasing consumer need for personalised devices which are safe, effective and cost-efficient.

This program includes 3D printed metal and composite devices, degradable scaffolds, surfaces and coatings, tissue engineered products, platforms and processes.

### Indicative Outcomes

- Cost-effective manufacturing of personalised 3D printed devices
- Biocompatible and biodegradable materials for high-value applications
- Improved safety, toxicity and efficacy of implantable devices for commercial readiness
- Identification and analysis of interactions between materials and body tissues



# Proposed programs



## Research Program 4: Clinical enablement

As the regenerative therapies sector grows, pathways for clinical translation need to be developed, optimised and implemented.

To address this growing sector need, this program will focus on streamlining access to pre-clinical models, establishing quality metrics and analyses that reflect mechanism of action, and the design of clinical trials and their coordination.

### Indicative Outcomes

- Improved *in vitro* and *ex vivo* preclinical models to accelerate clinical impact
- Pathways to translate therapies into clinical products
- Use of biomarkers for clinical decision making and the establishment of quality assays
- Improved clinical trial design, optimisation, enrolment and data analysis
- Alignment with regulatory requirements to accelerate translation



# Proposed programs



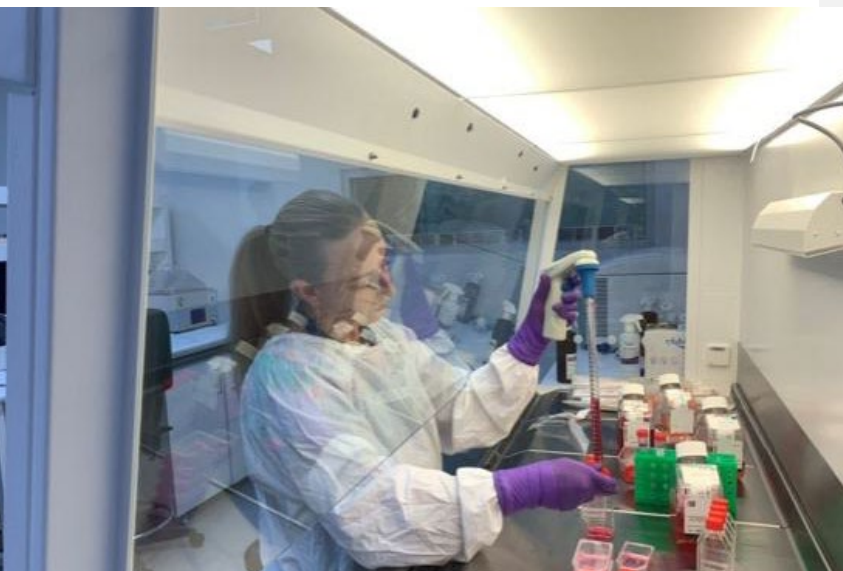
## Future workforce

This program will address the critical skills gap in the Australian regenerative therapies sector. This gap is multi-faceted and growing, with personnel required across a range of specialisations with knowledge gaps in hands-on manufacturing, stringent regulatory requirements and quality control.

The need for nationally available training programs and more skilled personnel have been identified as barriers impeding growth of the sector, as highlighted in AusBiotech's 2023 National Cell and Gene Manufacturing Blueprint.

### Indicative Outcomes

- Assessment of current and future workforce requirements that identify workforce gaps.
- Development of mature training programs that target workforce gaps.
- Enhanced education and training platforms that generate highly-skilled talent to expand and increase investments in Australia.
- Generate a pipeline of industry-led career paths for PhD graduates.



# Our people



**Dr Leanna Read**  
Interim Chair



**Silvio Tiziani**  
CCRM Australia



**Prof Simon Cool**  
The University of  
Queensland



**Prof Hala Zreiqat**  
University of Sydney



**Prof Justin Cooper-  
White**  
The University of  
Queensland



**Dr Chih Wei Teng**  
CCRM Australia



**Dr Sarah Costanzo**  
The University of  
Queensland



**Nunzio Cristaudo**  
The University of  
Queensland



## To find out more

Silvio Tiziani  
Chief Executive Officer  
CCRM Australia  
M: +61 418 536 209  
E: [silvio.tiziani@ccrmaustralia.com.au](mailto:silvio.tiziani@ccrmaustralia.com.au)

Prof Simon Cool  
Professor of Biomedical Engineering  
The University of Queensland  
M: +61 467 543 642  
E: [s.cool@uq.edu.au](mailto:s.cool@uq.edu.au)

Dr Sarah Costanzo  
Senior Manager, Business Development  
The University of Queensland  
M: +61 417 013 063  
E: [s.costanzo@uq.edu.au](mailto:s.costanzo@uq.edu.au)

[www.smart.crc.com.au](http://www.smart.crc.com.au)

