

# CCRM Australia Solutions



Commercializing  
Living Therapies



## About CCRM Australia

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, CCRM Australia's mission is to address bottlenecks in translating regenerative medicine discoveries in Australia.

CCRM Australia is taking regenerative medicine from bench to bedside by treating and potentially curing some of the most devastating and costly diseases in the world today. As a member of the Global CCRM Network, CCRM Australia is a partner to a leading-edge industry consortium.



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## Why partner with CCRM Australia?

By partnering with CCRM Australia, businesses, researchers, and other Australian stakeholders can access our world-leading capability and expertise. We have worked to design and deliver impactful solutions tailored to our partners' niche requirements and, with expertise available throughout the Global CCRM Network, assist our stakeholders in their translation and commercialisation activities.

Being part of the Global CCRM Network means CCRM Australia has access to in-house expertise that covers key growth markets including, but not limited to: Canada, United States, Europe, Israel, Japan, South Korea and China/Hong Kong. Enabling us to assist Australian businesses and partners in their international expansion.

Locally, the Australian Partner Network brings together academia, industry, healthcare services and venture capital to create an ecosystem that exemplifies:

- World-class basic and applied research capability
- Demonstrated experience and track record in research translation
- Industry association advocacy and support
- World-leading research infrastructure
- A technology transfer hub with regenerative medicine, and commercialisation expertise and international connections.

CCRM Australia's commercially focused solutions enable businesses and research partners to optimise their international objectives by providing customised country, market and industry-specific support, including:



**Executive leadership capabilities** – building executive skills, knowledge, and ability to identify, manage and grow scientific and business opportunities.



**Market awareness and opportunity assessment** – supporting informed decisions by building awareness into key markets, sectors, trends and operating environments.



**Commercialisation knowledge** – to develop individual and organisational capabilities.



**Sustainable partnerships** – enhancing skills, knowledge and capabilities to forge lasting business partnerships, partner-profiling, negotiations and in-market support.



**Stakeholder engagement** – providing a leading platform to engage and shape the discussion on contemporary developments through events, thought leadership and business facilitation.



## Current CCRM Australia Solutions





The needs of biotechnology companies are becoming increasingly complex and require substantive orchestration between different activities. This primarily results from industry best practices of concurrent product and process development. This is especially true for the field of regenerative medicine, where the process is the product. CCRM Australia has access to a successful commercialisation model and has further developed it for the local market by collaborating with the Australian ecosystem. By doing this, we have developed a series of consulting services to support translation and commercialisation activities targeting the preclinical stage onwards.

The various programs offered by CCRM Australia are designed to support the development of the Australian regenerative medicine sector. Through varying activities, CCRM Australia coordinates opportunities addressing the challenges faced by the industry. Below is a brief on the programs currently on offer.

### The Clinical Trial Launch Platform

The Clinical Trial Launch Platform provides a single touchpoint for a comprehensive delivery of cell and gene therapy solutions. Our alliance partners and CCRM Australia each have complementary domain expertise within the cell and gene therapy value chain and an extensive network of partners to provide a complete end-to-end solution service.

Core members in the Clinical Trial Launch Platform include:

			
<ul style="list-style-type: none"> <li>• Access to a proven commercialisation model</li> <li>• Connectivity into the CCRM global network that taps into a consortium of world-leading regenerative medicine companies</li> <li>• Strong link to industry trends and needs through the industry consortium</li> </ul>	<ul style="list-style-type: none"> <li>• Premier site for medical research and clinical trials</li> <li>• Smooth start to clinical trial with a highly competitive timeline to gain ethics approval (Research Valet)</li> <li>• Access to Aikenhead Centre for Medical Discovery, a hospital-based bio-engineering innovation hub</li> </ul>	<ul style="list-style-type: none"> <li>• High quality research to solve industry challenges through development, characterisation and assessment of biologics</li> <li>• CSIRO's BMFT facility provides full development and preclinical assessment of biomaterials</li> <li>• Multipurpose cGMP manufacturing facility to enable the rapid translation of biological discoveries into the clinic</li> </ul>	<ul style="list-style-type: none"> <li>• Niche full service Contract Research Organisation with extensive experience and knowledge in therapeutic areas in neurological indications</li> <li>• Strong capability to manage complex trials, auditable standard operating procedures and state of the art facilities</li> <li>• Has strategic alliances with many therapeutic disease groups and clinical trial expertise through a range of tailored services</li> </ul>

Just from the small sample of partners above, the Clinical Trial Launch Platform can provide expertise in commercialisation, proof of concept, product development, pilot manufacturing, pre-clinical activities. The Platform is equipped to assist in manufacturing and product delivery for clinical trials. The Platform will also provide services and support in establishing a subsidiary in Australia to benefit from local incentives or provide linkage to other services and technologies.

Biotechnology firms may also wish to engage in process development and other areas of innovation such as drug delivery systems or leveraging 'omics technology for quality control etc. CCRM Australia, with its partners, can help identify mechanisms and opportunities to help facilitate collaborations with Australian research institutes to progress the pipeline of innovations in the regenerative medicine sector.



# CCRM Australia Partner Network

CCRM Australia has established a Partner Network comprising over sixty of Australia's leading regen medicine organisations. These include research institutes and universities, startup companies and SME's, funders and investors, peak bodies, service providers and ecosystem enablers. This Network provides a comprehensive resource enabling an understanding of the services, facilities and expertise available in Australia and allows CCRM Australia to be recognised for its referral and project management services to international and local companies.

<b>FOUNDING ORGANISATIONS</b>								
<b>SPOTLIGHT PARTNERS</b>								
<b>ECOSYSTEM PARTNERS</b>								
<b>GOVERNMENT SUPPORT</b>								

## Focus on NTA, a member of the CCRM Australia Partner Network:

NTA (Neuroscience Trials Australia) is one of the few full-service contract research organisations (CRO) globally that specialises in neuroscience.

Based in Australia, with over 20 years of specialty experience, NTA collaborates with pharmaceutical, biotechnology and cell therapy companies, device manufacturers and university/private/hospital-based investigators. NTA has expertise in all phases (Phase I-IV) of clinical research and extensive knowledge of global regulatory requirements, including the TGA, FDA and EMA.

NTA partners with The Florey Institute of Neuroscience and Mental Health, the largest brain research institute in the southern hemisphere, facilitating a unique network. NTA has direct access to therapeutic disease specialists, key opinion leaders and clinical trial sites that collectively enable the delivery of high-quality, world-class clinical trials with solid recruitment outcomes. NTA has a reputation for delivering clinical trials on time and on budget with a personal, agile, client-centric approach.



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## CCRM Australia Clarity

CCRM Australia Clarity is a multi-disciplinary think tank with a market research and reporting mission to accumulate thought leadership and analysis to facilitate the commercialisation and diffusion of regenerative medicine into the healthcare sector.

CCRM Clarity activities will include but are not limited to:

- researching and developing regenerative medicine business models and the diffusion of regenerative medicine technologies into the local and global healthcare sector
- curating industry and research sector data to support the development of new policies and strategies concerning Australian and international markets
- analysing clinical and social information that help support funding, grant applications and business strategies
- developing and writing opinion and blog articles for publication in appropriate print and online publications.

Our interdisciplinary, multi-institutional, demand-driven, team-based approach is fundamental to the way we collectively tackle problems that transcend disciplinary boundaries as support the Australian regenerative medicine sector in delivering impactful outputs.

Through Clarity, CCRM Australia provides business services tailored to suit our partners' different translation and commercialisation stages and timelines. Local service packs will be focused on market analysis to assist researchers and early bio entrepreneurs in determining the market potential of their technology, competitive landscape and value proposition. CCRM Australia will also provide access to service offerings made available through the Global Hub network, including regulatory consulting, process development and bioinformatics.

## Internship Programs

CCRM Australia actively participates in and accepts undergraduate and postgraduate students from Australia's universities interested in the commercialisation of regenerative medicine or to gain operational experience from the industry.

### CCRM Australia Intern for CCRM Clarity

This critical new role supports the development of an opinion leader activity regarding the development of critical ideas and policy for the Australian regenerative medicine sector at CCRM Clarity, which is CCRM Australia's Think Tank unit. The initiative aims to accumulate thought leadership and analysis to facilitate the commercialisation and diffusion of regenerative medicine in Australia. The intern will be expected to:

- Assist in the research and development of alternative regenerative medicine business models and the diffusion of regenerative medicine technologies into the healthcare sector
- support the curation and updating of industry and research sector data to support the development of new policies and strategies concerning Australia and international markets
- Support the curation and analysis of clinical and social information that help support grant applications and business strategies
- Assist in developing and writing opinion and blog articles for publication in appropriate print and online publications.



## Technology Evaluations

Technology evaluations are offered as part of CCRM Australia's pursuit to support the development of foundational technologies to accelerate the commercialisation of regenerative medicine. CCRM is developing innovative solutions to manufacturing cell and gene therapy products and is currently seeking disclosures from researchers for novel enabling technologies. Relevant and promising disruptive solutions that have strong patentability, scalability and clear market need may be eligible for joint intellectual property protection and co-development towards commercial applications.

## SuperPitch Series

The SuperPitch was designed to provide a forum for a select group of venture funds and other commercial investors to evaluate technologies curated for their interests in regenerative medicine. It also provides selected presenters with expert feedback on their development at different commercialisation cycle stages and a potential source of alternative/non-government-based funding. Participants also benefit from commercialisation support from CCRM Australia for suitable projects and further development funding.

The SuperPitch brings international venture interest into Australia and to encourage interactions between Australian venture funds and international investors. In addition, the SuperPitch aims to increase private capital sources for the translation and commercialisation of regenerative medicine.

Submissions may relate to cell therapies, gene therapies, combination therapies, gene editing tools, enabling technologies such as vector production, automated analytical assays, biosensors, novel media, and other projects related to regenerative medicine in a wide range of therapeutic areas. Shortlisted participants will be invited to provide a forty-minute presentation, including objective data on their technologies or ideas, to a panel of regenerative medicine, venture capital and commercialisation experts from the Consortia.

## The Future

CCRM Australia will be establishing a Translation and Commercialisation Facility that will offer fee for service preclinical activities that will include process development, scalability and automation, determination of good laboratory practices for a given protocol, assay development, clinical study design, scale-up for Phase I, and process transfer to the cGMP facility.

This Translation and Commercialisation Facility is a reflection of CCRM Australia and its partner networks to provide expertise and deliver resources supporting the translation and commercialisation of breakthrough regenerative medicine discoveries and technologies across Australia. The facility will develop and leverage in-house technologies (e.g. PC2, cell and tissue banking, cGMP, high-throughput facilities, data mining and analytics, clean rooms and characterization technology expertise. Together with ecosystem partners, the facility will also be a centre that will offer training and development courses that will enable a local workforce for commercial manufacturing.



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**To become more involved in CCRM Australia or for further information please contact:**

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**CRM Australia acknowledges the Traditional Owners of Country throughout Australia.  
We pay our respects to their Elders past, present and emerging.**

### CCRM Australia founding partners



This venture has received funding through the MTPConnect Project Fund Program – a dollar-for-dollar matched program investing in big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect is supported by the Australian Government Industry Growth Centres Initiative – learn more at [mtpconnect.org.au](http://mtpconnect.org.au)